BSAVA
BRITISH SMALL ANIMAL VETERINARY ASSOCIATION

BSAVA Guide to the **Use of Veterinary Medicines**

VETERINARY MEDICINES VMD DIRECTORATE

ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

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

British Small Animal Veterinary Association
Woodrow House, 1 Telford Way, Waterwells Business Park, Quedgeley, Gloucester GL2 2AB
Tel: 01452 726700 Fax: 01452 726701 Email: administration@bsava.com Web: www.bsava.com

Contents

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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 *BSAVA Guide to the Use of Veterinary Medicines*.

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 on veterinary medicines, just as we have done.

Everyone who uses veterinary medicines has a legal 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.

Fred Nind
Pam Mosedale

January 2009

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Contributors

Sally Anne Argyle **MVB CertSAC PhD MRCVS**
Royal (Dick) School of Veterinary Studies, The University of Edinburgh, Easter Bush Veterinary Centre, Roslin, Midlothian EH25 9RG

Matthew GI Brash **BVetMed CertZooMed MRCVS**
Battleflatts Veterinary Clinic, 88 Klinwick Road, Pocklington, York YO42 1TX

John Chitty **BVetMed CertZooMed MRCVS**
Strathmore Veterinary Clinic, London Road, Andover, Hants SP10 2PH

Stephen Dawson **MA**
NOAH, 3 Crossfield Chambers, Gladbeck Way, Enfield EN2 7HF

John FR Hird **MA BVSc DVA DipECVAA MRCA MRCVS**
Red Bank House, Neston Road, Burton, Cheshire CH64 5SY

Mike Jessop **BVetMed MRCVS**
Ash Veterinary Surgery, Aberdare Road, Georgetown, Merthyr Tydfil, Mid Glamorgan CF48 1AT

Erica Martin **BVM&S PhD MRCVS**
Harper Adams University College, Newport, Shropshire TF10 8NB

Pam Mosedale **BVetMed MRCVS**
The Cottage, The Wash, Chapel-en-le-Frith, High Peak SK23 0QW

Fred Nind **BVM&S MRCVS**

Liz Shipley **MRPharmS**
The Royal (Dick) School of Veterinary Studies, The University of Edinburgh, Easter Bush Veterinary Centre, Roslin, Midlothian EH25 9RG

Philip Sketchley **BSc(Hons)**
NOAH, 3 Crossfield Chambers, Gladbeck Way, Enfield EN2 7HF

Michael Watts **MVB MSc DipFoodSci MRCVS**
38 Manse Road, Glastry, Kircubbin, Newtownards BT22 1DR

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Medicines classification

Authorized veterinary medicines fall within the first four categories established by the Veterinary Medicines Regulations (VMR) 2005. These categories have continued through subsequent revisions of the VMR and are as follows:

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

In addition, medicines marketed under the Small Animal Exemption Scheme (SAES) do not have a legal distribution category but may be considered for sale and supply purposes to be equivalent to AVM-GSL.

AVM-GSL

Medicines in the AVM-GSL category may be legally supplied by any retailer, to anyone, without restriction. However, veterinary surgeons should take account of their professional duties in deciding when to supply all medicines, regardless of classification.

AVM-GSL medicines are authorized through the same process as medicines in 'higher' classifications and the manufacturer will have had to prove safety, quality and efficacy to the same standards; however, label claims may be different.

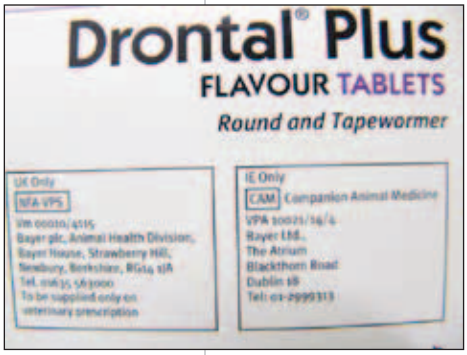
A medicine is classified as an AVM-GSL when:

- There is no statutory requirement for a prescription-only status
- Its use has a wide margin of safety
- It is used to alleviate or prevent the signs of disease or support the treatment of common ailments
- Special advice is not required to permit safe and effective use.

All medicines previously classified as GSL were automatically reclassified as AVM-GSL on 30 October 2005.

NFA-VPS

Medicines in the NFA-VPS category are for companion animals (excluding horses). They must be supplied by a veterinary surgeon, pharmacist or SQP from registered premises.



A clinical assessment of the animal(s) is not required for supply of this category of veterinary medicine.

Each time a supplier supplies a NFA-VPS medicine they must:

- Before doing so, be satisfied that the person who will be administering the medicine is competent to do so safely, and intends to use it for a purpose for which it is authorized
- Advise on the safe administration of the medicine and on any warnings/contraindications stated on the label or package leaflet
- Not supply more than the minimum amount required for treatment.

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In respect of the last point, it is a defence under the VMR to show that:

1. The medicine was in a container specified in the marketing authorization.
2. The manufacturer does not supply that medicine in a smaller container.
3. The person supplying the medicine is not authorized to break open the package before supply.

Since veterinary surgeons are permitted to break open packages before supply, that defence may be difficult to invoke, and so it is particularly important for veterinary surgeons in complying with the VMR to ensure that only the minimum amount of a medicine required for treatment is supplied.

A medicine is classified as NFA-VPS when:

- It is indicated for use only in non-food animals
- There is no statutory requirement for a prescription-only status
- It is used routinely to prevent or limit the effects of endemic disease in non-food animals
- Its use implies risks for the user, the animal, for consumer safety or for the environment but users can be made aware of suitable countermeasures through simple oral or written advice
- The animal owner/keeper can be given sufficient practical advice to permit effective and safe usage.

All medicines for companion animals (excluding horses) previously classified as PML and a small number of P medicines were automatically reclassified as NFA-VPS on 30 October 2005.

POM-VPS

Medicines in the POM-VPS category must be both prescribed and supplied by a veterinary surgeon, pharmacist or SQP. This can be more than one person: any authorized supplier may supply in accordance with a written prescription from any authorized prescriber. The medicine must be supplied from registered premises.

The client may request a written prescription if they do not want the prescriber to supply the medicine.

A clinical assessment of the animal(s) is not required when prescribing this category of veterinary medicine.

Each time a prescriber prescribes a POM-VPS medicine they must:

- Before doing so, be satisfied that the person who will be administering the medicine is competent to do so safely, and intends to use it for a purpose for which it is authorized
- Advise on the safe administration of the medicine and on any warnings/ contraindications stated on the label or package leaflet.

A medicine is classified as a POM-VPS when:

- It is used to reduce or prevent the effects of endemic disease in herds, flocks or in individual animals
- Its use implies risks for the user, the animal, for consumer safety or for the environment but users can be made aware of suitable countermeasures through simple oral or written advice
- A professional user can be given adequate training in its regular use.

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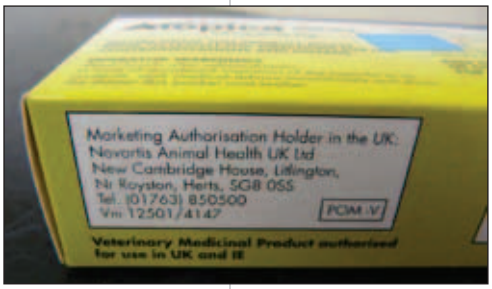
POM-V

Medicines in the POM-V category must only be prescribed by a veterinary surgeon following a clinical assessment of the animal or group of animals, which must be under their care. The medicine may then be supplied by that veterinary surgeon or in accordance with a written prescription by another veterinary surgeon or a pharmacist. The medicine must be supplied from registered premises.



There is no definition of 'clinical assessment' in the VMR and veterinary surgeons are expected to use their professional judgement in deciding how this should be interpreted in their particular circumstances. The **RCVS (www.rcvs.org.uk)** interprets 'clinical assessment' as meaning an assessment of relevant clinical information, which may include an examination of the animal under the veterinary surgeon's care.

The client may request a written prescription if they do not want the prescribing veterinary surgeon to supply the medicine.

A medicine is classified as a POM-V when:

- It requires a strict limitation on its use for specific safety reasons
- It requires the specialized knowledge of a veterinary surgeon for its use/application
- It has a narrow safety margin requiring above average care in its use
- It is government policy to demand professional control at a high level (for example, antimicrobials and Controlled Drugs).

All medicines previously classified as POM and a small number of P medicines were automatically reclassified as POM-V on 30 October 2005.

Small Animal Exemption Scheme

Medicines for use in certain pet species (aquarium fish, cage birds, ferrets, homing pigeons, rabbits, small rodents and terrarium animals), the active ingredient of which has been declared by the Secretary of State as not requiring veterinary control, may be marketed under the SAES.

These medicines are exempt from the requirement for a marketing authorization and therefore are not required to prove safety, quality or efficacy, but must be manufactured to the same standards as authorized medicines and are subject to pharmacovigilance reporting. These medicines do not have a legal distribution category, but may be considered for sale and supply purposes to be equivalent to AVM-GSL.

Labelling

To allow manufacturers to update packaging (inner, outer and leaflet, for each pack size) and obtain approval from the **Veterinary Medicines Directorate (www.vmd.gov.uk/General/VMR/vmgn/VMGNote03.pdf)**, manufacturers were permitted to continue to release medicine batches for sale and supply labelled in accordance with the 'old' categories until 30 October 2008.

Sale and supply by wholesalers and retailers (including veterinary surgeons) of medicines with the old-style label is legal: as some medicines have multi-year shelf-lives, the old abbreviations will continue to appear on the labels of medicines for some time; nonetheless the new legal categories apply.

All authorized medicines must include the distribution category on the box label. SAES medicines must include a reference to the Scheme on the label.

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Premises licensing and inspections

Premises licensing and inspections

All premises where veterinary medicinal products (VMPs) are stored or supplied are required to be listed on a register maintained by the Royal College of Veterinary Surgeons (RCVS) on behalf of the Veterinary Medicines Directorate (VMD). The VMD will be able to inspect these premises.

Those practices that are members of the RCVS Practice Standards Scheme (PSS) will not currently be inspected by the VMD inspectors, as their pharmacies will be inspected as part of the PSS. Both inspections by the VMD and under the RCVS PSS will include a check on the RCVS registration of veterinary surgeons and premises, as well as the registration and qualifications of any suitably qualified persons (SQPs).

Premises

Premises will be inspected to ensure that:

- They are housed in a permanent and secure building, which does not allow the entrance of birds or vermin
- The medicines storage areas are designed to allow drugs to be stored at the correct temperature. This needs to be monitored by the use of maximum and minimum thermometers to check that temperatures do not fluctuate from the manufacturers' recommended range. Medicines should be stored in areas away from excessive light and/or moisture
- There are appropriate staff amenities, toilets and hand washing facilities, and that these are separate from the drug storage areas.

