Section 1: General information

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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 are also new sections on the very important topics of responsible use of anthelmintics and cytotoxic medicines, and prescribing for backyard poultry. We have added multiple choice questions at the end of each section to enable this 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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April 2018
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### Useful links

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<td>Animal Medicines Training Regulatory Authority</td>
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<td>ABPI</td>
<td>Association of the British Pharmaceutical Industry</td>
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<td>BP</td>
<td>British Pharmacopoeia</td>
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<td>BVA</td>
<td>British Veterinary Association</td>
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Section 2:
Medicines

Authorization and classification

KEY POINTS

- Veterinary Medicinal Products (VMPs) 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 VMPs must display a VM or EU code.
- There are four main categories of authorized veterinary medicines:
  - POM-V medicines can only be prescribed by a veterinary surgeon.
  - POM-VPS medicines can be prescribed by a vet, pharmacist or suitably qualified person (SQP).
  - NFA-VPS medicines can be supplied by a vet, pharmacist or SQP.
  - AVM-GSL medicines 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’s regulatory authority for veterinary medicines and has responsibility for development of the Veterinary Medicines Regulations (VMR). The VMR regulate the authorization, manufacture, distribution and use of veterinary medicines in the UK.

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

Authorization of Veterinary Medicinal Products (VMPs)

VMPs 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 VMPs

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

i. Prescription-only medicine – veterinarian (POM-V)
ii. Prescription-only medicine – veterinarian, pharmacist, suitably qualified person (POM-VPS)
iii. Non-food animal – veterinarian, pharmacist, suitably qualified person (NFA-VPS)
iv. 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 there are a small number 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 VMPs 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 selling 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

Exemption for Small Pet Animals (ESPA) products

These products, formerly known as SAES (Small Animal Exemption Scheme) products, are VMPs for administration to minor species of small animals kept as pets (e.g. caged birds, fish, companion rabbits and small rodents). They may be supplied by anyone and do not have an MA.

Homeopathic remedies

Homeopathic remedies are considered to be VMPs 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.
"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 Special Treatment Certificate (STC).

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 VMPs 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 CSQPs only
   d. Anyone

ANSWERS
1 – b; 2 – d; 3 – b; 4 – c; 5 – d
Prescribing, supplying, dispensing and labelling procedures

Prescribing 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 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 vet, 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 medical product (VMP) to supply.

Products classified as ‘non-food animal medicine – 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 the 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.

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 animals 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 vet 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 medicines are supplied the owner must be advised 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 vet at the time of supply (e.g. during a consultation). For supply in the absence of the vet (e.g. clients requesting repeat prescribing of long-term medicines), the veterinary surgeon could meet the requirement to authorize each transaction:

- By the vet 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
- Or, 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 would 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 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 or Special Treatment Certificate. A human wholesale licence 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 (VMPs) 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, both the Veterinary Medicines Directorate (VMD) and the RCVS consider 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.

For a **VMP supplied in its authorized packaging** for a condition and species listed on its summary of product characteristics (SPC) there is no legal requirement to label, but the RCVS Code of Professional Conduct states that VMPs must be supplied in appropriate containers and with appropriate labelling.

Whilst there are no specific labelling requirements in the VMR or in the RCVS’s 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’s requirements (see below)
- And providing a copy of the package insert or the 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 VMPs**

**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”.

**VMPs 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
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 vets 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 vet 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 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 (VMPs) are set out in the Veterinary Medicines Regulations (VMR). Records of the retail supply (which includes administration) of ‘prescription-only – veterinarian’ (POM-V) and ‘prescription-only – 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.

Also, 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
KEY POINTS

- Regulation of Controlled Drugs (CDs) within veterinary practice is enforced by the Home Office, 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 the veterinary surgeon and the veterinary nurse 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 medical and 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 on 30th November 2015

1. **The rescheduling of ketamine to Schedule 2.** Further details on the requirements for each of the Controlled Drug Schedules are given below.

2. **The requirement to use a mandatory form for requisition of Schedule 2 and 3 Controlled Drugs.** There are separate forms for England, Wales and Scotland:
   - **England** form FP34PCD – available on the NHSBSA website.
   - **Wales** form WP10CDF – available from NHS Wales.
   - **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 Authorised Signatory for your Local Health Board and passed to eVadis to receive a Unique Prescriber Code. This enables you to purchase CDRF forms (£44.43 per pad (100 forms) plus VAT).

Further details can be found on the VMD website.

Changes introduced on 1 March 2016

As of the 1 March 2016, the Misuse of Drugs Regulations (Northern Ireland) 2002 have been updated to bring them in line with the provisions already in place in the UK under the Misuse of Drugs Regulations 2001. This means that:

- Ketamine has been moved from Part 1 of Schedule 4 to Schedule 2 of the 2002 Regulations. All requirements applicable to Schedule 2 drugs, including record keeping, safe custody, witnessed destruction, prescribing, etc. now apply to the use of ketamine in research, industry, veterinary and healthcare sectors.
- Tamazepam is subject to all the requirements applicable to Schedule 3 drugs.

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 these regulations (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 Note Number 20 is a useful reference for veterinary surgeons.

The VMD also delegate 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 (MDA) 1971**

This legislation controls the availability of drugs that are considered ‘dangerous or otherwise harmful’. The 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 has 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 vet.
Misuse of Drugs (Safe Custody) Regulations 1973

This document describes the requirements for CD cabinets, safes and rooms, and the standard to which they must be manufactured or built. For veterinary surgeons, a cabinet is acceptable for the amount of stock likely to be held, but the cabinet should be situated in a secure place away from public view. 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.

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 storage, prescription, dispensing, destruction and record keeping requirements (e.g. morphine, methadone, pethidine, fentanyl and ketamine).

**Schedule 3**

These drugs (e.g. barbiturates, buprenorphine and midazolam) also have therapeutic value, but potential for abuse is less. They are, therefore, subject to less strict requirements compared with Schedule 2 drugs. Tramadol, previously uncontrolled, has now been classified as a Schedule 3 (and Class C) CD. It is exempt from safe custody requirements 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. There is a list of all veterinary authorized medicines containing Controlled Drugs available on the UK Government website.

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Schedule 2</th>
<th>Schedule 3</th>
<th>Schedule 4</th>
<th>Schedule 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safe custody</td>
<td>✓ except quinalbarbitone</td>
<td>✓ except buprenorphine</td>
<td>✗ except ketamine*</td>
<td>✗</td>
</tr>
<tr>
<td>Extra prescription requirements</td>
<td>✓</td>
<td>✓</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>Prescription validity</td>
<td>28 days</td>
<td>28 days</td>
<td>28 days</td>
<td>6 months</td>
</tr>
<tr>
<td>CD register</td>
<td>✓</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>Witness for destruction</td>
<td>✓</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>Invoice kept for 2 years</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

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

**Special cases**

**Ketamine**

As of 30 November 2015, ketamine has been classified as a Schedule 2 Controlled Drug in England, Wales and Scotland. As of 1 March 2016, ketamine has been classified as a Schedule 2 Controlled Drug in Northern Ireland.

**Quinalbarbitone**

This drug is currently classified as a Schedule 2 CD but it does not require safe custody – 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 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 a CD register is not required.

### Ordering Controlled Drugs requisitions and stock

A requisition, for the purpose of this guide, is supply of a CD for stock purposes rather than that for a named patient. A written requisition is required, which can be computer generated or hand written. Dedicated requisition forms are available from veterinary wholesalers and should be used where available. For CDs not supplied by a veterinary wholesaler, a written prescription for stock is acceptable providing it contains the following:

- Name, address and profession of the recipient
- Purpose for which the drug is required (e.g. for hospital use)
- Total quantity required
- Signature of the recipient

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 Controlled Drugs is required. There are separate forms for England, Wales and Scotland:

- **England** form FP34PCD – available on the NHSBSA website (http://www.nhsbsa.nhs.uk/PrescriptionServices/Documents/PrescriptionServices/6-1387-Form_FP10CDF_v5_final.pdf)
- **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 Authorised Signatory for your Local Health Board and passed to eVadis to receive a Unique Prescriber Code. This enables you to purchase CDRF forms (£44.43 per pad (100 forms) plus VAT).

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.

The requirement to use a specified form which complies with Regulation 14 for the requisitioning of Schedule 2 and 3 drugs will come into force on 30 November 2015. The Home Office has not yet announced where the specified requisition form will be made available.

### 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 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 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.

The requirement to include the RCVS number of the vet on veterinary prescriptions for Schedule 2 and 3 drugs came into force on 1 July 2015.

Prescription validity and repeats

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

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’.

Prescription errors

If an error is made, it is best practice to rewrite the prescription. There are some exceptions to this, such as pharmacists may make minor alterations to spelling provided that they sign or initial their alteration.

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. This author brackets the mistake and then makes a footnote at the bottom of the page detailing the mistake. The running balance is then corrected as necessary
- Be kept at the premises to which they relate and be available for inspection at any time. A separate Register must be kept for each set of premises
- Not be used for any other purpose
- Be kept for a minimum of 2 years after the date of the last entry.

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 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 Member of the RCVS number (good practice); and running balance.

For ambulatory vets carrying CDs in their vehicle, ideally there should be a separate Register. If the CDs are moved back to the practice after each visit then it may be acceptable to have just one Register in which the CD is signed out on departure and signed back in again upon arrival.