Supply of medicines

The supply of medicines will be checked to ensure that:

- There is no self-service of medicines, except for those in the AVM-GSL category
- There is an effective stock control system in operation and that out-of-date, damaged or returned medicines are disposed of correctly
- Out-of-date medicines are not used or supplied to clients
- All medicines are supplied and labelled correctly
- For all POM-VPS medicines there is evidence that each act of prescribing and supplying has been authorized by a veterinary surgeon, pharmacist or SQP
- For all POM-V medicines there is evidence that each act of prescribing has been authorized by a veterinary surgeon, and that each act of supplying has been authorized by a veterinary surgeon or pharmacist
- For all NFA-VPS and POM-VPS medicines there is evidence that before the medicine is supplied, a veterinary surgeon, pharmacist or SQP has checked that the person who will be administering the medicine is competent to do so safely, and intends to use it for a purpose for which it is authorized. They must also advise on the 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 standard operating procedures)

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- All veterinary medicines, including medicines prescribed in accordance with the cascade, are labelled correctly
- Written prescriptions include all the information required under the Veterinary Medicines Regulations (VMR).

Records

Records will be checked to ensure that all the following information is recorded and kept for at least 5 years:

- Receipt and supply of prescription medicines
- The date of supply/receipt
- Name of medicine
- Batch number
- Quantity of medicine
- Name and address of supplier or recipient
- Copies of all written prescriptions
- Record of the most recent drug audit
- All imported medicines have the correct relevant paperwork (special import certificates (SICs) and special treatment certificates (STCs)).

Inspectors will also check that medicines prescribed and supplied in accordance with the cascade are only done so to avoid unacceptable suffering, and that the practice is aware of the Suspected Adverse Reaction Surveillance Scheme (SARSS) and is reporting adverse reactions or lack of efficacy.

Controlled Drugs

The storage and use of Controlled Drugs will be inspected to ensure that:

- Schedule 2 Controlled Drugs are kept in a secure lockable and immoveable container, which can only be opened by a veterinary surgeon or a person authorized by them
- A Register is kept of the receipt, use and supply of specified categories of Controlled Drugs. This Register may be computerized but if so the system must be secure
- An informal Register of ketamine use is kept. Again, this can be computerized if secure.

Advertising

Advertising will be checked to ensure that:

- POM-V and POM-VPS medicines are only advertised to permitted persons (but veterinary practices are allowed to display price lists of these VMPs to the public).

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Correct storage and dispensary management

Stock control

- Efficient stock control ensures that the right medicine is available at the right place and the right time.
- Efficient stock control 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 medicines in a logical order and in their original packaging
  - Supply a product leaflet or summary of product characteristics (SPC) with all medicines dispensed
  - Dispense medicines with the shortest expiry date first
  - Store medicines with the same batch number together.
- The date of delivery from the manufacturers or wholesalers should be recorded, unless this information is on the invoice or delivery note which is retained.
- Packs with damaged or defaced packaging and out-of-date stock should be stored separately whilst awaiting disposal.
- Once stock has been dispensed it should not be accepted back into the medicines store.
- The date of first use of each batch should be recorded.

Premises

- All premises from which veterinary medicinal products (VMPs) are to be supplied must be registered with the Royal College of Veterinary Surgeons (RCVS).

Storage conditions

- Medicines should be stored at the temperature recommended in the SPC, usually under 25°C (ambient room temperature) or between 2°C and 8°C in a refrigerator.
- Any medicine requiring refrigeration should be removed from the delivery cool chain protection as soon as possible and placed in the refrigerator.
- Biological samples and food should not be stored in refrigerators used to hold medicines.
- Ambient temperature should be monitored if it goes outwith normal limits for any significant period of time.
- Fridges should be checked daily by a named person and a log made of maximum and minimum temperatures. This log can be recorded on paper or electronically.

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- If the refrigerator temperature goes outside 2–8ºC, information should be sought from the manufacturer(s) as to the safety of the medicine(s) for use and the new expiry date(s).
- Cars should be fitted with refrigeration units and the temperature of these should be checked daily. If temperature sensitive medicines are to be transported to clients by vehicle there must be a suitable mechanism for maintaining correct temperature, e.g. cool box or refridgerated unit.
- To protect medicines from extremes in humidity, autoclaves should not be used in the medicines store.
- Many medicines are sensitive to light, so blinds should be fitted at any windows and medicines should be stored in their outer protective containers.
- Flammable medicines must be stored in an appropriate flammables cupboard, preferably situated on the floor to prevent breakages.

Return of medicines

- As correct storage conditions (and therefore safety and efficacy) of medicines returned by owners cannot be guaranteed, such medicines should be disposed of and not accepted back into stock.
- Medicines supplied for animals on the premises can be accepted back into stock, providing the storage conditions are known to be acceptable.
- Returns to wholesalers should be completed as soon as possible. There may be restrictions on such returns as returned VMPs are usually destroyed.

Expiry dates

- A named person should be in charge of date-checking the medicines store once a month.
- A log should be kept of this check.
- 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.
- Multi-dose 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 multi-dose vials with an in-use shelf-life now have a space to write this information. Any drug left in the vial after the specified time must be discarded.
- Any medicine remaining in a single-use ampoule should be discarded once the required dose has been withdrawn.
- Administering a medicine that is past its expiry date or obscuring the expiry date is an offence.

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Labelling

- Unless the prescribing veterinary surgeon administers the VMP themselves, it should be labelled.
- Administration of the medicine, even if not performed by the prescribing veterinary surgeon, remains the responsibility of the veterinary surgeon.
- The supplier has a responsibility to ensure that the owner understands any instructions from the prescribing veterinary surgeon.

Containers

- Medicines should be stored in their original packaging with the lid tightly closed.
- Where possible, medicines should be dispensed in their original container.
- If a medicine is repacked or prepared extemporaneously, it should be placed in a container suitable for the medicine and the user.
- All containers should be stored in such a way that they remain free from contaminants.
- Suitable containers for solid dosage forms include paper envelopes, paperboard wallets, paperboard boxes and glass/plastic amber bottles.
- Paper wallets and plastic bags are only suitable as containers for blister packs and should not be used as the sole packaging.
- Liquid preparations should be dispensed in amber bottles.
- Bottles containing topical preparations should be fluted to allow recognition by touch.
- This requirement does not apply to containers over 1.14 litres or to pre-packaged eye/ear drops.
- Some tablets or capsules are adversely affected by moisture and are supplied with a desiccant. This desiccant should not be dispensed; the quantities and packaging of such medicines should be such that deterioration after supply is prevented.
- Medicines sensitive to light should be supplied in suitably opaque or coloured containers.
- Creams, ointments, powders, granules, dusting powders, etc., should be dispensed in glass or plastic wide-mouthed jars.

Personnel

- All those involved in the supply of medicines should be suitably trained.
- A pharmacy manual should be prepared containing standard operating procedures and Control of Substances Hazardous to Health (COSHH) assessments. This manual should be available to, and read by, all those involved in dispensing medicines.
- One person should be responsible for ensuring that the legal requirements, safety assessments and best practice procedures are carried out.
- Medicines should only be administered by a suitably competent person or under the supervision of a veterinary surgeon.
- A high standard of personal cleanliness is required and hands should be washed regularly.
- Any infections or open wounds should be reported to the responsible person. Open wounds must be covered at all times when dispensing VMPs.
- Protective clothing should be worn when recommended in the COSHH assessments, and staff should avoid direct contact with all medicines, including tablets, either by wearing gloves or by using a tablet counter and spatula.

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Advertising

- 'Advertising' means the provision of any information on the medicine, including prices, summary of product characteristics (SPC) leaflets, advertisements in journals/magazines and materials from the manufacturer or its representative including electronic data.
- It is an offence to advertise a VMP if the advertisement is misleading or contains a medicinal claim that is not in the SPC.
- It is an offence to advertise an authorized human medicine for administration to an animal, except when wholesalers supply a price list of, or including, authorized human medicines at the request of a veterinary surgeon.
- VMPs available only on prescription can not be advertised except in the following circumstances:
  - In the case of medicines containing psychotropic drugs or narcotics, the advertisement is aimed at veterinary surgeons or pharmacists
  - In the case of POM-V medicines, the advertisement is aimed at veterinary surgeons, pharmacists, veterinary nurses or professional keepers of animals
  - In the case of POM-VPS medicines, the advertisement is aimed at veterinary surgeons, pharmacists, suitably qualified persons (SQPs), veterinary nurses, other veterinary healthcare professionals and owners or keepers of horses.
- It is accepted that advertisements in professional journals, newsletters and websites, etc. may be read by those other than the target audience.
- These regulations do not apply to price lists displayed in veterinary practices.
- Publications for health education are not considered advertising, provided that there is no promotion other than the name of the company and medicine. Advertising information aimed at the general public may not include the brand name of a POM-V/POM-VPS in relation to treatment, but may contain the name of an active ingredient and a small strapline at the top or bottom of the article stating "this information was provided by [company] makers of [product]."
- There are no restrictions on the advertising of NFA-VPS or AVM-GSL medicines.
- There are no restrictions on veterinary surgeons providing information to clients during a consultation.

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Supply and dispensing procedures

Supply of POM-V/POM-VPS medicines in the presence of a veterinary surgeon

- A clinical assessment must have been carried out.
- Animals must be under the care of a veterinary surgeon.
- The veterinary surgeon must advise on safe administration, warnings for use and contraindications.
- Only the minimum amount required for treatment should be supplied.
- The veterinary surgeon must ensure that the user intends to use the medicine for an authorized use and is competent to use it safely.
- The veterinary surgeon must supply from practice premises registered with the Royal College of Veterinary Surgeons (RCVS).

Supply of POM-V/POM-VPS medicines in the absence of a veterinary surgeon

- Each individual transaction must be authorized by a veterinary surgeon.
- The veterinary surgeon must be satisfied (via a standard operating procedure (SOP) or otherwise) that the person handing over the medicine to the client is competent to do so.
- Only the minimum amount required for treatment should be supplied.
- The veterinary surgeon must ensure that the user intends to use the medicine for an authorized use and is competent to use it safely.

Supply of POM-VPS/NFA-VPS medicines by a suitably qualified person

- The SQP must personally supply the medicines, or be in a position to intervene when the medicines are handed over, or check the medicines before despatch.
- The same requirements to advise on safe administration, warnings and contraindications, to ensure that the user is competent and to supply the minimum amount required for treatment apply (as for veterinary surgeons).
- There should be no supply of medicines for use outside their marketing authorizations.
- SQPs may break open any packaging other than the immediate packaging of a veterinary medicinal product (VMP).
- The SQP must supply either from premises approved by the Secretary of State, a registered pharmacy or a RCVS registered practice premises.

Supply of AVM-GSL medicines

AVM-GSL medicines can be supplied by any retailer to any purchaser without restriction.

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General information

Where possible all VMPs should be supplied in their authorized packaging. If a VMP is supplied in a container other than that specified in the marketing authorization (known as non-authorized packaging), the person supplying the VMP should ensure that the container is suitably labelled and must supply sufficient written information (which may include a copy of the summary of product characteristics or the package leaflet) to enable the medicine to be used safely.

No out-of-date medicines may be supplied.

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Prescription notice

ANY VETERINARY PRACTICE LTD

Prescriptions are available from this practice.

You may obtain prescription-only medicines, category V (POM-V) from us OR ask for a prescription and obtain these medicines from another veterinary surgeon or pharmacy. A prescription may not be appropriate if your animal is an in-patient or if immediate treatment is necessary.

You will be informed on request of the price of any medicine that may be prescribed for your animal.

The general policy of this practice is to re-assess an animal requiring repeat prescriptions every **X** months, but this may vary with individual circumstances.
The standard charge for re-examination is **£X**.

The current prices for the top 10 POM-Vs most commonly prescribed or supplied during **June–September 2008** were:

The standard charge for issuing a prescription to be filled elsewhere is **£Y**.

Further information on the price of medicines is available on request.

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Suitably qualified person

What is a suitably qualified person?

'Suitably Qualified Person (SQP)' is a phrase used in the medicines legislation in relation to the prescription and supply of medicines. In practical terms this means either:

- RQP – a registered qualified person: a veterinary surgeon registered with the Royal College of Veterinary Surgeons (RCVS) or a pharmacist registered with the Royal Pharmaceutical Society of Great Britain (RPSGB)
- SQP – a suitably qualified person registered with the Animal Medicines Training Regulatory Authority (AMTRA).

AMTRA (www.amtra.org.uk) has been involved with the training and registering of saddlers and merchants (the predecessors of SQPs) for many years. Currently it is the only professional body for SQPs. All have to be registered with AMTRA and pay an annual fee, which varies with the category of SQP. AMTRA also monitors continuing professional development (CPD).

An SQP can prescribe and supply POM-VPS and supply NFA-VPS and AVM-GSL medicines, but only from authorized premises and only from within the animal group category they are trained and registered for. The SQP works according to a Code of Practice issued by the Veterinary Medicines Directorate (VMD) and distributed by AMTRA.

SQP categories

All SQPs have to pass a base examination, which covers legislation, basic anatomy and physiology and basic disease challenges. In addition to the base element, there are species modules: farm animal; equine; and companion animal. In order to supply medicines the SQP must have passed the relevant species group module as well as the base examination. Thus, SQPs will have different qualification levels:

- R-SQP – 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 at **www.harper-adams.ac.uk/files/AMTRA_Introduction.pdf**

Where can an SQP work from?

SQPs must operate from approved premises. Currently, this means a permanent building registered with the Animal Medicines Inspectorate (AMI; a part of the VMD). The AMI will inspect premises and register them annually. For more information, see **Code of Practice for the requirements of authorized premises (www.harper-adams.ac.uk/files/code2008.pdf)**.

As of 1st April 2009, when all veterinary practices had to be registered as places of veterinary medicine supply, an SQP can operate from those practices registered with the RCVS (on a register maintained on behalf of the VMD) without the premises being separately registered with the AMI.

British Small Animal Veterinary Association
Woodrow House, 1 Telford Way, Waterwells Business Park, Quedgeley, Gloucester GL2 2AB
Tel: 01452 726700 Fax: 01452 726701 Email: administration@bsava.com Web: www.bsava.com

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What can an SQP do?

An SQP can mentally, orally or in writing prescribe a POM-VPS medicine for a client. They do not need to see the animal. They may not diagnose disease but can identify infestation, e.g. lice. They may not treat disease but can advise on prevention and control of disease. Most of the medicines in the VPS categories do have preventive uses, e.g. antiparasitic medicines, nutritional supplements, antiseptic medicines and some local anaesthetics.

The SQP is required to ensure that the medicine they supply (POM-VPS, NFA-VPS, AVM-GSL) is appropriate for the animal and its circumstances and the owner and their circumstances; so some sort of discussion must take place before supply. The SQP also has to be confident that the **owner is competent to administer the medication (www.harper-adams.ac.uk/files/code2008.pdf)**; advice must be given or a check made .

Exotic species and 'off-label' use

On their own authority, an SQP may only supply medicines and advise on use strictly according to the datasheets or summary of product characteristics (SPC). If a client wishes to use a medicine for a species for which it is not authorized, e.g. a clostridial vaccine or a wormer for a llama, then an SQP may only dispense the medicine to a veterinary prescription. Similarly, if an NFA-VPS product authorized, for example, for tick control in cats was to be used for aviary birds, then a veterinary prescription with advised administration and dose instructions would be required.

POM-V medicines

Being an SQP gives no extra rights in relation to POM-V medicines. Any supply of a POM-V medicine in a veterinary practice would be under the authority and responsibility of the prescribing veterinary surgeon.

How to become an SQP

Registration

No prior qualifications are required. All aspiring SQPs must register with AMTRA as an SQP 'trainee'. Once registered, they will be sent a manual and a password to the online learning tool.

Training

A potential SQP may use these online tools and prepare themselves for the examinations, attend company training or attend a course at one of the colleges in the UK that provides them. These courses vary from half day revision sessions to 2-week full courses. It is important that the potential SQP matches the course with their required qualification. Courses can be sourced through the **AMTRA website (www.amtra.org.uk)**.

Assessment

A potential SQP is assessed by examinations set and marked by Harper Adams University College. These examinations take place at regular intervals at examination centres throughout the country. A potential SQP will register for a specific examination place and date with AMTRA. All potential SQPs have to pass a *viva* run by AMTRA, and sit and pass a base examination. Each SQP must also pass one or more species group examinations. This will define their SQP title and the species of animals that they may supply for. Additional species modules may be added at future dates to extend the range of medicine groups available to the SQP.

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How does a qualified veterinary nurse become an SQP?

If a qualified veterinary nurse wishes to become an SQP, then recognition is given of the previous assessed study. Production of their veterinary nursing certificate will allow APL or APEL (credit given for prior learning) to be awarded and the veterinary nurse would then only be required to sit a shortened assessment, 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 and equine modules. Student nurses or non-qualified practice staff have to sit the full examination process.

Continuing professional development

Once qualified, an SQP has to show they are keeping up to date. There is a 3-yearly requirement for CPD points. These can be gained from attending accredited meetings, private study and internet assessments. More information can be found at **www.amtra.org.uk/CPD**

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Record keeping and audits

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. Records of the most recent drug audit will be checked by the Veterinary Medicines Directorate (VMD) and Royal College of Veterinary Surgeons (RCVS) Practice Standards Scheme (PSS) inspectors during practice inspections.

The **VMD (www.vmd.gov.uk)** states that 'a system linking incoming and outgoing transactions with stock held may provide an ongoing running total which, with the addition of a periodic physical stock count to verify stock held, may meet the audit requirement'.

Record keeping

Any veterinary surgeon who supplies a prescription medicine must keep the following records for at least 5 years for all incoming drugs (purchased from wholesalers) and outgoing drugs (prescribed and supplied to clients):

- Date and nature of transaction
- Name of the veterinary medicinal product (VMP)
- The batch number (in the case of a medicine for a non-food producing animal, this need only be recorded either on the date the batch was received or the date the batch was first used)
- Quantity received or supplied
- 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.

The requirement for keeping records of drugs purchased may be met by retaining the invoices or delivery notes from wholesalers.

Audits

At least annually, a detailed audit should be carried out; incoming and outgoing medicines should be reconciled with the stock held and any discrepancies noted. To achieve this the practice needs to:

- Perform a full stock take of all prescription drugs
- Keep records of all drugs received (e.g. by retaining invoices or delivery notes from wholesalers)
- Keep records of all drugs supplied to clients (e.g. by practice computer system or by sales log)
- Record any out-of-date or damaged drugs discarded.

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 and decide what level is acceptable. There will obviously be discrepancies in the case of drugs used during procedures and not priced individually (e.g. premedicants, anaesthetics and euthanasia drugs).

One category of drugs which should be audited continuously is Controlled Drugs. 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 this with stock-in-hand regularly.

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Prescribing and labelling

Prescribing and labelling veterinary medicines are activities that every veterinary practitioner performs many times each day. It should be noted that these activities are subject to detailed legal provisions and in getting it wrong the veterinary surgeon is breaking the law.

Prescription writing

Before writing a prescription the prescriber should:

- Be satisfied that the person who will be administering the product is competent to do so safely, and intends to use it for a purpose for which it is authorized
- Advise on the safe administration of the product and on any warnings/ contraindications stated on the label or package leaflet.

Only the minimum amount required for treatment should be prescribed, except when:

- The product prescribed is supplied in a container specified in the marketing authorization
- The manufacturer does not supply that veterinary medicinal product (VMP) in a smaller container, and the supplier is not a person authorized to break open the package before supply.

Who may write a prescription?

- Only a veterinary surgeon is legally permitted to write a prescription for a Controlled Drug or for a medicine classified as POM-V.
- Veterinary surgeons, pharmacists and suitably qualified persons (SQPs) can all write prescriptions for medicines classified as POM-VPS.
- No prescriptions are legally required for medicines classified as NFA-VPS or AVM-GSL, but this does not stop the veterinary surgeon from writing one if preferred.

Prescriptions may be oral or written, but in the case of written prescriptions the following information must be included indelibly:

- The name, address and telephone number of the person prescribing the medicine
- The qualifications of the person writing the prescription
- The name and address of the owner or keeper of the animal
- The identification (including the species) of the animal or group of animals to be treated
- The premises at which the animal(s) is kept if this differs from the address of the owner or keeper
- The date that the prescription is written
- The signature of the person writing the prescription
- The name and amount of the medicine prescribed
- The dosage and administration instructions
- Any necessary warnings.

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Only a veterinary surgeon is legally allowed to prescribe a medicine in accordance with the cascade. In this case, the prescription must include a statement that states that:

- The medicine is to be used under the prescribing cascade.

Prescriptions are valid for up to 6 months unless specified otherwise on the prescription. The prescriber may specify that the prescription can be repeated. If the number of times that it may be repeated is not specified on the prescription, it may only be repeated once.

Controlled Drugs

In the case of Controlled Drugs, more regulations apply to prescription writing:

Note: *prescriptions for Controlled Drugs no longer need to be handwritten*

- The address of the prescriber must be in the UK
- The total quantity of the drug must be written in words ***and*** numbers
- The prescription must include a declaration that the animal(s) being treated is under the veterinary surgeon's care.

It is recommended that no prescription should be written for more than 30 days' supply of a medicine. Repeat prescriptions are not allowed for Schedule 2 or 3 drugs. Prescriptions for Controlled Drugs are only valid for 28 days.

For further information on writing a prescription, see the *BSAVA Small Animal Formulary*.

Dispensing

The person dispensing the prescription must also meet legal requirements:

- The person dispensing the prescription should check whether or not they are legally allowed to supply the medicine
- Only the product specified in the prescription may be supplied – no substitution is allowed
- The person dispensing the prescription must ensure that it has been written by the person named on the prescription and that that person has the necessary qualifications. A telephone call should be made to confirm these details if needed
- The person dispensing the prescription should ensure that the medicine is supplied to the person specified as the keeper/owner of the animal. Identification can be requested if required. This applies particularly with the supply of Controlled Drugs
- The person dispensing the prescription should check whether or not they are allowed to break the packaging containing a VMP.

Breaking packaging

- A veterinary surgeon or a person acting under their responsibility may open any package containing a VMP.
- A pharmacist may break open any package containing a VMP for the purposes of supply, other than the immediate packaging of an injectable medicine.
- An SQP may break open any package containing a VMP for the purposes of supply, other than the immediate packaging.