Electronic Registers

A computerized Register must not be alterable at a later date after an entry has been made: it must be auditable, printable and appropriate back-up must be kept. There are currently no suitable electronic 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 deadspace. 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 deadspace 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 deadspace volume is to add this to each dose dispensed, but the volume is likely to vary depending on manufacturer of the needle and syringe, and the size of syringe used. An example 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 does not necessarily have to be a veterinary surgeon. If this is carried out daily or at least weekly depending on workload, then discrepancies are much easier to trace. Wherever possible, this should be countersigned.
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. 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. Other requirements include the following:

- The cabinet must be bolted to the wall or floor
- Preferably it is double locked (with separate keys) (left figure)
- Cabinets must be kept locked when not in use
- The lock must be different to any other lock on the ward
- 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 (right figure).

Keyholders

Access to the cabinet should be restricted to the veterinary surgeon or any persons authorized by him or her. Keyholders of the cabinet can be any nominated persons within the practice. Those persons holding keys should have appropriate training and, ideally, should be a qualified veterinary surgeon or veterinary nurse. 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).

SOPs should be in place to control access to the CD cabinet and a risk assessment carried out if deemed necessary.

Controlled Drugs in vehicles

Ideally, CDs should never be left unattended in a vehicle. However, if this is necessary there should be a locked container fixed within the boot of the car, which must meet the requirements of the Safe Custody Regulations. Other options include keeping the CD on one’s person at all times (not ideal) or keeping the CD in a constantly attended locked bag. A locked vehicle alone is not enough. The VMD also suggest that a locked glove compartment is suitable – however, long-term storage of any medicine in a vehicle is not acceptable. 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

There is much confusion regarding the destruction of CDs. It is good practice that all CDs be destroyed in the same way although, legally, this only applies to Schedule 2 CDs.

CDs may be presented for destruction in three different circumstances.

1. **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 a good practice (this does not have to be witnessed by an independent witness).

2. **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 drug. It should not be marked out of the running balance in the Register until it is destroyed. The destruction must be witnessed by an RCVS or VMD inspector, a Controlled Drug Liaison Officer (CDLO) from the police force, or an independent veterinary surgeon provided that they are not a member of the practice or associated with a member of the practice. A list of CDLOs can be found on the Association’s website (CDLO).

3. **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.

Advertising and internet sales

Advertising of CDs to clients is prohibited (as is the advertisement of all prescription medicines) (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 VMD’s advice 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), then recorded delivery or ‘signed for’ courier delivery are most appropriate. Prescription medicines may be sent via Royal Mail, but it is advisable to check current details on prohibited goods to travel to the practice and unable to send a representative), then recorded delivery or ‘signed for’ courier delivery are most appropriate. Prescription medicines may be sent via Royal Mail, but it is advisable to check current details on prohibited goods and packaging guidelines with the Royal Mail first.

Standard operating procedures for Controlled Drugs

SOPs are unambiguous documents (i.e. they cannot be misinterpreted), and describe a procedure or task that must be followed. They are working documents and subject to change 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 the following:

- Who has access to CDs
- Where the CDs are stored
- Dispensing CDs
- Disposal and destruction of CDs
- Who to alert if complications arise
- Record keeping

SOPs must, however, be appropriate to the setting (there is no one size that fits all).

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 Controlled Drug 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 has published advice to practices on Controlled Drug use (CD)).

There are now two veterinary authorized fentanyl products – both of which are POM-V Schedule 2 Controlled Drugs. One is a transdermal solution authorized for use in dogs for control of significant postoperative pain. Personal protective equipment must be used when applying this product and it cannot be ordered without first watching a short training video.

There is also an injectable solution authorized for use in dogs, again for the control of significant postoperative pain and also intraoperative analgesia.

Whichever product is used, practices should be particularly mindful of the risks of this powerful analgesic.

- Ideally, neither the transdermal solution nor fentanyl patches should be used if there are small children in the household.
- Veterinary surgeons should be mindful of the risks of ingestion by other animals.
- It is vital to get the client’s informed consent, which must include an explanation of the risks 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.

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

QUESTIONS

1. It’s Monday. Muffy the dog is having surgery and requires premedication with morphine. The morphine dose is calculated as 4 mg. A 10 mg vial is opened and 4 mg drawn up and injected. What happens to the remaining 6 mg?
   a. Tape is placed over the top and it is left on the shelf for someone else to use
   b. It is placed back in the cupboard because there is another dog coming in on Wednesday for which it can be used
   c. It is placed in the sharps bin
   d. It is placed in the sharps bin and recorded in the Register as a residual

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 denatured and not recorded in the Register
   b. It can be squirted down the sink
   c. It is denatured and needs to be 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 treatment has become more and more 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 has become more and more 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

Risk assessment is a simple process with practical outcomes that reduce risk to employees as far as reasonably possible. Via risk assessment a competent person should identify what might cause harm and prioritise 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 identified on Material Safety Data Sheets (readily available on the internet by searching the name of the medicine and the company producing it), which should be consulted as part of general Control of Substances Hazardous to Health (COSHH) management.
   - Cytotoxic drugs can be carcinogenic, mutagenic and teratogenic.
   - 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., 2009).

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, 2004).
   - Pay attention to groups of workers who may be at particular risk (e.g. young workers, trainees and new and expectant mothers). Pregnant workers are especially at risk, as some drugs may be harmful to the unborn child.

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 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 for 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 – the final control option.
   ■ 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 organisations 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.
References

- HSE website (Link)
- Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Healthcare Settings. *National Institute for Occupational Safety and Health. DHHS (NIOSH) Publication No 2004-165; 2004*
- RCVS Supporting guidance on Cytotoxic Medicines & COSHH (Link)

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
Section 3: Dispensary management and staff training

Premises licensing and inspections

**KEY POINTS**

- Veterinary surgeons 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 VPPs 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 and any deficiencies found 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 (VMPs) 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 on the RCVS’s website. Completed forms and the registration fee (currently £34) must be sent to the RCVS’s 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’s 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’s 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 write to the practice 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.

The VMD aims to inspect non-PSS practice premises at least once every 4 years, and charges an inspection 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 it is repeated in their Code of Practice.

The on-site inspection

The VMD’s inspection criteria are set out on the Retail of veterinary medicines page of the VMD’s website (formerly VMGN No 3 – Guidance for Retailers). A summary of the VMD’s general inspection findings is also published on the VMD’s 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 Manual (☞); Section 8 (Medicinal Products) covers Medicines and the Dispensary area.

Both the VMD’s and the PSS’s 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 inspectors 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 inspector 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 inspector will record the number of veterinary surgeons, veterinary nurses and other members of staff spoken to in the course of an inspection.

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

Premises

- The premises is 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 VMPs 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.
- VMPs are stored in areas away from excessive light/moisture.
- VMPs are stored in areas that are not accessible to the public or domestic pets.
There are no VMPs on self-service, except AVM-GSLs.

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.

Record

Appropriate records are kept of all VMPs, and in particular those supplied under the cascade and for food producing animals.
See also Record keeping and audits.

Supply procedures

- Out of date VMPs, including those past their ‘broached 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 GP, 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 and PSS inspectors 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 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 VMPs are appropriately disposed of and recorded (e.g. by logging disposed products against a ‘dummy’ client 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 inspectors 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.

Conditions may be major, where re-inspection is required, or minor, where written or photographic evidence may be submitted. If more than 20 minor conditions are found these may be considered cumulatively as a major condition and a re-inspection advised.
The timeframe for minor evidence is stated on the report to the practice, as is what evidence is required (e.g. photographs, copies of documents). For most deficiencies, evidence will have to be submitted within 3 months, but for Controlled Drugs deficiencies evidence is required within 1 month.
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 apply an inspection interval based on the number and type of deficiencies noted, as follows:

<table>
<thead>
<tr>
<th>Inspection findings</th>
<th>Compliance rating</th>
<th>Max inspection interval (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 6 others (minor)</td>
<td>Good</td>
<td>48</td>
</tr>
<tr>
<td>&gt; 6 minor ≤ 3 major</td>
<td>Acceptable</td>
<td>36</td>
</tr>
<tr>
<td>&gt;3 ≤ 5 major</td>
<td>Poor</td>
<td>24</td>
</tr>
<tr>
<td>≥ 6 major; any critical</td>
<td>Unacceptable</td>
<td>Follow up inspection as specified on Improvement Notice, then next scheduled inspection within 9–12 months</td>
</tr>
</tbody>
</table>

Enforcement

The VMD remains responsible for enforcement of the VMR in all VPP. The VMD’s 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’s website and in its quarterly 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 will check that for POM-V and POM-VPS medicines there is evidence that the
   prescribing vet 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’s 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 who are inspected by the RCVS as part of this scheme. See also Premises licensing 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 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 on the VMD website product information database (1).

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.

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 ambient room temperature do not require refrigeration and should be kept between 8°C and 25°C. Storage of products at ambient temperatures 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. Temperatures should be monitored at least daily, and this should ideally be the responsibility of a named person. Maximum/minimum thermometers and a log book can be used for this purpose. The use of continuous data loggers to monitor the temperature can be convenient, but these should only be used if an audible alarm alerts the user to temperatures deviating from the required range. Monthly or quarterly 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. Generally data loggers should be downloaded at least weekly.

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.

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

Stock Control

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

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.

It is good practice to:

- Set stock levels to allow accurate stock holding
- Have a named person 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 should 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: \( \text{OUTL} = D \times L \) \( (D = \text{daily demand}; L = \text{lead time}) \).

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 is 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 maximises 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

Because 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 product mean that some products such as injectables have an in use shelf life. 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 28 days, thus making it an offence to administer the product after 28 days of opening (unless the original expiry date is shorter).

Multidose vials should be marked with the date of first opening and the date of expiry. 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 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.

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 or the University of Glasgow dispensing course. 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 in the last 5 years.

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:

- Decision arrows lead away from a diamond and towards an appropriate action
- Follow up decision. If the answer to a decision is not a yes or no, there may be more than two decision arrows leading from a decision diamond. For example, after taking a temperature you may have several options to follow, depending on the result
- A rectangle with a ragged bottom edge indicated that a record or notation should be made

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>START/END</td>
<td>A flattened oval represents a starting or an end point</td>
</tr>
<tr>
<td>ACTION</td>
<td>A rectangle indicates the staff member should perform an action of some sort</td>
</tr>
<tr>
<td>DECISION</td>
<td>Unlabelled arrows between other symbols indicate the direction of flow</td>
</tr>
<tr>
<td>&gt;32°</td>
<td>Diamonds are the accepted symbol for a decision point. They must have two or more arrows leading away from them towards alternatives</td>
</tr>
<tr>
<td>RECORD</td>
<td>Yes</td>
</tr>
</tbody>
</table>

BSAVA GUIDE TO THE USE OF VETERINARY MEDICINES
Edited by Fred Nind and Pam Mosedale. © BSAVA 2015. Updated April 2018
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. Injectable 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.
2. 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 must be witnessed.
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”.

### Date checking at the dispensary

- **Develop date checking 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.

- **Perform date checking**
  - 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 stock within 1 month of the expiry date. 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.

- **Deal with out of date drugs**
  - Record quantities and values of out of date medicines for accounts purposes and annual audit and dispose of this stock appropriately in a yellow DOOP bin.

- **Complete matrix**
  - Record completion of date checking of each area on the matrices by initializing and writing the date of completion in the relevant box. Every 4 weeks, check the short dated stock book and remove any stock that is within 1 month of its expiry date. Retain matrices for 6 months. The matrices must be available for inspection by authorized persons.
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).

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 7 years.

Medicines returned by customers or not used for in-patients

START

Take the returned medicine to the dispensary for sorting and put on protective clothing

Tip the drugs into a tray to avoid contact with ‘sharps’ or cytotoxic drugs and remove any Schedule 2 and 3 Controlled Drugs for separate destruction

Has the medicine left the premises?

YES

Is the medicine dangerous?

NO

Ensure dispensing labels from outer packaging are removed and placed in confidential waste

Remove dispensing labels and place in confidential waste

Remove blister strips from outer carton, place blisters, bottles of medicines and ampoules in blue Pharmaceutical Waste bin – do not decant from blisters or containers

Return pack to dispensary shelf in expiry data order. If the medicine was dispensed in a bottle other than the manufacturer’s original packaging, label the bottle with the name, strength and quantity of drug, batch number and expiry date

After waste collection, file the collection despatched issued by the waste contractor and retain for 3 years

Credit the patient’s account with the required amount

END
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 should 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 it has been stored according to its SPC
   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**
- Suitably 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 POM-V products or use 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 for small pet animals (ESPA).

Over 6000 SQPs are registered with the Animal Medicines Training Regulatory Authority (AMTRA). 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.

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 SOP 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 Retail of veterinary medicines guidance page (formerly VMGN No 3 – Guidance for Retailers).

See also Premises licensing and inspections.

**Legal duties**

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

- Circumstances of the holding and the animals being treated
- Available authorized veterinary medicines
- The need for responsible use of medicines and the requirement to prescribe the minimum amount of product necessary for the treatment
- 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 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.

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
- 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).

Off-label 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, then an SQP may only supply the medicine in accordance with a prescription from a veterinary surgeon under the prescribing cascade.

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) and outlines the required syllabus.

Candidates are assessed by examinations set and marked by Harper Adams University taking place at locations throughout the country. All 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 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 veterinary nurses may become SQPs via an accreditation of prior learning (APL) and 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 recognised by AMTRA as the academic basis for SQP registration.

Continuing professional development

Once qualified, an SQP must show they are keeping up to date. There is a 2-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 AMTRA’s CPD webpage (🔗).

SQPs in veterinary practice

An SQP working in 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 ‘prescription-only medicine – veterinarian’ (POM-V) medicines. The vet must prescribe the product and authorize each transaction individually, but may authorize another person to hand over the product provided the vet 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
   b. VMD
   c. NOAH
   d. The Home Office

2. Which categories of medicines can SQPs supply and 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 vet
   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).
- The information in summary of product characteristics (SPC) or safety datasheets should be used to perform risk assessments.

Health and safety in the dispensary requires the identification of hazards and risks.

- A hazard is anything that may cause harm (e.g. chemicals, electricity, working from ladders, an open drawer).
- 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 (COSHH)

The COSHH Regulations require employers to control substances that are hazardous to health. Exposure to hazardous substances can be prevented or reduced 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 they 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.

Hazardous substances include:

- Substances used directly in work activities (e.g. cleaning agents and medicines).
- Substances generated during work activities (e.g. waste fumes from anaesthesia equipment).
- Naturally occurring substances (e.g. dust from litters).
- Biological agents such as bacteria and other microorganisms.

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.

Substances regarded as hazardous to health include:

- Substances classified as dangerous to health under the Registration, Evaluation, Authorisation and restriction of Chemicals (REACH) legislation 2007 (recognizable by their warning symbols).
- Biological agents.
- Any kind of dust if concentrations in the air exceed levels specified in the COSHH Regulations.
- Other substances that may pose a risk to health but are not covered by the Chemicals (Hazard Information and Packaging for Supply) Regulations (CHIP) for technical reasons (e.g. medicines).

For further information on COSHH Regulations 2002 see the Health and Safety Executive (HSE) website.
Risk assessment

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 significant findings.
5. Review assessment and update if necessary.

Areas of work in the dispensary requiring risk assessment include:

- General medicines handling
- Handling cytotoxic medicines
- Spillage of medicines
- Manual handling (e.g. accessing high shelves and moving medicine orders)
- Trip hazards
- Waste disposal.

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 the SOPs have been read and understood.

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

See also Cytotoxic drugs.

For further information on risk assessments see the Health and Safety Executive (HSE) website ( ).

Low and medium risk substances

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.

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 medicines
- Micotil® (tilmicosin)
- Hormones
- Oil-based vaccines
- Glutaraldehyde disinfectants
- Large animal Immobilon (etorphine).

General guidelines for handling medicines

In general when handling medicines a member of staff must:

- Treat all medicinal products as potentially harmful
- Be aware of the hazards associated with medicines and know the results of the Control of Substances Hazardous to Health (COSHH) and risk assessments
- Wear disposable gloves when handling any open or loose products
- Be familiar with the practice SOP for handling medicines and use additional protective clothing and equipment as and when specified
- Inform the health and safety officer if they are or expect to become pregnant. In the case of pregnancy, be aware of and avoid handling teratogenic medicines (see the BSAVA Small Animal Formulary for a listing) likely to harm the unborn child or medicines likely to cause miscarriage
- 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
- 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 data sheets for medicines. Information of the safe use of each medicine can be found in the SPC. The VMD product information database (http://www.vmd.gov.uk) has a full list of veterinary SPCs for:

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

For non-veterinary authorized medicines (e.g. human prescription-only medicines) used under the prescribing cascade, SPCs can be found online at the electronic Medicines Compendium (eMC) (http://www.medicines.org.uk).

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

**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

**ANSWERS**

1 – d; 2 – c; 3 – b
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 corrected 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 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 guidance booklet Safe Management of Healthcare Waste
- The practice’s waste contractor’s systems and processes.

Veterinary surgeons 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 guidance booklet or BVA or waste contractor should be sought.

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.

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 | Medicinal hazardous waste is mainly purple waste. HP9 – infectious waste is the most relevant code |
| Orange                        | Hazardous waste for treatment prior to disposal | Any waste that is deemed to fall into definition laid out in the hazardous property codes | Treatments include autoclaving or disinfection |
| Purple                        | Hazardous medicinal waste | Cytotoxic or cytostatic medicines or items contaminated with these | Cannot be moved between branches |
| Blue (The ‘pharmacy bin’)      | Non-hazardous medicinal waste | Medicines | Denatured Controlled Drugs in this stream |
| Black & 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 |
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, be that 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 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 includes:

- 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.

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 include:

- 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).

Domestic waste

Domestic waste should be placed in a black bag and put out for regular collections. Where possible, waste should be recycled. 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 the 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.

<table>
<thead>
<tr>
<th>European Waste Catalogue (EWC) waste codes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Non-hazardous</strong></td>
</tr>
<tr>
<td>18 02 01 Sharps (except 18 02 02)</td>
</tr>
<tr>
<td>18 02 02 Wastes subject to special requirements in order to prevent infection</td>
</tr>
<tr>
<td>18 02 03 Wastes not subject to special requirements in order to prevent infection</td>
</tr>
<tr>
<td>18 02 05 Chemicals consisting of or containing dangerous substances</td>
</tr>
<tr>
<td>18 02 06 Chemicals other than those mentioned in 18 02 05</td>
</tr>
<tr>
<td>18 02 07 Cytotoxic and cytostatic medicines</td>
</tr>
<tr>
<td>18 02 08 Medicines other than those mentioned in 18 02 07</td>
</tr>
<tr>
<td><strong>Hazardous</strong></td>
</tr>
</tbody>
</table>

BSAVA GUIDE TO THE USE OF VETERINARY MEDICINES
Edited by Fred Nind and Pam Mosedale. © BSAVA 2015. Updated April 2018
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 and never used. It is illegal to 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 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.

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.
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.

**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-blisters 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 CD when prepared by a pharmacist under the prescribing cascade and ketamine, must be witnessed by a Veterinary Medicines Directorate (VMD) inspector, an inspector of the Royal College of Veterinary Surgeons (RCVS) Practice Standards Scheme (PSS) or a veterinary surgeon who is independent of the practice, or a police officer (such as a Controlled Drugs Liaison Officer (CDLO)).

  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.