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Labelling

If a medicine is supplied in the container provided by the manufacturer, all information on the label/packaging must remain readable. Changes may only be made by a veterinary surgeon or by a pharmacist acting on instructions contained in a prescription written by a veterinary surgeon, and even then all of the original information must still be readable.

If the medicine is intended for a condition and species listed on the datasheet there is no **legal** requirement for any additional label. However, it is the recommendation of the RCVS Professional Conduct Department that all supplied medicines should be labelled with the information listed below.

If a VMP is supplied in a container other than that specified in the marketing authorization (details can be found in the datasheet), then the person supplying the VMP must ensure that there is sufficient information for the medicine to be used safely. Under the Veterinary Medicines Regulations (VMR) 2008, this legal requirement may be met by writing the information on a label or by providing a copy of the package insert. However, it is the recommendation of the RCVS Professional Conduct Department that all supplied medicines should be labelled with the information listed below.

Only when using a medicine prescribed under the cascade is it legally necessary to attach a label, which must contain the following details:

- The name and address of the pharmacy, veterinary surgery or approved premises supplying the VMP
- The name of the veterinary surgeon who has prescribed the medicine
- The name and address of the animal's owner
- The identification (including the species) of the animal or group of animals
- The date of supply
- The expiry date of the medicine (if applicable)
- The name or description of the medicine, which should include at least the name and quantity of the active ingredient(s)
- The dosage and administration instructions
- Any special storage precautions
- Any necessary warnings with reference to the user, target species, administration or disposal of the product
- The words 'Keep out of reach of children' and 'For animal treatment only'. The words 'For external use only' for topical preparations.

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Prescribing cascade and 'off-label' use

Legislative background

The EU Directive on veterinary medicines, and thus UK legislation, starts from the principle that all veterinary medicines must be authorized, and that use of an unauthorized medicine or use 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 medicines.

However, recognizing that there are circumstances where the benefits of treatment with unauthorized medicines outweigh the risks, the legislators have given veterinary surgeons a unique privilege by way of an exemption from the general rule. This privileged exemption is known as the prescribing cascade, or simply the cascade.

The authorization process assesses veterinary medicines against statutory criteria of safety, quality and efficacy when used in accordance with the manufacturer's recommendations for use. The use of medicines in ways that have not been authorized may pose potential risks that the authorization process seeks to minimize. Where there is no suitable authorized veterinary medicine in the UK, there is still a need to balance risks and benefits within the freedoms granted to veterinary surgeons.

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

The importance of using authorized medicines

Animal species may have many physiological differences from humans and from each other. As a result they may each react differently to medicines. The authorization system for veterinary medicines requires a medicine to have proven quality and effectiveness and, most importantly, safety for the animal, the user (veterinary surgeon, farmer, pet owner, etc.), the environment and, for food animals, the consumer of animal produce. This assurance has to be provided for each species and each indication on the label.

In addition, animal medicines containing the same active ingredient as human medicines may be formulated differently. For instance, the formulation needs to ensure that the medicine is properly absorbed through the gut (which is rather shorter in a cat than a human). Human medicine formulations may contain different excipients or have different bioavailability from veterinary medicines. Therefore, using a medicine which is not authorized for animals increases the risk of harm to the patient.

In addition, the cost of developing a medicine for animal use is high and can involve much research and many tests not carried out for human medicines.

The use of human medicines, in place of the equivalent authorized veterinary medicine, may sometimes use information produced by veterinary companies on dosage regimes or safety. Assuming that the data on the veterinary medicine is directly relevant to the human medicine is potentially hazardous.

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 capable of being supported by clear auditable clinical evidence to justify the veterinary surgeon's decision.

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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 animal medicines. However, human generic medicines that are similar to the authorized veterinary medicines may **not** be used unless there is no suitable veterinary medicine available.

The cascade provides a legal mechanism allowing veterinary surgeons to use their clinical judgement to prescribe a suitable medicine where no authorized veterinary medicine exists. Prescription and use by veterinary surgeons of human generic medicines where a suitable veterinary medicine is available is a criminal offence and contrary to the **Royal College of Veterinary Surgeons (RCVS) Guide to Professional Conduct (www.rcvs.org.uk)**.

Compliance with the cascade

A medicine prescribed in accordance with the cascade may be administered by the prescribing veterinary surgeon or by a person acting under their direction. Responsibility for the prescription and use of the medicine remains with the prescribing veterinary surgeon.

If there is no medicine authorized in the UK for a specific condition, the veterinary surgeon responsible for treating the animal(s) may, in particular in order to avoid unacceptable suffering, treat the animal(s) in accordance with the following sequence:

1. A veterinary medicine authorized in the UK for use in another animal species or for a different condition in the same species.
2. If there is no such medicine, use either:
   (a) A medicine authorized in the UK for human use
   (b) A veterinary medicine from another Member State or country outside the EU in accordance with an import certificate from the Veterinary Medicines Directorate (VMD).
3. If there is no such medicine, a medicine prepared extemporaneously by a veterinary surgeon, pharmacist or a person holding an appropriate manufacturer's authorization.

If the patient is a food-producing animal, then additional conditions apply.

Treatment in exceptional circumstances

Although not formally forming part of the cascade, where the health situation so requires, and where there is no suitable medicine available either as an authorized UK medicine or under the cascade, a veterinary surgeon may treat an animal with a veterinary medicinal product (VMP) authorized in a country outside the EU, but only in accordance with a Special Treatment Certificate (STC) granted by the VMD.

Supply under the cascade

Medicines prescribed by a veterinary surgeon in accordance with the cascade may be supplied against a written prescription by another veterinary surgeon, a pharmacist or a suitably qualified person (SQP), provided the medicine is of a classification and for a species for which the supplier would normally be permitted to supply it. For instance, a POM-VPS medicine authorized for dogs and horses, but prescribed under the cascade for cats could be prescribed by a veterinary surgeon and supplied against a written

British Small Animal Veterinary Association
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prescription by an SQP, but only if that SQP were qualified to supply companion animal medicines. Only veterinary surgeons and pharmacists may supply POM-V medicines.

The other conditions of supply, including the labelling requirements must still be met.

Small Animal Exemption Scheme

A veterinary surgeon may choose to use a Small Animal Exemption Scheme (SAES) 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 SAES medicine.

However, should the veterinary surgeon wish to use the SAES medicine in a different way than that recommended, 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.'

EU and UK 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.

However, the cascade may be invoked in other appropriate circumstances, such as where microbiological tests show that a particular strain of an organism has developed resistance to all medicines whose labels contain indications against it. In this situation, a veterinary surgeon may consider that no authorized treatment exists for that condition and would, of course, wish to prescribe a treatment that will be effective (taking account of the other provisions of the cascade).

Other examples given by the VMD are as follows:

- Dosage considerations – sometimes a veterinary surgeon may consider that the effective treatment of a particular condition in a particular animal requires a different dosage from the one that appears on the label of a medicine. In such circumstances recourse to the cascade may be appropriate and the next option would be to consider the merits of using that medicine at an 'off-label' dosage (another condition in the same species) or a different authorized veterinary medicine. If neither can be administered safely at the dosage required, the veterinary surgeon should consider further options under the cascade
- Individual characteristics – if a particular animal has characteristics, such as age, general condition or known sensitivity to a particular substance, which the veterinary surgeon judged to present unacceptable risks and to contraindicate the use of the authorized medicine, they could conclude that no authorized medicine existed for that condition in that animal and consider other treatments
- Chronic infections – if a condition persists following treatment with an authorized medicine, the veterinary surgeon may consider in a particular case that there is no authorized treatment for that particular condition and that further use of medicines containing similar substances is contraindicated. In such circumstances it would be legitimate to consider alternatives in accordance with the cascade
- Build-up of resistance – in relation to anthelmintics, current advice is that resistance is likely to be encouraged by the repeated use of a single medicine.

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This can be avoided, with beneficial consequences for the health and welfare of the treated animals, by the use of two or more medicines in rotation. If there is only a single medicine authorized for anthelmintic use in a particular species, the veterinary surgeon may consider that the condition cannot be controlled using only the authorized medicine and use it in rotation with another medicine selected according to the cascade

- Complex conditions – diagnosis is a matter for the veterinary surgeon under whose care an animal or animals have been placed. Some conditions can be viewed overall and treated accordingly. For instance, pneumonia may be regarded as a single condition. On the other hand, the diagnosis may be of more than one concurrent condition, such as pneumonia with fluid retention. In such circumstances the veterinary surgeon would need to exercise their professional skills to reach a diagnosis and prescribe the most effective treatment. If they consider that in the circumstances there are two or more concurrent conditions, the treatment of each would need to be considered in accordance with the Veterinary Medicines Regulations (VMR). However, due account of the usual factors, such as drug incompatibilities and side-effects, must be considered
- Unavailability of medicines – if a medicine cannot be obtained despite diligent search and in a reasonable time, the veterinary surgeon may conclude that in the circumstances it does not exist. In such circumstances the cascade should be followed to identify a suitable alternative. However, it is appreciated that there may be cases where urgency dictates that a veterinary surgeon uses whatever is to hand, whether authorized or not.

Suspected adverse reactions

If a veterinary surgeon concludes that an authorized medicine 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 or unauthorized, should be reported as suspected adverse reactions to the VMD where they are recorded and monitored.

Import certificates

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

A VMP authorized in another EU Member State requires a special import certificate (SIC); a veterinary medicine without a full marketing authorization, or an authorized veterinary medicine from outside the EU, or a human medicine from outside the UK all require a STC.

Further information

Veterinary Medicines Directorate
Veterinary Medicines Guidance Note 7 – Import Certificate Schemes
Veterinary Medicines Guidance Note 14 – Marketing Authorisation Exemption Scheme for Pet Animal Medicines
Veterinary Medicines Guidance Note 15 – Controls on the Administration of Veterinary Medicines

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Consent

Part 1D of the **Royal College of Veterinary Surgeons (RCVS) (www.rcvs.org.uk)** Guide to Professional Conduct states that:

- 'You should obtain the client's informed consent to treatment unless delay would adversely affect the animal's welfare (to give informed consent, clients must be aware of the risks).'

Who can give consent?

- The veterinary surgeon should be satisfied that the person being dealt with is the owner registered in the clinical records.
- If 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 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 be a satisfactory 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. Whilst a minor is defined as someone under 16, and an 18-year-old can be considered an adult, there is a grey area between the two. In such cases it is up to the veterinary surgeon to make a decision, based on their judgement, as to the capability of the client to understand both what they are proposing to do, and the consequences.
- 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.

What is consent?

- Consent is the owner's formal agreement to the medical or surgical course of action proposed, which should ideally also include acknowledgement of an estimate of the associated costs.
- Consent does not have to be written, although it is useful to be able to produce a signed consent form in the event of a dispute.
- 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.
- Consent must be 'informed'. The owner must understand the nature of the procedure to be undertaken, and the risks and possible side-effects which may ensue.
- Owners must understand what they are signing.
- It is no longer enough to add the catch-all phrase, 'and all other procedures which may be considered necessary', 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.
- Consent may include reference to the use of unauthorized drugs. Owners should understand why it is sometimes necessary to use a medication 'off-label' and give consent for their animal to receive such treatment.