  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/pharmacorubicin, methotrexate and all similar classes of tumour toxic medicines)
- Antiviral medicines, including interferon
- Ciclosporin medicines in any form
- Certain hormonal preparations, 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, unless specific dispensation is allowed (e.g. there may be a local agreement with the Environmental Agency). 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.

**New regulations update**

The new 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 Regulations and such waste was called DOOP (Destruction of Old Pharmaceutical) 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 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 via:
   a. A white-topped sharps bin
   b. An orange-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, passed its 28 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 landfill
   d. Hazardous waste that needs special treatment before disposal

4. Controlled Drug wastes, once denatured, are disposed 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
Section 4: Responsible use of medicines

Prescribing cascade

KEY POINTS

- The legal provisions for ‘cascade use’ exist to allow prescribing veterinary surgeons to ensure animal health and welfare where authorized veterinary medicines are not available.
- Where authorized veterinary medicinal products (VMPs) 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. 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 ‘cascade use’ of products should be reported to the regulatory agency, the Veterinary Medicines Directorate (VMD).
- Where VMPs 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 VMPs 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 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 under review. It is expected that a new VMR will come into effect across the EU in late 2017 or early 2018.

The current law starts from the principle that all VMPs 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 VMPs.

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, especially for species that are not usually in captivity. 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. 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 globally is worth approximately 2% 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 will not obtain a return on investment and the financial incentives to develop products for all conditions in all species are not there.

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 VMPs 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 animals, the consumer of food from animals. This assurance has to be provided for each species and each indication on the VMP’s summary of product characteristics (SPC), 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 differs between animal species and between animals and people. Human medicine formulations may contain different excipients or have different bioavailability from VMPs. 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.

Generics

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

- 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 (See the Veterinary Medicines Regulations 2013 Schedule 4 (i, ii, iii, iv, v, vi, vii, viii, ix, x, xi, xii, xiii, xiv, xv, xvi, xvii, xviii, xix, xx, xxi, xxii, xxiii, xxiv, xxv, xxvi, xxvii, xxviii, xxix, xxx, xxxi, xxxii, xxxiii, xxxiv, xxxv, xxxvi, xxxvii, xxxviii, xxxix, xli, xlii, xliii, xlv, xlvi, xlvii, xlviii, xlix, li, lii, liii, liv, lv, lix, lx, lxi, lxii, lxiii, lxiv, lxv, lxvi, lxvii, lxviii, lxix, lxx, lxxi, lxxii, lxxiii, lxxiv, lxxv, lxxvi, lxxvii, lxxviii, lxxix, lxxx, lxxxi, lxxxii, lxxxiii, lxxxiv, lxxxv, lxxxvi, lxxxvii, lxxxviii, lxxxix, xc, xci, xcv, xcvii, xcviii, xcix, xcii, xci, c, cc):
  - A VMP authorized in the UK for use with another animal species for that condition, or another condition for that animal.
  - If there is no such medicine:
    - An authorized human medicine; or
    - 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)
  - If there is no such medicine, a VMP prepared extemporaneously by a pharmacist, veterinary surgeon or person holding a manufacturing authorization for that type of product (often referred to as ‘veterinary specials’).

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.

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 medicine’s recommended use, regardless of whether there is an authorized medicine available. 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.

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 because it is cheaper. Any use of a human medicine instead of the authorized veterinary medicine has to be justified by the veterinary surgeon on clinical grounds alone. Every case will be examined on its merits.

Some examples given by the VMD to provide guidance on how the cascade should work in practice can be found on the VMD webpage, The Cascade: Prescribing unauthorised medicines (formerly VMGN Number 13) (1).
Suspected adverse events

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

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 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.

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 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. The information provided must include:

- Name and address of the pharmacy, surgery or approved premises supplying the product
- Name of the veterinary surgeon who has prescribed the product
- Name and address of the animal owner
- Identification (including species) of the animal or group of animals
- Date of supply
- Expiry date of the product, if applicable
- Name or description of the product, which should include at least the name and quantity of the active ingredient
- 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’.

Record keeping requirements

There are specific record keeping requirements for veterinary surgeons who administer or supply medicines to be dispensed under the cascade. These are set out below and must be retained for at least 5 years and be made available on request to a duly authorized person:

- Date of examination
- Animal owner’s name and address
- Identification and number of animals treated
- Result of the veterinary surgeon’s clinical assessment
- Trade name of the product(s) prescribed
- Batch number
- Name and quantity of the active substance
- Doses administered
- Duration of treatment
- Withdrawal period.

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. Veterinary surgeons may also find it helpful to include information identifying treated animals among their records.

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 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. In the case of exotic species, most of the medicines used are unlikely to be authorised for use in the UK and owners should be made aware of, and consent to, this from the outset.’
QUESTIONS

1. Is it legal to use a human medicine where an authorized VMP exists for the treatment of a condition
   a. Yes. The authorized VMP should be the first option considered by the veterinary surgeon, but it would be permitted to use a human medicinal product if there was evidence that the product with a veterinary authorization was not appropriate for the animal being treated and it was not possible to obtain a veterinary medicine via a special import license in a timely manner.
   b. No
   c. Yes, but only if it’s cheaper
   d. Yes, but only if it’s 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 fulfill RCVS requirements:
   a. Explain to the animal owner that they are prescribing under the cascade
   b. Explain to the animal owner that they are prescribing under the cascade and obtain the owner’s written consent to do so
   c. Not mention to the animal owner that they intend to prescribe under the cascade
   d. Obtain written consent from the animal owner, 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 a ‘copy’ of 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 – b; 2 – c; 3 – b; 4 – b

Further information

- VMD
- Apply to change a marketing authorisation for a veterinary medicine (formerly VMGN Number 2 – Marketing Authorization for Veterinary Medicinal Products)
- Apply for a certificate to import a Veterinary Medicine into the UK (formerly VMGN Number 5 – Import Certificate Schemes)
- Exemption from authorisation for medicines for small pet animals (formerly VMGN Number 12 – Exemption Scheme for Small Pet Animals)
- The Cascade: Prescribing unauthorised medicines (formerly VMGN Number 13 – Guidance on the use of the cascade)
- VMD statement – Responsible antibiotic use under the cascade
- RCVS
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 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 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 a medication off-licence 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.

The concept of informed consent arose in human medicine during the early 20th century based on the opinion that 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 his or her 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 owners or authorized agents are 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.

Section 11 of the Supporting Guidance to the Royal College of Veterinary Surgeons (RCVS) Code of Professional Conduct (June 2014) outlines the professions’ obligations on consent and advises inter alia:

11.1 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.

11.3 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.

11.4 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.

11.5 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.

11.6 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.

11.8 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.

Consent forms

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, preoperative and postoperative checks and any diagnostic tests. The owner should be warned that additional charges may arise if complications occur. If a quote is given, it may be binding in law.

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 on the clinical records.

For consent to be informed, owners must understand what they are signing. It is no longer considered sufficient to add the catch-all phrase ‘and any other 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 to 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.

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.’

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:

11.16 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.

11.17 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.

11.18 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.

11.19 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 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 a medication off-licence and give consent for their animal to receive such treatment.

The law states that owners must be fully informed when a medication is used off-licence. Section 4.17 of the Supporting Guidance to the RCVS Code of Professional Conduct makes clear the need for informed consent to be obtained, in writing, for the use of any medicine off-licence, under the principles of the cascade.

The RCVS Practice Standards Scheme (PSS) inspectors will ask to see examples of signed off-licence consent forms.

Off-licence use in practice

Datasheets are not legally binding documents and do not override 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.

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 medicine(s) which caused the problem. It is therefore extremely important that the right message should be given. Practices may even consider creating a generic client information sheet on the subject. Specific client information leaflets covering the common medications prescribed off-licence are available for members to download from the BSAVA website.

Use of information sheets

An information sheet could include the following points:

- Medications the practice may wish to use that have been in general veterinary use for years, for example those found in the emergency box in most operating theatres (e.g. adrenaline, atropine, potassium chloride).
- 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. As many are related to anaesthesia and analgesia (e.g. morphine, diazepam), the sight of such familiar names often quells any concerns the client may have.
- The reason why these medications do not have a UK marketing authorization, which in many cases is purely due to the prohibitive cost of obtaining a product licence.

Off-licence use consent forms

It is not a legal requirement to obtain written consent to prescribe a medicine under the cascade, but the RCVS Code designates that consent for use of a medication off-licence must 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, which is paramount to ensure fully informed consent is obtained.

Single-use consent form

As the wording implies, this is used in a situation where a specific medication, which does not carry a veterinary marketing authorization, is required. For example, this would be in a case where the veterinary surgeon wishes to use a cytotoxic medicine to treat a specific type of neoplasia.

Single-use consent forms should be used each time a new medication is prescribed off-licence for an individual animal. If an animal is on a long-term repeat prescription for a medication used off-licence 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 no authorized medicines for use in the species concerned. An increasing variety of non-traditional 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 medicines are likely to be used as part of the anaesthetic routine, to provide perioperative 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 medicines 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.

Further information

BSAVA Client Information Leaflets (1)
RCVS Code to Professional Conduct Section 11 (2)
Veterinary Defence Society Consent Form Templates (3)
Veterinary Medicines Guidance pages (replacing the previous Veterinary Medicines Guidance Notes) (4)

QUESTIONS

1. If a veterinary surgeon is using a medication off-licence under the cascade in a dog or cat, when should they obtain a signed off-licence consent form?
   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 involved 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 authorised for use in the species involved

ANSWERS

1 – d; 2 – a; 3 – b; 4 – c
KEY POINTS

- Antibacterials are essential medicines for treating bacterial infections
- Increasing usage of antibacterials has 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 PROTECT the effectiveness for future use

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 antibacterials.

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 medicine target, 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 changes 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 medicine target. 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 antimicrobial agent through its inherent structural or functional characteristics (see above).