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The cascade and 'off-label' use

The RCVS considers that there is now a requirement for veterinary surgeons to obtain consent from owners if they intend to use drugs 'off-label'. The RCVS Practice Standards Scheme (PSS) inspectors will ask to see examples of signed 'off-label' consent forms, in order to ensure that this message has got through.

'Off-label' use

- Datasheets are not legally binding 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 good clinical reason for the decision; a theoretical whim is not enough. If challenged by either a client's solicitor or the Veterinary Medicines Directorate (VMD) inspectorate, they should be able to cite some scientific justification for the action.
- 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 immediately jump to the conclusion that some sort of experimentation is going on, and are sensitized to the possibility of something going wrong. When it does, they may conclude that it was the use of an unauthorized drug(s) which caused the problem. Therefore, it is very important that the right message should be given. Practices may even consider creating a generic information sheet on the subject, which owners can read at their leisure.

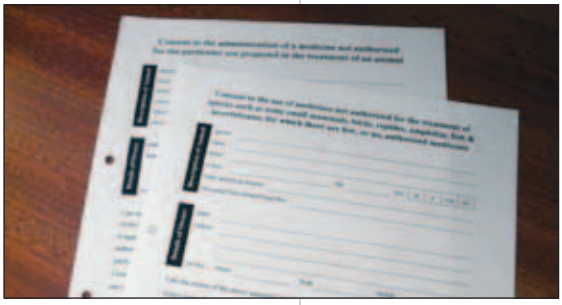
Information sheet

An information sheet could include the following points:

- The drugs which the practice may wish to use have been in general veterinary use for years, e.g. those found in the emergency box in most operating theatres (adrenaline, atropine, potassium chloride)
- The names of the drugs themselves can usefully be inserted, as this increases the degree of the owner's informed consent. Many are related to anaesthesia and analgesia (e.g. morphine, methadone, diazepam). In other words, the practice is not seeking permission to do an experiment. The sight of such familiar names will go a long way to quell any lingering feeling among owners that some sort of sinister experimentation is going to take place
- The reason why these drugs do not have a UK marketing authorization, which in some cases is purely due to the prohibitive cost of obtaining the authorization, which would never be recovered through sales.

Consent forms

As has already been emphasized, it is not the signature on the form, but the fact that the owner understands the reason for signing it, which is paramount.



Single-use consent form

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

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Multiple-use consent form

This is used in situations where there are no authorized medications for use in the species concerned. An increasing variety of species are now kept as pets and their owners are usually able to appreciate the reason why the veterinary surgeon needs 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 for general anaesthesia

If unauthorized drugs are going to be used as part of the anaesthetic routine, or to provide peri- and postoperative analgesia, then the consent form should contain some reference to this fact. For example, by adding the phrase '…which will/may include the use of drugs unauthorised for use in…(insert species)…'

The fact that the use of these drugs is 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

RCVS – consent forms (www.rcvs.org.uk)

Veterinary Defence Society (www.veterinarydefencesociety.co.uk)
Consent form for 'off-label' single use
Consent form for 'off-label' lifetime use

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Controlled Drugs

Classification

Under the Misuse of Drugs Regulations 2001, Controlled Drugs are classified into five Schedules according to their therapeutic usefulness, need for legitimate access and potential for misuse. Schedule 1 Controlled Drugs have the highest level of restriction, Schedule 5 the lowest. A veterinary surgeon has the authority to supply Schedule 2, 3, 4 and 5 Controlled Drugs.

Schedule 1 drugs

- Schedule 1 includes hallucinogenic drugs, ecstasy and cannabis, which have virtually no therapeutic use.
- Production, possession and supply of these drugs is limited in the public interest and veterinary surgeons have no authority to possess drugs in this Schedule.

Schedule 2 drugs

- Schedule 2 includes morphine, pethidine, fentanyl, alfentanil, methadone, the amphetamines and secobarbital.
- These drugs are subject to safe custody requirements and should be stored in a suitable locked cabinet secured to the fabric of the building at all times.
- Receipt and supply of Schedule 2 Controlled Drugs must be recorded in a Controlled Drugs Register.
- Written requisitions must be made to wholesalers.
- Schedule 2 Controlled Drugs must not be destroyed, except in the presence of a person authorized by the Secretary of State.
- Written prescriptions are valid for 28 days.
- There are special requirements for extra information on written prescriptions.
- Repeat prescriptions are not permitted.
- Prescriptions cannot be faxed or sent electronically.

Schedule 3 drugs

- Schedule 3 includes buprenorphine, pentobarbital, phenobarbital, midazolam and some minor stimulants, including benzphetamine.
- These drugs are subject to safe custody requirements (with some exceptions) but do not have to be recorded in the Controlled Drugs Register.
- Written requisitions must be made to wholesalers.
- Written prescriptions are valid for 28 days.
- Witnessed destruction requirements apply only to importers, exporters and manufacturers.
- There are special requirements for extra information on written prescriptions.
- Repeat prescriptions are not permitted.
- Prescriptions cannot be faxed or sent electronically.

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Schedule 4 drugs

- Schedule 4 is split into two parts: part I includes benzodiazepines and ketamine; part II contains anabolic and androgenic steroids.
- They are not subject to safe custody requirements. However, as ketamine is a substance of abuse, the Royal College of Veterinary Surgeons (RCVS) recommends that it is stored in the Controlled Drugs cabinet and its use recorded in an informal Register.
- Written prescriptions are valid for 28 days.
- Witnessed destruction requirements apply only to importers, exporters and manufacturers.

Schedule 5 drugs

- Schedule 5 includes preparations of certain Controlled Drugs, such as codeine and morphine, which are exempt from full control when present in medicinal products of low strength.
- They are exempt from all Controlled Drug requirements, other than the requirement to keep invoices for 5 years.

Summary of legal requirements

Legal requirements	Schedule 2 drugs	Schedule 3 drugs	Schedule 4 drugs: part I	Schedule 4 drugs: part II	Schedule 5 drugs
Prescription required	Yes	Yes	No	No	No
Validity of prescription	28 days	28 days	28 days	28 days	6 months
Repeat prescriptions permitted	No	No	Yes	Yes	Yes
Safe custody	Yes[a]	Yes[b]	No	No	No
Record in Controlled Drug Register	Yes	No	No	No	No

[a] = Except secobarbital.
[b] = Although safe custody requirements apply, currently most Schedule 3 Controlled Drugs are exempted. Those requiring safe custody are buprenorphine, temazepam, flunitrazepam, diethylpropion and midazolam.

A search can be performed to check the legal class of veterinary and human medicines, using the generic name of the drug. The Royal Pharmaceutical Society of Great Britain (RPSGB) online search can be accessed at **www.rpsgb.org.uk/worldofpharmacy/useofmedicines/searchlegalclassificationofmedicines.html**.

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Storage

- Schedule 2 and 3 Controlled Drugs should be kept in a locked cabinet. This cabinet should conform to British Standards and be attached to the fabric of the building.
- The specifications with which safes, cabinets and rooms must comply are given in detail in the Misuse of Drugs Regulations 2001 (available from **The Stationery Office, www.tso.co.uk**).
- Special storage boxes are available that can be secured to the car for storage of Controlled Drugs, and these should be used where possible. A locked bag or box can be used to store Controlled Drugs for short periods of time if a veterinary surgeon requires them on a house call, but this bag or box should not be left unattended in the car for any length of time.
- Each veterinary surgeon is responsible for the record keeping on incoming and outgoing Controlled Drugs from their bag, box or car.
- Access to the Controlled Drugs cabinet should be restricted, with keys kept by a responsible person(s) at all times. It is not acceptable to have a communal key kept in a drawer or other non-secure place.
- A key register can be used to pass responsibility from one key holder to another, e.g. for overnight and during the day.
- Alternatively, each veterinary surgeon can be issued with their own key which they are responsible for.
- If a practice is found not to be complying with the Misuse of Drugs Regulations 2001, they can be prevented from keeping Controlled Drugs by the Home Office.

Record keeping

- When ordering Schedule 2 and 3 Controlled Drugs, a written requisition signed by a veterinary surgeon should be supplied to the wholesaler. This requisition must state the veterinary surgeon's name, address and professional qualifications.
- All invoices relating to Controlled Drugs should be kept for 2 years.
- A separate Register should be kept for each premises and for each cupboard within a premises if there is more than one. This Register should be in the form of a bound book or computerized record.
- Within this Register, each drug, form and strength must have a separate section with the medicine name and strength written at the top of each page.
- Entries must be made in chronological order with no alterations. If a mistake is made, an explanatory note must be made at the bottom of the page or margin.
- Registers may only be kept electronically if safeguards are built into the software to ensure the following:
  - The author of each entry is identifiable
  - Entries cannot be altered at a later date
  - A log of date entered is kept and can be recalled for audit purposes.
- The Register must be completed within 24 hours. For example, it is acceptable during procedures to mark on a white board the quantities administered and complete the Register at the end of the day.
- Legally the Register should be kept for 2 years; however, since all other paperwork relating to the Veterinary Medicines Regulations (VMR) must be kept for 5 years, this is recommended.

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Controlled Drugs Register

The following information should be recorded in the Controlled Drugs Register:

- Controlled Drugs received:
  - Date received
  - Name and address of the person or supplier from whom the drug was obtained
  - Amount received
  - Form in which received
  - Running total (recommended).
- Controlled Drugs supplied:
  - Date supplied
  - Name and address of the person to whom the drug was supplied
  - Name and signature of veterinary surgeon
  - Amount supplied
  - Form in which supplied
  - Running total (recommended).

If a Schedule 2 Controlled Drug is dispensed to a client, the following should also be recorded:

- Name of the person collecting the Controlled Drug
- Was proof of identity of the person collecting the drug requested (yes/no)? Record details.

Standard operating procedures

All healthcare providers holding stock of Controlled Drugs are required to have in place standard operating procedures (SOPs) that cover the following:

- Who has access to the Controlled Drugs
- Where the Controlled Drugs are stored
- Security in relation to the storage and transportation of Controlled Drugs
- Who is to be alerted should complications arise
- Record keeping, including maintaining the Controlled Drugs Register and maintaining a record of Controlled Drugs returned by clients.

Prescription requirements

- One of the changes as a result of the Shipman enquiry is that prescriptions for Controlled Drugs are now only valid for 28 days. Prescriptions for other POM-V veterinary medicinal products are valid for 6 months or such shorter period as may be specified in the prescription.
- Written prescriptions for Controlled Drugs should be limited to 30 days' supply.
- Repeat prescriptions are not allowed for Schedule 2 and 3 Controlled Drugs.
- Unlike prescriptions for Controlled Drugs for human use, written prescriptions for Controlled Drugs for animal use do not have to be on a standard form.
- In addition to the usual prescription requirements, written prescriptions for Schedule 2 and 3 Controlled Drugs must include:
  - The name and form of the drug
  - The quantity to be supplied in words and figures
  - The strength of preparation (if more than one strength available)
  - The dose to be administered (not 'give as required' or 'give as directed')
  - The name of the person to whom the Controlled Drug is to be delivered
  - The RCVS registration number of the veterinary surgeon
  - The words 'for animal(s) under my care' or similar

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Destruction of Controlled Drugs

- Controlled Drugs awaiting destruction should be stored separately from current stock but within the Controlled Drugs cabinet.
- If a client returns a Controlled Drug that the practice has dispensed, it should not be entered into the Controlled Drugs Register.
- A separate book should be kept to record the return and destruction of these products. Although this is not a legal requirement, it is strongly recommended as there is a requirement to have in place an SOP detailing how medicines returned from clients should be handled.
- Destruction of out-of-date Controlled Drugs must be witnessed by either a member of the Animal Medicines Inspectorate, an inspector of the RCVS Practice Standards Scheme, a veterinary surgeon who is independent of the practice, or a police officer (such as a Controlled Drugs Liaison Officer).
- An entry must be made in the Controlled Drugs Register detailing the items destroyed and the running total updated. This entry must be signed by the authorized witness.
- Method of destruction:
  - Use a denaturing kit where possible
  - Wear gloves
  - Crush solid dosage forms in a mortar and pestle and add to the denaturing kit
  - Pour in liquids
  - Add parenteral preparations, open ampoules and empty into denaturing kit, and remove medicines from vials
  - Fold any transdermal patches in on themselves and add
  - Fill denaturing kit with water and store in the Controlled Drugs cupboard for 24 hours until denaturing is complete
  - Incinerate with other pharmaceutical waste.

Controlled Drug Liaison Officers

- Most police forces in the UK have Controlled Drug Liaison Officers (CDLOs) who can advise on all aspects of Controlled Drug use within veterinary medicine, as well as providing information on the abuse of drugs and crime statistics. CDLOs are authorized to witness the destruction of Controlled Drugs.
- A list of CDLOs can be found at **www.vmd.gov.uk/VetSQP/pcdl_officers.pdf**

Useful websites

Royal College of Veterinary Surgeons (RCVS) – Advise note No. 23
www.rcvs.org.uk/shared_asp_files/uploadedfiles/rcvs/56b9fbdc-ffd1-4d6c-9217-2fe41aa971e6_an23_accesscontrolleddrugs.pdf

Veterinary Medicines Directorate (VMD)
www.vmd.gov.uk/General/VMR/vmgn/VMGNote29.pdf
www.vmd.gov.uk/vetsqp/cdi.htm

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Responsible use of antimicrobial agents

The rationale for prudent use of antimicrobial agents is to maximize therapeutic success and at the same time minimize development of antimicrobial resistance, thereby safeguarding antimicrobials for future veterinary and human use. This is done by optimizing drug choice, drug dose and dosing regimens, in addition to reducing unnecessary use of antimicrobial agents.

Resistance

Antimicrobials do not make organisms resistant but they do create selective pressure on a population of organisms. Those that are resistant flourish. If the resistant population is of a pathogen, then this may have serious implications for animal and human health, and for disease control.

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

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

Veterinary antimicrobials are the same as, or closely related to, antimicrobials used in human medicine. In the past this had led to the suggestion that emerging resistance to antimicrobials in human pathogens was associated with the overuse and misuse of antimicrobials in veterinary medicine.

It now seems most likely that resistance in human pathogens is more closely associated with patterns of antimicrobial use by the medical profession; nevertheless, it is vitally important that the veterinary profession uses antimicrobials prudently in order to:

- Minimize selection of resistant veterinary pathogens and therefore safeguard animal health
- Minimize possible resistance transfer to human pathogens
- Retain the right to prescribe certain antimicrobials that are important in human medicine, e.g. the fluoroquinolones and third generation cephalosporins.

The conceptual hurdle

It is natural for veterinary surgeons to judge the appropriateness or success of therapy by clinical response; in the case of antimicrobials, does the infection resolve? There are several criteria used to assess therapeutic success, including:

- Is the antimicrobial effective against the causal organism?
- Has resistance to the antimicrobial agent developed?
- Individual animal factors
- Will the antimicrobial reach the site of infection in sufficient concentration?
- Size of the inoculum and other local factors.

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Although some of these criteria may also help reduce the development of resistance, there are other important considerations. In order to include these it is necessary to shift from thinking about the individual animal(s) requiring treatment to the population as a whole. Treatment with a broad-spectrum, highly potent, relatively new antimicrobial may be highly effective in the short term, but overuse will select for resistance and reduce usefulness in the medium to long term. It is easy to realise this but harder to have the confidence to act upon it.

Guidelines on how to be prudent

In the UK all antimicrobials are prescription-only medicines (POM-V), therefore the responsibility and control for prudent use rests solely with the prescribing veterinary surgeon.

1. Veterinary surgeons should arm themselves with a working knowledge of commonly used antimicrobials.
2. If possible, a narrow-spectrum antimicrobial should be chosen.
    - Many drug formularies (including the *BSAVA Small Animal Formulary*) provide information on suggested antimicrobials for infections involving particular pathogens and organ systems. These can be helpful, but ultimately it is important that choices are made on an individual basis.
    - In reality the majority of authorized veterinary antimicrobials are broad-spectrum, increasing the challenge.
    - Veterinary surgeons need to have a good idea of the likely pathogen involved and/or results from culture and sensitivity tests to be able to make a choice about which antimicrobial to use.
3. Prophylactic use should generally be avoided. However, there are some situations where prophylactic use may be merited, including:
    - High-risk immunosuppressed patients
    - Perioperatively. It is difficult to define precisely which surgical procedures do and which do not merit prophylactic antimicrobial use. Long complex procedures where the consequences of infection would be catastrophic clearly do merit prophylactic antimicrobial use.
4. If use of an antimicrobial is justified, the correct dose, dose frequency and duration of treatment should be used.
    - Too much or too little antimicrobial is equally bad in terms of resistance development.
    - Sub-therapeutic dosing is more of a risk for in-feed or in-water medication.
    - Environmental contamination with antimicrobials should be avoided.
    - Optimal dosing regimes maximize bacterial killing and minimize the window for resistance development to occur.
    - Time- and concentration-dependent killing should be taken into consideration.
    - The client should be educated in terms of the correct use of the antimicrobials prescribed.
    - Topical or local use should be considered (if appropriate) as this will, for example, reduce selective pressure on gastrointestinal flora.
5. If combinations of antimicrobials are considered necessary, care should be taken to choose rational combinations.

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6. Routine use of antimicrobials considered to be important in treating resistant infections in human and veterinary medicine (e.g. fluoroquinolones, third- and fourth-generation cephalosporins and amikacin) should be absolutely avoided. In reality there are few, if any, options for treating organisms that are or have become resistant to these antimicrobials so they must be safeguarded.
    - The European Medicines Agency (EMA, formerly EMEA) has a Committee for Medicinal Products for Veterinary Use (CVMP), which makes recommendations for action (**www.ema.europa.eu/htms/general/contacts/CVMP/CVMP.html**).
    - In food-producing species the CVMP has specifically advised that third- and fourth-generation cephalosporins for systemic administration should be reserved for those conditions that have responded poorly or are likely to respond poorly to other antimicrobials. Use in groups or flocks of animals (as opposed to treatment of individuals) is strongly discouraged as is 'off-label' use. Ceftiofur and cefquinome are examples of such antimicrobials currently authorized in the United Kingdom. The same guidelines should also be applied to the fluoroquinolones.
    - In all species fluoroquinolones and third- and fourth-generation cephalosporins should be used judiciously and never considered as first-choice options.
    - Failure to adopt these prudent measures is likely to be countered with restrictions on veterinary use being placed on these antimicrobial classes.
    - There is also a strong argument that 'last resort' antimicrobials, such as imipenem and vancomycin, should not be used for veterinary patients.
7. Taking time to institute practice-based guidelines for antimicrobial use should be considered.
    - For example, it is feasible to work out appropriate first option antimicrobials for uncomplicated urinary tract infections, pyoderma and surgical prophylaxis, which should then be used by all practice members.
    - Proven human guidelines can be looked towards as a starting point for veterinary practice. In the case of preoperative human use, the guidelines from the American Society of Health-System Pharmacists (1999) are:
        - Use antimicrobials only in clean-contaminated, contaminated or dirty procedures
        - Administer the first dose 1 hour before the incision
        - Re-administer during surgery if the procedure is ongoing after two half-lives of the drug have passed
        - Restrict treatment to the duration of the surgery or less than 24 hours, except in certain situations (i.e. gross contamination, pre-existing infection)
        - Avoid the use of newer broad-spectrum antimicrobials.
    - Creating a table of first-, second- and third-choice antimicrobials to be considered.
        - First-choice antimicrobials would comprise agents appropriate for initial treatment, not necessarily based on culture and sensitivity information.
        - Second-choice antimicrobials should be prescribed based on culture and sensitivity data, provided that no first-choice agents are appropriate.
        - Third-choice antimicrobials 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.
    - The key considerations are that all guidelines should be reviewed regularly and be flexible so that change could easily be adopted should inadequacies arise or new information become available.

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- Many human hospitals have adopted such guidelines with positive outcomes. The Infectious Disease Society of America together with the Society for Health Care Epidemiology have put together a **guidelines document (www.journals.uchicago.edu/doi/pdf/10.1086/510393)**; some of the guidelines suggested could be adapted and applied to veterinary practice situations.

8. Report treatment failures. This is a vital part of monitoring for developing and emerging resistance.
   - 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 (**www.vmd.gov.uk**).
   - Situations where this would be appropriate include:
     - Treatment failure despite culture and sensitivity results indicating that an appropriate antimicrobial class had been used
     - Treatment failure where a particular antimicrobial product is authorized for the specific condition and species, and where the clinician's experience would suggest that a positive response should have occurred.

Further information

American Society of Health-System Pharmacists (1999) ASHP therapeutic guidelines on antimicrobial prophylaxis in surgery. *American Journal Health-System Pharmacy* **56,** 1839–1888

Giguere S, Prescott JF, Baggot JD, Walker RD and Dowling PM (2006) *Antimicrobial Therapy in Veterinary Medicine, 4th edition*. Wiley-Blackwell, Oxford

Ramsey I (2008) *BSAVA Small Animal Formulary, 6th edition*. BSAVA Publications, Gloucester

Useful websites

Defra antimicrobial resistance coordination group (DARC) (www.vmd.gov.uk/General/DARC/pubs.htm)

Health Protection Agency (HPA) (www.hpa.org.uk)

National Office of Animal Health (NOAH) (www.noah.co.uk)

Responsible use of medicines in animals (RUMA) (www.ruma.org.uk)
(this website relates only to food-producing animals)

Veterinary Medicines Directorate (VMD) (www.vmd.gov.uk)
Of specific interest are the antibiotic-related publications

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Resistance

There are three types of resistance:

- Inherent
- Chromosomal
- Plasmid-mediated.