Chromosomal resistance

It is estimated that 1 in 10,000,000 bacterial cells give rise to a daughter cell with a mutation. If this change confers antibacterial resistance in the organism through a change in the cell structure, target molecule or metabolism of the antibiotic it may provide a survival advantage in the face of antibacterial treatment.
Plasmid-mediated resistance
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 on the BSAVA Antibacterial resistance page ( ).

Guidance and regulations
UK Five Year Antimicrobial Resistance (AMR) Strategy 2013 to 2018
The AMR Strategy was drawn up by the UK’s Department of Health and Department for Environment, Food and Rural Affairs (Defra). The stated goal of the Strategy is to slow the development and spread of antimicrobial, including antibacterial, resistance. There are three 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:

- 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 and nurses, and their professional bodies, need to take action to improve the knowledge and understanding of antimicrobial resistance, 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 ( ).

There is also a European Union action plan ( ) against antimicrobial resistance.

UK regulations and guidance on antimicrobial prescribing
The Royal College of Veterinary Surgeons (RCVS) has said that ‘The development and spread of antimicrobial resistance is a global health problem that is 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’.

The Veterinary Medicinal Products Directive 2001/82/EC (as amended) sets out controls on the manufacture, authorization, marketing, distribution and post-authorization surveillance of veterinary medicinal products (VMPs) in all European Member States. This directive is implemented in the UK through the Veterinary Medicines Regulations (VMR) which first came into force in October 2005 and are regularly updated. The current VMR and supporting guidance can be accessed on the Veterinary Medicines Directorate (VMD) website ( ).

In September 2014, the European Commission adopted new proposals to replace the current Veterinary Medicinal Products Directive with a new European Regulation on VMPs. These proposals will now be considered by the European Parliament.

In the UK, all veterinary antibacterials 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 VMR do not define the phrase ‘under his care’ the RCVS has interpreted it as meaning that:

- The veterinary surgeon must have been given the responsibility for the health of the animal or herd by the owner or the owner’s agent
- That responsibility must be real and not nominal
- The animal or herd must have been seen immediately before the prescription; or
- Recently enough or often enough for the veterinary surgeon to have personal knowledge of the condition of the animal or current health status of the herd or flock to make a diagnosis and prescribe
- The veterinary surgeon must maintain clinical records of that herd/flock/individual.

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.

Guidance on adverse reactions
Adverse reactions are harmful and unintended reactions to a medicine when administered to an animal at the recommended dose and route of administration. 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 was used, or where a particular 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 should be made to the Veterinary Medicines Directorate (VMD) using the Suspected Adverse Reaction Surveillance Scheme (SARSS) forms. These forms are available to download from the VMD website (3).

See also Pharmacovigilance.

Prescribing antibiotics under the cascade

The VMD have issued a position statement entitled ‘Responsible antibiotic use under the cascade’ (6), which states that the VMD considers that it is justified, on a case-by-case basis, to prescribe an antibiotic on the cascade in the interests of minimizing the development of resistance. This applies 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 VMP 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 – using scientific evidence – their decision making process.

See also Prescribing cascade.

Veterinary access to critically important antimicrobials in humans

The World Health Organization (WHO) has developed a list of antimicrobial agents used in human medicine classified by importance. No antimicrobials in use were considered unimportant, and three categories were defined: critically important; highly important; and important.

Antimicrobials were assigned to these categories based on two criteria:

1. Where the medicine is the sole therapy or one of few alternatives to treat serious human disease
2. Where the medicine 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 medicines that meet both these criteria are classified as critically important, while those that only meet one of the criteria are classified as highly important. The current list can be accessed on the WHO’s website (4).

The World Organization for Animal Health (OIE) has produced a similar list (5) of the antimicrobials considered important in veterinary medicine, which used the same categories of importance identified via slightly different criteria met:

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

Unfortunately, many of the antibacterials that are relied on in veterinary medicine are considered critically important in human medicine, so veterinary surgeons have a duty to use them responsibly, not only to ensure their efficacy in the treatment of animal patients but also to endeavour to minimize the development of resistance to critically important human medicines. There are three categories of antibacterials that have been classified as “highest priority” critically important antimicrobials and their use should receive particular consideration:

- Quinolones
- Third- and fourth-generation cephalosporins
- Macrolides.

Responsible antibacterial prescribing

The responsible use of antimicrobials, according to the Heads of Medicines Agencies (6) ‘...does not simply mean using less antimicrobials, it means justified use (based on a properly established diagnosis) of the most appropriate sensitive antimicrobial in a way optimising its clinical efficacy in the specific clinical cases and taking reasonable steps to ensure the method of use (including dose regime) applied help limit the potential for resistance to develop.’

There is no doubt that the use of antibacterials is frequently justified in the treatment of bacterial disease and leads to improvements in animal health and welfare. Treatment with a broad-spectrum highly potent relatively new antibacterial may be highly effective in the short term, but overuse will select for resistance and reduce usefulness in the medium to long term.

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 done by reducing the unnecessary use of antibacterial agents and optimizing medicine choice, dose and dosing regimens. This requires that knowledge of clinical disease is integrated with knowledge of the pharmacology of antibacterial agents in order to inform clinical decision making.

The first decision to be made is whether antibacterial treatment is appropriate in a particular case; 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?
Once it has been decided that the use of antibacterials in a particular case is justified, it is important to select the antibacterial that is most likely to be effective based on the species being treated, the site of infection and knowledge of the bacteria likely to be involved. Where possible, it is better to use a narrow-spectrum rather than a broad-spectrum antibacterial to limit the effects on commensal bacteria. The veterinary surgeon can maximize the likelihood of therapeutic success and minimize the likelihood of selecting resistant bacteria by considering the following in their choice of antibacterial medicines:

**The animal under treatment**

The first consideration will be the species of animal under treatment as this will affect not only the diagnosis and organisms likely to be involved, but also the range of antibacterial medicines that are appropriate and available for treatment. Details of previous antibacterial medication can provide information about possible antibacterial resistance and current medication should lead to consideration of possible interactions. Co-morbidity, especially in terms of renal or hepatic conditions which may affect metabolism and elimination of medicines, should also be considered when selecting an appropriate antibacterial product.

**Likely pathogenic organisms**

The veterinary surgeon may have a good idea of the likely organism(s) involved in a particular condition. Some organisms have stable and predictable resistance patterns enabling rational antibacterial selection from empirical research and experience. However, it should be remembered that some bacteria have variable resistance patterns (e.g. *Staphylococcus aureus*, which may be methicillin-susceptible *S. aureus* (MSSA) or methicillin-resistance *S. aureus* (MRSA)). Other bacteria, such as *Escherichia coli* and *Pseudomonas*, are known to have unpredictable resistance patterns, which are likely to require culture and sensitivity testing to be undertaken to establish antibacterial susceptibility. Clinical resistance (whether the antibacterial will or will not work in a patient) is a more complex concept in which many other factors are involved, such as the precise location of the infection, the testing to be undertaken to establish antibacterial susceptibility. Clinical resistance (whether the antibacterial will or will not work in a patient) is a more complex concept in which many other factors are involved, such as the precise location of the infection, the distribution of the medicine in body fluids and the state of the patient’s immune system.

**Distribution**

In order to assess the ability of the antibacterial to reach the site of infection at an appropriate concentration, the veterinary surgeon needs a working knowledge of the pharmacokinetics of the antibacterial, in particular knowledge of its distribution.

**Severity of the infection**

The severity of the infection may determine the need to start antibacterial treatment before culture and sensitivity results are obtained. In these cases, it may be appropriate to start broad-spectrum antibacterial therapy, possibly using a combination of medicines while awaiting results. Combinations can be particularly useful if there is a mixed infection (e.g. an aminoglycoside (Gram-negative spectrum) with clindamycin (anaerobic spectrum)). Combinations may also be indicated for agents where resistance develops rapidly, so rapid antibacterial killing is desirable.

**Spectrum of activity**

Veterinary surgeons should have a working knowledge of the spectrum of activity of the main antibacterials used in veterinary practice. In order to minimize resistance, veterinary surgeons should opt for the narrowest spectrum agent. For example:

- a. Anaerobic infections: metronidazole; clindamycin; many of the penicillins and cephalosporins (especially the narrow-spectrum penicillins such as Penicillin G)
- b. Gram-positive infections: penicillins; cephalosporins; lincosamides; macrolides
- c. Gram-negative infections: aminoglycosides; fluoroquinolones.

**PROTECT poster**

The PROTECT 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 poster, produced by BSAVA and SAMSoc. The PROTECT message is that antibacterials need to be used responsibly – therefore, before they are prescribed, the following should be considered:

**Practice policy**

A practice policy for empirical prescribing (whilst awaiting cultures) can optimize therapy and minimize inappropriate use of antibacterials. The PROTECT poster can provide a useful reminder of practice prescribing policy.

**Reducing 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. in immunocompromised patients).
Other options for treatment

Before prescribing antibacterials it is worth considering whether there are other options.

- It is possible to reduce inappropriate antibacterial prescribing (e.g. due to client pressure, in uncomplicated viral infections or self-limiting disease) by providing symptomatic relief (e.g. analgesia, cough suppressants).
- Effective lavage and debridement of infected material can also reduce the need for antibacterials.
- Using topical preparations reduces selection pressure on resistant intestinal flora.

Types of bacteria and medicine

Before prescribing antibacterials, the following should be considered:

- Which bacteria are likely to be involved (e.g. anaerobic/aerobic, Gram-positive/Gram-negative)
- The distribution and penetration of the medicine
- Any potential side effects.

Employing the correct antibacterial

Where possible it is better to use a narrow-spectrum rather than a broad-spectrum antibacterial, to limit the effects on commensal bacteria.

Cytology and culture

Use cytology and culture to diagnose bacterial infection correctly. Culture is not required in every case, but when prolonged courses of antibacterials are likely to be needed (e.g. pyoderma, otitis externa, deep or surgical wounds, or following failure of empirical dosing), culture first, ask questions later!

Treating effectively

In order to treat effectively, it is necessary to:

- Treat for long enough and at a sufficient dose to kill the bacteria, and then stop
- Avoid under-dosing and consider how the medicine will penetrate the target area
- Repeat culture after long courses of antibacterials.

Development of practice guidelines

Antibacterial prescribing is a common part of practice and many, though not all, of the conditions treated 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 tests 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.

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
- Conditions that are commonly encountered
- Causal organisms that are likely to be involved in particular conditions, with cytology or culture being used to provide confirmation where appropriate
- Antibacterials to which they are most likely to be sensitive.

It can be useful to start by creating a table of first-, second- and third-choice antibacterials:

- First-choice antibacterials would comprise agents appropriate for initial treatment, not necessarily based on culture and sensitivity
- Second-choice antibacterials should be prescribed on the basis of culture and sensitivity data, where no first-choice agents are appropriate
- Third-choice antibacterials should only be prescribed for serious and life-threatening infections, based on culture and sensitivity data, and only where no first- or second-choice agents are appropriate.

Certain antimicrobials should be used judiciously. This means that their use as first-choice agents should be avoided, and they should only be used when other agents are ineffective (ideally determined by culture and sensitivity testing). These include:

- Fluoroquinolones
- Third- and fourth- generation cephalosporins
- Amikacin.
Certain antimicrobials should probably not be used in veterinary species. These are agents of last resort in human patients and include:

- Vancomycin
- Carbapenems such as imipenem.

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

**Prophylactic antibacterial use**

Prophylactic antibacterial use is the administration of antibacterials in the absence of infection, with the aim of preventing it. The most common reason for the prophylactic use of antibacterials in small animal veterinary practice is in the perioperative period, but their use may also be appropriate in certain medical situations; for example, when an animal is considered to be at increased risk due to concurrent disease or immunosuppressive therapy and is in contact with other infected animals.

Ideally, the prophylactic use of antibacterials should be based on careful risk assessment. It is important for any risk assessment to balance the risks of developing infections in the individual animal with the risk of selecting for resistance bacteria.

**Surgical prophylaxis**

Prophylactic antibacterial use may be appropriate in the perioperative period, although it should not be a substitute for good asepsis. The perioperative use of antibacterials can reduce the incidence of postoperative surgical site infection, but where the risk is low inappropriate use of antibacterials is most likely to result in unnecessary costs for the owner and can increase the occurrence of bacterial resistance and super-infection. It should be remembered that surgical site infection is most likely to arise from colonization of the wound by the animal’s own endemic flora and the inappropriate use of perioperative antibiotics may increase the risk of surgical site infection with opportunistic organisms, which are more difficult to treat.

Examples of appropriate criteria for perioperative antibacterial use include:

- Prolonged surgical procedures (>1.5 hours)
- Introduction of an implant into the body
- Procedures where introduction of infection would be catastrophic (e.g. central nervous system surgery)
- Where there is an obvious identified break in asepsis
- Bowel surgery with a risk of leakage
- Dentistry with associated periodontal disease
- Contaminated wounds.

To be effective, prophylactic antibacterials at appropriate concentrations must be present in tissues at the surgical site at the time of contamination to prevent bacterial growth and subsequent infection.

- Administer the first dose 1 hour before the incision.
- Re-administer during surgery if the procedure is ongoing after two half-lives of the medicine have passed.
- Restrict treatment to the duration of the surgery or less than 24 hours, except where therapeutic doses are required (e.g. gross contamination, pre-existing infection).
- Avoid the use of newer broad-spectrum antibacterials.

For further details of surgical asepsis see the BSAVA Manual of Canine and Feline Surgical Principles.

**Immunocompromised patients**

Patients may be immunocompromised for a number of reasons including chemotherapy. Mild neutropenia is common and often not a clinical problem, but severe neutropenia can be complicated by sepsis and can be life threatening. Current guidelines in human oncology recommend avoiding the routine use of antibacterial prophylaxis because of concerns of emerging medicine-resistant bacteria. Therefore, it would seem prudent to adopt similar measures in veterinary species and only use antibacterial prophylaxis in patients receiving chemotherapy if the neutrophil count is $1 \times 10^9/l$ ($1000$ neutrophils/$\mu l$).

**Alternatives to antibacterials**

The best ways to minimize the use of antibacterials are through:

1. Disease prevention, including improved hygiene, biosecurity measures, vaccination and parasite control
2. Infection control including reducing the need for prophylactic use of antibacterials in clean surgery
3. Accurate diagnosis and restriction of the use of antibacterials to those cases where it is known or strongly suspected that the disease is caused by bacteria
4. Consideration of alternative treatments.

One of the best ways of protecting the effectiveness of antibacterials is to use them sparingly. This means that veterinary surgeons may need to consider other options when faced with bacterial infections in patients.

Before prescribing antibacterials, it may be worth considering the following:

- Not all animals with bacterial infections require antibacterial treatment. In healthy individuals, reducing the bacterial load may be sufficient to enable recovery. The use of antiseptic washes and ear cleaners may reduce the need for antibacterials in pyoderma and otitis externa, respectively.
Effective lavage and debridement of infected material reduces the need for antibacterials. Antiseptics and antibacterial wound dressings also reduce the need for systemic antibacterials.

The use of topical prescriptions reduces selection pressure on resistant intestinal flora.

It is possible to reduce inappropriate antibacterial prescribing (e.g. due to client pressure, in uncomplicated viral infections or self-limiting disease) by providing symptomatic relief (e.g. analgesia, cough suppressants).

Rectifying the underlying cause of disease may reduce the need for antibacterial treatment.

Culture and sensitivity testing

Sampling for bacterial disease is common in veterinary practice and can give information that aids in the rational selection of antibacterial treatment. Culture and sensitivity test results considerably assist the choice of which antimicrobial to use. Culture is not required in every case, but when prolonged courses of antimicrobials are likely to be needed (e.g. pyoderma, otitis externa and deep or surgical wound infections) or when there is uncertainty about the presence or sensitivity of a bacterial infection then culture and sensitivity testing will improve the animal’s treatment.

Direct microscopy of smears

This is a useful but underutilized tool in the initial investigation of an infection. It can enable:

- Detection of bacteria and other microorganisms
- Determination of bacterial morphology (coccii or rods, streptococci or staphylococci) and Gram staining
- Prediction of the identification of microorganisms detected
- Appropriate selection of empirical antibacterial treatment in the absence of or while awaiting culture and sensitivity test results.

Samples suitable for cytology

- Impression smears from cutaneous lesions or tissue biopsy samples.
- Smears from swabs of aural, nasal or vaginal discharge.
- Direct smears from peritoneal or pleural fluids and abscess material.
- Concentrated sediment from urine, bronchiolar lavage, prostatic washes and cerebrospinal fluid.

Samples for bacteria culture

These should be:

- Taken from live animals as early as possible and before antibacterial treatment commences
- Taken carefully to minimize contamination
- Appropriate in type and quantity to the type of culture required
- Taken into the correct transport medium to maximize bacterial survival
- Packaged appropriately in accordance with Health and Safety requirements
- Kept at room temperature and dispatched for culture within 24 hours wherever possible.

The isolation of bacteria from an animal is not proof of pathogenicity; the normal bacteria for the species and sample should be considered when assessing their significance.

In vitro testing

This is indicated for any bacterial pathogen when the susceptibility cannot be reliably predicted and/or the organism is capable of developing resistance to antibacterial medicines.

- **Agar gel disc diffusion** – a uniform suspension of the bacterium under investigation is spread across an agar gel plate and paper discs impregnated with a known concentration are added. The plate is then incubated. If the bacterium incubated is sensitive to a particular antibacterial medicine, a zone of inhibition occurs around the disc. Zone diameters are compared to standard figures to decide whether the bacterium is sensitive or resistant to a particular antibacterial medicine.

- **E-test strip** – a variation in which a strip containing gradations of medicine concentration is placed on the surface. Following incubation the point on the strip that intersects with the line of bacterial inhibition is recorded as the minimum inhibitory concentration (MIC).

- **Broth dilution MIC** – the lowest concentration of an antibiotic that inhibits the growth of the bacterium under test. MICs are determined by inoculating a bacterial isolate into a series of test wells with doubling dilutions of the antibacterial medicine under test. The test provides information on the antibacterial concentrations at which the bacterium is able to grow or is inhibited.

The MIC is the lowest medicine concentration inhibiting the growth of the bacterial inoculum. These results are interpreted in the light of likely serum concentrations of antibacterial to describe the bacterium as sensitive or resistant to a particular antibiotic, with the breakpoint being determined by the medicine’s *in vitro* activity, achievable medicine concentrations in the host, distribution and elimination data and medicine toxicity. Bacteria described as having an intermediate sensitivity may be sensitive where the antibacterial can safely be given in high doses or at sites in the body where the antibacterial medicine is concentrated.
Rational antibacterial combinations

The most commonly used combinations in companion animal practice are potentiated amoxicillins, where potassium clavulanate is used to extend the spectrum of activity through the inhibition of beta-lactamase, and trimethoprim, a tetrahydrofolate inhibitor, which has a synergistic effect with sulphonamides leading to bactericidal activity and reducing required dosage. Both of these may be regarded as rational choices and advantageous in reducing the likelihood of resistance emerging.