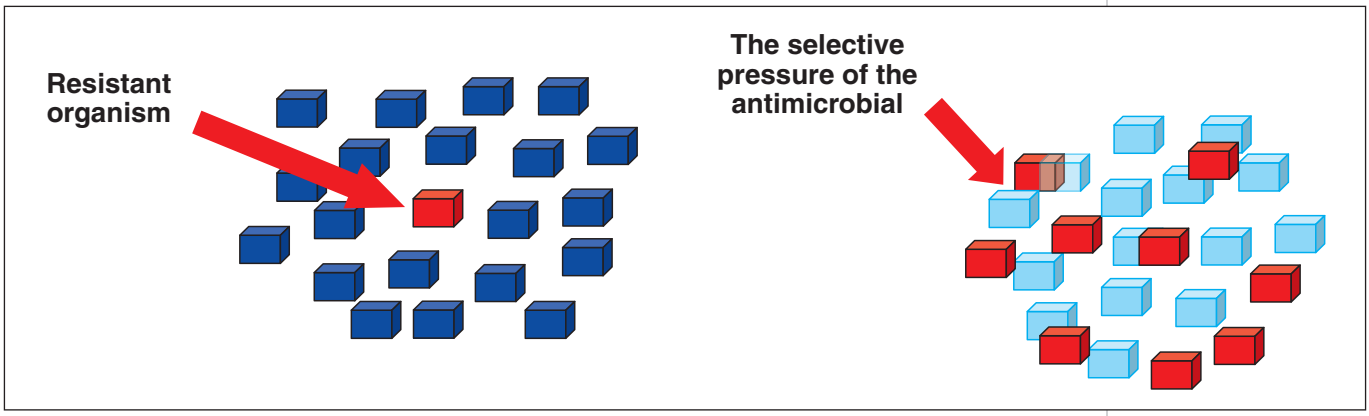
Inherent resistance

An inherent feature of an organism to a particular antimicrobial or group of antimicrobials. Examples include:

- Anaerobic organisms and aminoglycosides. The aminoglycosides require an oxygen-dependent carrier to enter the bacterial cell
- Mycoplasmal organisms and beta-lactams. Mycoplasmas have no cell wall, which is the target for beta-lactam antimicrobials.

Chromosomal resistance

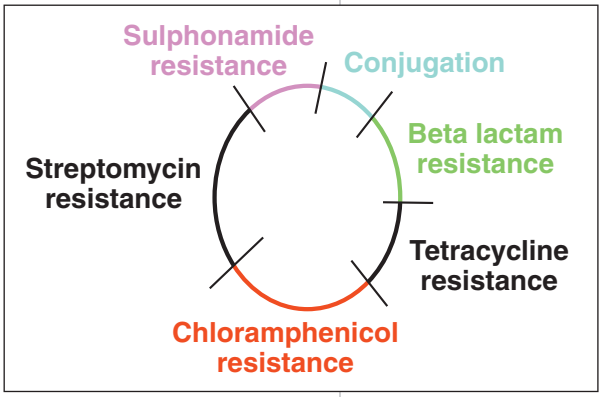
- 1:10,000,000 bacterial cells give rise to a daughter cell with a mutation.
- This may lead to a change which confers resistance on that organism.
- This type of resistance develops slowly and often requires multiple steps.



Plasmid-mediated resistance

- Plasmids are small circular pieces of DNA carried by many bacterial cells.
- They may be transferred between bacteria – even between different bacterial species, e.g. from a non-pathogenic to a pathogenic organism.
- They may carry genes which impart resistance to several different types of antimicrobial.

Thus, in a single step an organism may become resistant to multiple antimicrobials.



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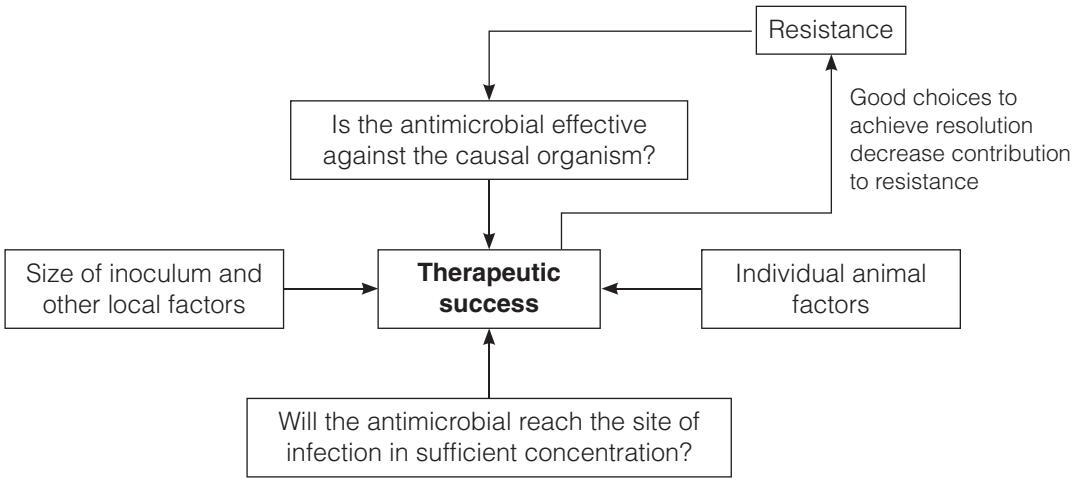
Therapeutic success

There are several criteria to assess therapeutic success:



Is the antimicrobial effective against the causal organism?

- Veterinary surgeons must have a working knowledge of the spectrum of activity of the main antimicrobials used in veterinary practice.
- The veterinary surgeon may have a good idea of the likely organism(s) involved. In addition, some organisms have:
  - Predictable/stable resistance patterns (e.g. β-haemolytic streptococci, *Erysipelothrix rhusiopathiae*, *Actinomyces pyogenes*)
  - Variable resistance patterns (e.g. *Staphylococcus aureus*, *Pasteurella* species)
  - Unpredictable resistance patterns (e.g. *Escherichia coli*, *Pseudomonas* species, *Salmonella* species).
- Culture and sensitivity testing should be considered if the causal organism is suspected to have variable or unpredictable resistance patterns. However, it should be noted that antimicrobial treatment will usually need to be started prior to obtaining the culture and sensitivity test results.

Will the antimicrobial reach the site of infection in sufficient concentration?

- Veterinary surgeons must have a working knowledge of the pharmacokinetics of the antimicrobial, in particular a knowledge of its distribution.
- Most veterinary antimicrobials are well distributed (see below).
- Subtleties exist within this broad categorization:
  - Fluoroquinolones and macrolides achieve particularly high concentrations within cells
  - Certain antimicrobials, such as penicillins, cephalosporins and fluoroquinolones, achieve high concentrations in the urinary tract
  - Potentiated sulphonamides and fluoroquinolones are more likely to cross the blood–prostate barrier
  - Beta-lactams struggle to attain reasonable concentrations in pulmonary secretions.

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Distribution of veterinary antimicrobials

High volume of distribution	Moderate volume of distribution	Low volume of distribution
Tetracyclines Macrolides Lincosamides Sulphonamides Chloramphenicol Fluoroquinolones	Penicillins Cephalosporins	Aminoglycosides

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Spectrum of activity

Narrow-spectrum antimicrobials

Please note that the table below is not a complete list.

Drug name	Spectrum (good susceptibility)
Penicillin (V or G)	Primarily Gram-positive aerobic organisms such as β-haemolytic streptococci and *Bacillus anthracis*. Also anaerobic organisms such as *Actinomyces* spp., *Fusobacterium* spp. and *Bacteroides*
Meticillin and cloxacillin	Antistaphylococcal penicillins (hence meticillin-resistant *Staphylococcus aureus*, MRSA)
Aminoglycosides (gentamicin, neomycin, amikacin)	Primarily Gram-negative aerobic organisms. Note: amikacin is considered to be a 'top-shelf' antimicrobial
Metronidazole	Gram-positive and Gram-negative anaerobic organisms. Note: they also have antiprotozoal activity, so not really narrow-spectrum but one of the few antimicrobials where resistance development is relatively rare

Moderate-spectrum antimicrobials

*Please note that the table below is not a complete list. * These antimicrobials are not authorized veterinary medicinal products and can only be used in accordance with the prescribing cascade.*

Drug name	Spectrum (good susceptibility)
Macrolides or macrolide-related (tylosin, tilmicosin, tulathromycin, clarithromycin*, azithromycin*)	Primarily Gram-positive organisms: ■ Aerobes: *Listeria* spp., *Corynebacterium* spp., *Bacillus* spp. and *Rhodococcus equi* ■ Anaerobes: *Actinomyces* spp., *Bacteroides* spp. and some *Fusobacterium* spp. Note: the newer generation agents such as azithromycin and clarithromycin have increased Gram-negative and Gram-positive activity (e.g. against mycobacteria)
Lincosamides (lincomycin, clindamycin)	Primarily Gram-positive aerobic and anaerobic organisms. Note: clindamycin is particularly effective against anaerobic organisms

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Broad-spectrum antimicrobials

Please note that this table below is not a complete list.

Drug name or group	Spectrum (good susceptibility)
Extended spectrum penicillins (amoxicillin ± clavulanate, ampicillin)	A good range of Gram-positive and Gram-negative aerobic and anaerobic organisms, including: all organisms susceptible to penicillin G and also *Borrelia* spp., *Pasteurella* spp., *Haemophilus* spp., *Moraxella* spp. and *Leptospira* spp.
Cephalosporins (cefalexin)	A good range of Gram-positive and Gram-negative aerobic and anaerobic organisms, similar to the extended spectrum penicillins
Tetracyclines (tetracycline, doxycycline)	A good range of Gram-positive and Gram-negative organisms. They also have activity against *Rickettsia*, *Chlamydophila*, *Ehrlichia* and *Mycoplasma*
Potentiated sulphonamides	A good range of Gram-positive and Gram-negative organisms. *In vivo* activity against anaerobic organisms is limited. Activity against some protozoal organisms is also limited
Fluoroquinolones (marbofloxacin, enrofloxacin)	Many Gram-negative aerobic organisms are highly susceptible. Gram-positive aerobic organisms also susceptible, although minimum inhibitory concentration (MIC) values tend to be higher compared with Gram-negative aerobic organisms. Variable susceptibility of anaerobic organisms and *Pseudomonas*

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Time- and concentration-dependent antimicrobials

Time-dependent antimicrobials

- Beta-lactams (penicillins and cephalosporins) are considered to be time-dependent antimicrobials.
- In this case, the key factor that correlates with efficacy of the antimicrobial is the percentage of time within a dosing interval that the concentration of antimicrobial remains above the minimum inhibitory concentration (MIC) for the organism.
  - For beta-lactams being used against Gram-negative organisms, the level of antimicrobial should ideally be above the MIC for at least 80% of the time.
- In other words, the dosing interval is critical and missed doses will impact on efficacy.

Concentration-dependent antimicrobials

- Fluoroquinolones and aminoglycosides are generally considered to be concentration-dependent.
- This means that the efficacy of the antimicrobial, in terms of bacterial killing, increases as the drug level increases above the MIC of the organism.
- In other words, a high concentration relative to the MIC is key and thus dose size is critical. It doesn't seem to matter if the level of the antimicrobial dips below the MIC for part of the dosing interval, provided this high concentration has been achieved.
  - This is reflected in the fact that aminoglycosides, despite having relatively short half-lives, are most often dosed at a relatively high dose rate but only once daily.