- Combinations may be useful if there is a mixed infection (e.g. an aminoglycoside (Gram-negative spectrum) with clindamycin (anaerobic spectrum)).
- Synergism is described for some combinations (e.g. aminoglycosides combined with penicillins or sulphonamides combined with diamiopyrimidines).
- Do not combine a bactericidal with a bacteriostatic antibacterial as an antagonistic effect occurs.

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. What do the letters MIC stand for?
   a. Maximum inhibitory concentration
   b. Minimum inhibitory concentration
   c. Maximum inoculated contamination
   d. Minimum inoculated contamination

ANSWERS

1 – c; 2 – d; 3 – d; 4 – b
Importing medicines

KEY POINTS
- It should always be remembered that it is illegal to import unauthorized medicines without the correct licences.
- There are two types of licence for medicine importation:
  - Special Treatment Certificate (STC) for non-European veterinary or human medicinal products
  - Special Import Certificate (SIC) for European veterinary medicinal products (VMPs)
- STCs and SICs may be obtained from the Veterinary Medicines Directorate (VMD) Special Import Site.

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 a manufacturing authorization 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 STC/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 STC/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 produce 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 manufacturing authorization 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 VMPs 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. It is the importing veterinary surgeon’s responsibility to obtain data about the product to clinically justify the use of such a product, and to keep full records of its use.

1. Establish a source – this may be the medicine manufacturer or it may be a special medicine importer.
2. 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 and the name, address 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 Medicine waste disposal), or the amount should be transferred on to a new STC/SIC. Stock should not be supplied to other veterinary practices unless they apply for separate STC/SIC citing the original veterinary surgeon as source (and that original STC/SIC).

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 concerned and has in place the necessary licences from the Home Office.

Types of licence

There are two types of licence for medicine importation:

Special Treatment Certificate (STC)

Initial applications for an STC for non-European or human medicinal products must be made in writing. Forms are available on the VMD website and each application costs £30 (price correct at July 2015) per animal treated. These may be posted as hardcopy or (preferably) submitted electronically via importcert@vmd.defra.gsi.gov.uk. Thereafter, repeat applications can be made online and require no additional payment.

Special Import Certificate (SIC)

These are for European VMPs and applications can be made online.

Applications for STCs/SICs

The costs of obtaining import certificates (as of March 2015) are:

<table>
<thead>
<tr>
<th>Situation</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>SICs processed as hard copy</td>
<td>£15.00</td>
</tr>
<tr>
<td>STCs processed as hard copy</td>
<td>£30.00</td>
</tr>
<tr>
<td>Repeat STCs processed as hard copy</td>
<td>£30.00</td>
</tr>
<tr>
<td>Online SICs</td>
<td>Free</td>
</tr>
<tr>
<td>Online repeat STCs</td>
<td>Free</td>
</tr>
<tr>
<td>WDIC where less than 100 SICs/STCs naming the wholesale dealer as the importer were supplied in the 12 month period before the application was made</td>
<td>Free</td>
</tr>
<tr>
<td>WDIC where more than 100 SICs/STCs naming the wholesale dealer as the importer were supplied in the 12 month period before the application was made</td>
<td>£760.00</td>
</tr>
</tbody>
</table>

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 (VibraVenōs®) 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 VibraVenōs for this reason can be made, especially where birds may be additionally stressed and handlers exposed to a zoonosis if the birds are handled for direct oral medication (as opposed to weekly injections of VibraVenōs). 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.
- On occasion, emergency importation will be required. For applications made online, the VMD can usually provide a licence within 48 hours. The licence and prescription can then be sent to the importer.
- The VMD website provides full instructions on how to apply for an STC or 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 treatment certificate (STC)
   - b. Special import certificate (SIC)
   - c. Written script posted to manufacturer
   - d. 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

**QUESTIONS**

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   - a. A veterinary surgeon
   - b. The owner
   - c. No one
   - d. Anyone

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   - 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 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, turkey, geese, ducks, guinea fowls, quails, pigeons, rats 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 tend to have a relatively narrow spectrum of activity, 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 must ensure that the active 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. It is debatable as to whether or not pre-pubescent chickens can be considered as egg-laying hens. Some preparations of doxycycline currently authorized in the UK state that they should not be used within 14 days of the onset of egg laying; however, in the Table of Allowed Substances in the EU, there is a side note stating doxycycline should not be given to birds producing eggs for human consumption. As such, it may be argued that pullets before the onset of lay are not producing eggs for human consumption at the time of treatment.

For owners using their eggs for hatching rather than eating, there may be a case to argue that such birds are not 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 first try to use a product with a defined MRL for eggs.
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 MRL 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

<table>
<thead>
<tr>
<th>Products with no MRL for eggs but that do not indicate 'not for use in birds producing eggs for human consumption'</th>
<th>Spectrum of activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marbofloxacin</td>
<td>Mycoplasma, Salmonella, E. coli, Pasteurella and Staphylococcus</td>
</tr>
<tr>
<td>Cefquinome</td>
<td>Mycoplasma, E. coli, Pasteurella and Staphylococcus</td>
</tr>
<tr>
<td>Ceftiocur</td>
<td>E. coli and Pasteurella (poor intestinal absorption)</td>
</tr>
<tr>
<td>Gamithromycin</td>
<td>Pasteurella</td>
</tr>
<tr>
<td>Tulathromycin</td>
<td>Pasteurella and Mycoplasma</td>
</tr>
</tbody>
</table>

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:

### Products for which an MRL cannot be established (Annex 4)

<table>
<thead>
<tr>
<th>Products for which an MRL cannot be established (Annex 4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chloroform</td>
</tr>
<tr>
<td>Chloramphenicol</td>
</tr>
<tr>
<td>Chlorpromazine</td>
</tr>
<tr>
<td>Colchicine</td>
</tr>
<tr>
<td>Dapsone</td>
</tr>
<tr>
<td>Dimetridazole</td>
</tr>
<tr>
<td>Metronidazole</td>
</tr>
<tr>
<td>Nitrofurans (including furazolidone)</td>
</tr>
<tr>
<td>Ronidazole</td>
</tr>
</tbody>
</table>
Anticoccidials

There are two currently authorized anticoccidial agents in the UK: toltrazuril and amprolium. Toltrazuril has no MRL for eggs and states that it should not be used for birds producing eggs for human consumption. As coccidiosis usually affects poultry before the onset of egg laying then technically the affected birds may not be considered as birds producing eggs for human consumption.

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.

Ectoparasite treatments

There are a number of ectoparasite treatments listed in the Table of Allowed Substances with no MRL 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 of such products have no MRL 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 milk 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 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 milk 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.

Note: Owners selling eggs must keep a veterinary medicines record book
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 sells 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 need be applied
   d. Advise the owner that no treatment is permitted and the bird must be euthanised

4. The veterinary surgeon decides to use a cattle product in a pet laying hen, under the cascade, for which there is a 15 day milk withdrawal. What should be the egg withdrawal set?
   a. 29 days
   b. 7 days
   c. 15 days
   d. 0 days

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); 4. a (milk withdrawal is 14 days and 15 days should be added to the incubation period of eggs).
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.
- Advertising of prescription-only medicines to the general public is an offence.
- Internet retailers can apply for accreditation under the Veterinary Medicines Directorate's (VMD) Accredited Internet Retailer Scheme, which provides reassurance to customers.

UK law permits the remote supply of all categories of veterinary medicinal products (VMPs), 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’, many are hosted by veterinary practices under the professional control of veterinary surgeons. Some internet sites are true pharmacies controlled by pharmacists, and a number of sites are under the control of suitably qualified persons (SQPs).

As well as online ordering, some businesses also promote mail order supply of VMPs through more traditional printed price lists and advertisements, and others may 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.

As a result, although the supply of VMPs 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, since legal and professional obligations cannot be met satisfactorily.

Veterinary surgeon’s 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 (formerly Veterinary Medicines Guidance Notes (VMGN) Number 3 – Guidance for Retailers) (\(\text{See also }\)).

Prescriptions

The requirements for the prescribing and supplying of VMPs 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, SOP’ (POM-VPS) medicines may be prescribed for animals not under the veterinary surgeon’s care, but the other professional and legal obligations must be met.

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.

Prescriptions for VMPs 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 should seek to ensure that a prescription is genuine and is only fulfilled once (unless it is repeatable, in which case the number of repeats must be stated on the prescription). It is good practice if the supplier does not recognize the prescriber’s signature to take steps to check the prescription is genuine.

Prescription misuse is a growing concern and veterinary surgeons should take care when writing and dispensing against written prescriptions. 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 website. Guidance on how to mitigate prescription misuse is also available on the Retail of veterinary medicines page (formerly VMGN Number 3 – Guidance for Retailers).
Vaccination
Veterinary surgeons should take account of whether the VMPs 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 Post Office (1) provides guidance on what can and cannot be sent in the post.

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.

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

- It is considered good practice for all businesses supplying VMPs 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. The VMD provides example ‘About us’ pages (2) for this purpose.
- 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 ‘non-food animal medicine – veterinarian, pharmacist, SQP’ (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 declarations 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.
- 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.
- All information provided must be carefully checked by the authorized supplier before any supply is made.
- Records of communication with clients should be made and retained.

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 VMPs cannot be advertised to professional keepers of animals. In addition, POM-VPS medicines cannot be advertised to horse owners or keepers.

However, price lists (printed or online) may be supplied to the general public, provided certain conditions are met:

- 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.

The VMD publishes guidance on the advertising of VMPs on its Advertise veterinary medicines legally webpage (formerly VMGN Number 4 – Controls on advertising) ( ).

Non-UK websites

UK law requires that (save for the exemptions provided to veterinary surgeons under the cascade) only authorized VMPs 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 (AIRS)

Internet retailers of VMPs can apply for accreditation under the VMD’s Accredited Internet Retailer Scheme. 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 AIRS is a means of facilitating self-regulation by UK-based internet retailers supplying VMPs. 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.

Illegal sales of VMPs 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 VMPs. 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 of veterinary medicines (formerly VMGN Number 1 – Controls of Veterinary Medicines) ( ) or contact the Enforcement Team for more details on enforcement@vmd.defra.gsi.gov.uk).

Useful links

Royal Pharmaceutical Society of Great Britain ( )
Veterinary Medicines Directorate ( )
Prescription misuse reporting ( )
Veterinary Medicines Guidance (formerly Veterinary Medicines Guidance Notes) ( )
VMD’s Accredited Internet Retailer Scheme ( )
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 (SARRS)

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 AIRS scheme do?
   a. Provides a means for customers to check they are buying from a reputable and appropriately UK supplier of VMPs
   b. Check the registered website’s systems and processes ensure compliance with the law
   c. Confirm that the retailers 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 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 is probable that it is not 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 (2), 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 on request; this advice is most easily accessed via the Society of Greyhound Veterinarians website (3). 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 remember 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.

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.

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. GBGB publishes a list of permitted topical treatments (3).

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 hope that 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 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 vet. 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 (7) and the Veterinary Medicines Directorate (VMD) (8). 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 (VMPs) are delivered to it directly from a wholesale dealer and/or the VMPs are stored there overnight. However, if VMPs 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.

Trainer responsibilities

All GBGB trainers are issued with a Trainer’s Treatment Book (9) for each Greyhound. It is the trainer’s responsibility to present the book, to provide details of previous medicines use and to enable the treating veterinary surgeon to record the administration or prescription of any POM-V 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 provision of written treatment details to the handler can assist other treating vets 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 in 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 (GBGB Rules) under certain conditions, including a written declaration of the treatment by the trainer.

GBGB statement on oestrus suppression

‘Following discussions with the Government’s Veterinary Medicines Directorate, we are pleased to confirm that from 23rd March 2011, veterinary surgeons will be allowed to prescribe norethisterone (Primolut-N) as a season suppressant in greyhound bitches.’

VMD statement on oestrus suppression

‘The VMD recognises that the current authorised veterinary medicines indicated for canine oestrus suppression may have adverse effects in some animals, these effects are noted on the individual products Summary of Product Characteristics. Specialist vets involved with greyhound racing had concerns regarding the long term effects on the health of racing greyhound bitches through existing oestrus suppression methods, including the use of testosterone. Accordingly, the VMD was approached in 2010 by the Greyhound Board of Great Britain (GBGB) regarding the legalities of using norethisterone under the prescribing cascade to treat racing greyhound bitches.

As a result of these discussions, the VMD advised the GBGB that veterinary surgeons could use their clinical judgement and if appropriate prescribe norethisterone under the cascade to suppress oestrus, if the authorised veterinary medicines did not produce a satisfactory clinical outcome in any individual animal. As you have seen the GBGB took this advice and publicised this in order to educate veterinary surgeons who were concerned that if they choose this treatment option they could be open to prosecution.

‘As with all instances where the cascade is used, it is the prescribing veterinary surgeon’s decision on which medicines to use in what circumstances. The use of norethisterone in greyhounds in this manner is not a derogation from the requirements of the Veterinary Medicines Regulations. As you are aware the cascade does allow the use of a human medicine and this is how norethisterone may be prescribed. It should be noted that this use must only be considered on a case by case basis and the authorised medicine must always be the first treatment option.’

Current VMD authorized products for oestrus suppression in dogs

- Delvosteron.
- Durateston.
- Ovarid.
- Laurabolin (nandrolone, an anabolic steroid) has historically been used for oestrus suppression without any indication for that purpose. Its use is prohibited by GBGB.

Norethisterone

The VMD draws attention to a Freedom of Information request and response (Freedom of Information request and response), which gives limited information about oestrus suppressants, including norethisterone.

Trainer’s declaration

GBGB Rules require any oestrus suppressant to be declared to GBGB.

Conclusion

If a Greyhound requires medical oestrus suppression, the VMD permits use of a veterinary surgeon’s clinical judgement to use the cascade provisions if an authorized product has proven unsuitable. It is prudent to check with the GBGB Veterinary Advice Line (GBGB Veterinary Advice Line) which suppressants are currently permissible for racing as this changes from time to time.
**Acknowledgements**

- Tim Morris – GBGB
- Richard Payne – GBGB
- Diana Illingworth and staff – Crayford Greyhound Stadium
- Lea Reynolds – VMD
- John Millward – VMD
- Colleague members of the Society of Greyhound Veterinarians
- Bill Bentall – photographs
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, clav/amoxycillin 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 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 – but prudent to check current advice with GBGB Veterinary Advice Line; 3 – any advice about excretion times should be empirical for uncertainty; and it would be prudent when dealing with racing Greyhounds to use short acting medications in dogs so up to 48h/day’s; so it would be prudent when dealing with racing Greyhounds to use short acting medications; 4 – d; 5 – a, b and c – cost is not a consideration of the prescribing cascade.
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, are essential to effective use. Experience combined with regular practice is vital and demonstrable training is often required before a firearms licence will be 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, or if 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 allowing 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 in their possession the firearm and ammunition without danger to public safety or to the peace. As such the local police force will be able to provide veterinary surgeons 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 (VMPs) 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 veterinary medicinal products (VMPs) 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 where 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 as 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 use a system that requires low operator skills supported by laser sites)
- 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 criteria 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, 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 exposed 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, improved welfare from reduced darting failure and decreased darting times. Manufacturer’s guidelines should be followed at all times.

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), all of which are extremely dangerous if inappropriately exposed to the operator or any bystanders. In addition, other VMPs such as vaccines and antibiotics are not benign and large doses, injected or inhaled in an aerosolised 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 of 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 use of 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 to 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

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. a pea shooter with the correct type of ammunition can be classed as 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 (VMPs) 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 VMPs in animals can be reported to the marketing authorization holder (MAH) or the Veterinary Medicines Directorate (VMD).
- 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 VMPs, 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:

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

However, none of the above is possible unless adverse events following the use of VMPs 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 according to approved labelling 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 on VMPs include:

- Lack of expected efficacy (e.g. vaccine failures and antimicrobial or anthelmintic resistance).
- Adverse reactions in the 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. needlestick injuries or stroking pets).
- 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 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 only 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 numbers that appears on the packaging or in the National Office of Animal Health (NOAH) Compendium (go.gov.uk). 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 (go.gov.uk). There are two separate forms, one for adverse events in animals, and another for humans, which can be found by searching go.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.defra.gsi.gov.uk) or by calling 01932 338427. Alternatively, paper forms (MLA 252) can be downloaded from go.gov.uk or can be found at the back of the NOAH Compendium (these forms are yellow and watermarked with ANIMAL or HUMAN).

Specific paper forms exist for environmental (MLA 1) or residues in milk (MLA 2), both of which can be downloaded from go.gov.uk and MLA 1 can be found at the back of the NOAH Compendium (this form is blue). Forms can also be requested to be sent 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. 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 ensured 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.

Causality assessments are carried out using the ABON system:

A the medicine probably caused the event observed
B the medicine possibly caused the event observed
O there is insufficient evidence to judge if the medicine caused the event observed
O1 inconclusive (other factors prevent a conclusion being drawn, but a product association could not be discounted)
N the medicine probably did not cause the event observed.

The VMD also analyses all reports in its database using a statistical technique called the proportional reporting ratio (PRR) and 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.

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 regular articles on issues of more general interest, based on adverse event reports received.

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. An adverse event has been classified as ‘B’. This means that:
   a. It was definitely caused by the use of the medicine
   b. There is insufficient evidence to tell
   c. The reaction was probably caused by the medicine
   d. The reaction was a serious adverse reaction

3. 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

4. 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
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 SARRS.

In theory, any of the ectoparasites (fleas, ticks, lice and mites) or the gastrointestinal helminths (excluding roundworms and tapeworms) challenging domestic pets could develop resistance to the antiparasitic medicines used to control them, although there is a consensus that resistance 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’. It should be noted that, within parasite populations, there may be considerable natural variation in susceptibility.

Evidence of resistance to pet antiparasiticides

To date, treatment failure of registered 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 gene mutations associated with resistance to dieldrin (rd) and knock down resistance (kdr) and super knock down resistance (skdr) have been identified in UK Ctenocephalides felis populations. The implications of these mutations for insecticide efficacy remain unclear. Reports exist of fleas developing resistance to many older classes of insecticide in the US. 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, 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 has been reported in the dog hookworm in Australia, and macrocyclic lactones in canine heartworm in the US (Bowman, 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 zero tolerance of parasites, particularly where there is a zoonotic risk. Therefore, alternative strategies must be sought. Parasiticide mixes and rotation have value in delaying or preventing resistance, particularly in combination with management strategies. Whilst these principles have been developed for crop pests, 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. Timely and effective control of parasite infections, thereby preventing them from becoming ongoing problems, 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 clearing 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 heartworm 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 US (Bowman, 2012).

Investigation and management of suspected resistance

When treatment failure may be associated with parasitic 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 on 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 regime?
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 or 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 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). It is good practice to also report the problem to the marketing authorization holder (MAH) or manufacturer of the product, so that they can investigate the problem quickly. Owners may be keen to eliminate the problem, thus destroying material for any investigation.

**References**

- Dryden MW, Payne PA, Smith V et al. (2013) Evaluation of indoxacarb and lindane (s)-methoprene topical spot-on formulations to control flea populations in naturally infested dogs and cats in private residences in Tampa Fl. USA. *Parasites & Vectors* 6, 366
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

ANSWERS
1 – a; 2 – b; 3 – a; 4 – a