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Rational antimicrobial combinations

- 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 diaminopyrimidines.
- Combinations may be indicated for agents where resistance develops rapidly, so that rapid bacterial killing is desirable – e.g. rifampin combined with a macrolide such as erythromycin, clarithromycin or azithromycin (in accordance with the prescribing cascade).

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Importing medicines

It should always be remembered that it is illegal to import unauthorized medicines without the correct authorization. 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.

1. The first step is to establish a source – this may be the drug manufacturer or it may be a specialist drug importer, e.g. **IDIS (www.idispharma.com)**.
2. The second step is to apply for permission from the Veterinary Medicines Directorate (VMD) to import the medicine. In general, this will be on a named patient basis only; however, where a drug 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. In these cases it is essential that the VMD is supplied monthly with a list showing drug use and the name, address and details of each animal for which the drug has been supplied. 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 or the amount should be transferred on to a new Special Treatment Certificate. Stock should not be supplied to other veterinary practices.

Types of licence

There are two types of licence for **drug importation (www.vmd.gov.uk/sis/default.aspx)**.

- Special Treatment Certificate (STC) for non-European or human medicinal products. The initial application must be made in writing. Forms are available on the VMD website and each application costs £30 (price correct at December 2009) per animal treated. Thereafter, repeat applications can be made online and require no additional payment.
- Special Import Certificate (SIC) for European veterinary medicinal products (VMPs).
  - These applications can be made online or in writing.
  - Where an SIC is requested for a medicine for the first time, a paper-based application must be made which costs £15 (price correct at December 2009).
  - Repeat applications can be made online and require no additional payment.
  - However, to apply online the VMD must have been notified in writing or by phone, so that the practice applying can be registered and allocated a specific VMD number.

In each case details must be given of:

- The veterinary surgeon applying for the drug importation (the applicant's Royal College of Veterinary Surgeons (RCVS) membership number should always be provided)
- The premises where the drug is to be used
- Details of the patient for which the drug is to be used (including pet name, owner name and owner address)
- Details of the drug and the importer. The authorization number of the drug in the country of production will also be required

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- Amount of the drug, 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 drugs only imported where there is no alternative.
  - 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 (Vibravenos) for the treatment of psittacosis in a Grey Parrot. There is an alternative form of doxycycline (Ornicure) available for use in parrots in the UK; however, this is authorized for use in water. As the larger parrots rarely drink consistently, it is hard to effectively treat psittacosis by this route of administration. Therefore, justification can be made for importing Vibravenos, especially where birds may be additionally stressed and handlers exposed to zoonosis if the birds are handled for direct oral medication (as opposed to weekly injections of Vibravenos). The dose rate is 100 mg/kg weekly by intramuscular injection on seven occasions, and the drug is supplied in 5 ml vials of 20 mg/ml. Once opened the drug quickly deteriorates. A 400 g Grey parrot will require 40 mg of the drug weekly, so justification can be made for importation of 7 x 100 mg vials.

On occasion, emergency importation will be required. For applications made online or by fax, the VMD can usually provide a licence within 48 hours. The licence and prescription can then be sent to the importer.

The **VMD website (www.vmd.gov.uk)** provides full instructions on how to apply for an SIC or STC. It is also vital that all adverse reactions involving imported medicines are recorded and reported to the VMD. Forms are available from **www.vmd.gov.uk/General/Adverse/adverse.htm**.

Remote supply of medicines through online and direct mail ordering

UK law permits the remote supply of all categories of veterinary medicines, provided the general legal requirements regarding the prescription and supply are met.

Such supply is commonly associated with internet sites. Although these are often informally described as 'pharmacies', the majority are currently hosted by veterinary practices under the professional control of veterinary surgeons, and thus are not legally pharmacies at all. Some internet sites are true pharmacies controlled by pharmacists, and a number of sites are under the professional control of suitably qualified persons (SQPs).

As well as online ordering, some businesses promote mail order supply of veterinary medicines through more traditional printed price lists and advertisements, and others may supply medicines by post/courier on an *ad hoc* basis as an occasional customer service.

Legislative requirements

There are no legislative requirements specific to the supply of veterinary medicines ordered online or through direct mail. 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 drugs online or through direct mail ordering must be able to demonstrate that they operate in accordance with the Veterinary Medicines Regulations (VMR), including the registration and inspection requirements with respect to the premises.

As a result, although the supply of medicines ordered online or via direct mail can be carried out legally, veterinary medicines (other than AVM-GSL and Small Animal Exemption Scheme (SAES) medicines) should not be offered or supplied via auctions, since legal and professional obligations cannot be met satisfactorily.

Premises that supply medicines ordered online or via direct mail under the professional control of a veterinary surgeon must be registered as a veterinary practice.

Prescription

The requirements for the prescription and supply of veterinary medicines are the same for remote supply as for face-to-face interactions. 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
- POM-V medicines may only be prescribed for animals under the veterinary surgeon's care
- 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.

Prescriptions may be faxed or emailed to an internet or mail order supplier. Electronic transmission of prescriptions for Controlled Drugs is not allowed.

Suppliers should seek to ensure that a prescription is only filled once. It is good practice if the supplier does not recognize the prescriber's signature to take steps to ensure that the prescription is genuine.

Veterinary surgeons providing a written prescription should seek to ensure that it will be legally filled (see below).

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Supply by post

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

Veterinary surgeons should take account of whether the medicines are potentially harmful to the general public. Medicines not in the manufacturer's packaging should be supplied in child-proof 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. In general, Controlled Drugs should not be sent via the 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 which ensures that the Controlled Drugs 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 medicine is competent to do so safely, and intends to use it for a purpose for which it is authorized
- Advising on safe administration and on any necessary warnings or contraindications on the label or package leaflet
- Supplying only the medicine 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 of duties at the time of supply can be met, including methods for use by internet and mail order retailers. This is not an exhaustive list and it is up to the retailer to choose their own method.

- It is considered good practice for all businesses supplying veterinary medicines to display clearly the appropriate authorization details (e.g. the name and registered number) of the veterinary surgeon, pharmacist or SQP who is responsible for prescription and/or supply, and this person should be available to advise clients directly.
- It must be possible for a client to be given direct advice so that the most appropriate medicine is prescribed and/or supplied to them, regardless of the medicines that the supplier currently holds in stock, those that are reduced in price, or those which are being promoted through the business by the manufacturer.
- Even if a client asks for a specific POM-VPS or NFA-VPS medicine, there must be an interaction between the client and the supplier to ensure that the medicine selected is appropriate for the animal to be treated and its circumstances (including husbandry and condition).
- For clients who wish to order specific 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, size, age, weight, etc., of their animals are recorded, kept up-to-date, and can be used to enable a supplier to make the necessary checks on the suitability of the medicine ordered before any medicines are prescribed and/or supplied. This would also enable returning customers to log-in without having to provide the 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 completion by clients to confirm whether they have administered the medicine previously, if they are aware of the relevant safety precautions relating to the medicine, and to confirm that they will read the packaging and product literature before using the medicine.

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- An email or telephone call may be made to the client following placement of their order to enable the supplier to discuss any problems before filling the prescription and or/supply. 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 such interchanges with clients (via the internet, emails, phone calls) should be made and retained.

Price lists

Advertising of prescription-only medicines (POM-V and POM-VPS) is only permitted to defined groups, which does not include pet owners, clients or the general public. However, price lists (whether printed or online) may be supplied to the general public, provided certain conditions are met:

- The 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 medicine's published summary of product characteristics (SPC). The name of the medicine should be exactly as per its full authorized name. This is important, as different medicines within the same brand should be clearly distinguished
- A description may be given, for example 'dog flea treatment', as long as this is in accordance with the SPC
- Any image of packaging used must show the UK authorized packaging.

Non-UK websites

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

It is an offence for an animal owner:

- To be in possession of a veterinary medicine not lawfully supplied in the UK (including, where appropriate, lawfully prescribed)
- To administer a veterinary medicine unless it has a marketing authorization valid in the UK
- To import a veterinary medicine into the UK, even if authorized for use in the UK (except for AVM-GSL medicines)
- To supply a veterinary medicine 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 contemplating sourcing medicines via the internet, are aware of the importance of using a UK-based and legal site. 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 medicines may be counterfeit, ineffective, or unsafe for the client's animals.

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Useful websites

Royal Pharmaceutical Society of Great Britain (www.rpsgb.org)
RPSGB Guidance on Internet Pharmacy Services

Veterinary Medicines Directorate (VMD) (www.vmd.gov.uk)

Veterinary Medicines Guidance Note 3 –
Veterinary Medicinal Products: prescription, distribution categories and supply

Veterinary Medicines Guidance Note 14 –
Marketing Authorization Exemption Scheme for Pet Animal Medicines

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Correct medicines use in racing Greyhounds

Besides being the second most popular spectator sport, Greyhound racing in the UK is a significant vehicle for gambling. Drugs, including legitimate medication, can affect a dog's performance. Although the distinction between legitimate therapy and unacceptable drug administration may be a fine one, to preserve the perceived integrity of the sport as a gambling medium it is necessary that the competing dogs should be seen to be 'drug free'.

National Greyhound Racing Club regulations

Drug use in racing Greyhounds is controlled by the National Greyhound Racing Club (NGRC), currently the regulatory body for most Greyhound racing in the UK. The NGRC's 'Rules of Racing' do not specifically prohibit the use of particular substances. However, they do prohibit the administration to a Greyhound, for any improper use, any quantity of any substance which by its nature could affect the performance or prejudice the wellbeing of the Greyhound, the origin of which substance cannot be traced to normal and ordinary feeding or care. There are some veterinary medicinal products (VMPs), which can be administered to racing Greyhounds in any circumstances. Rule 217 of the NGRC's 'Rules of Racing' permits the use of:

- 'medicinal products which have been authorized by the **Veterinary Medicines Directorate (www.vmd.gov.uk)** for the suppression of a bitch's season, prescribed by a veterinary surgeon'
- 'medicinal products which have been authorized by the Veterinary Medicines Directorate as anti-parasitic drugs (for internal/external) parasites or as vaccines.'

Apart from these few notable exceptions, Rule 217 requires that:

- 'Any tonics, medicaments or other substances administered or applied to a Greyhound by a trainer or veterinary surgeon shall be duly recorded in the trainer's Greyhound treatment book, and that that Greyhound must not race or trial for seven days thereafter.'

The NGRC also advises that:

- 'Although most prohibited substances will clear the Greyhound's system within seven days, some products may still be detectable more than seven days after administration. However, it is the responsibility of owners and trainers to satisfy themselves in every case that a Greyhound complies with Rule 217 when taking part in a race or trial.'

Therefore, it is incumbent upon the prescribing veterinary surgeon to advise the owner and/or trainer of a Greyhound under their care accurately as to how long that Greyhound must be withheld from trialling and racing.

- A particular problem arises with the use of depot or other long-acting injectable medicines. It is not always possible to give guidance on the excretion times of specific medicines as, since this information is not legally required to be furnished by the manufacturer as part of an application for a marketing authorization, it may simply be unknown. The NGRC's advisory note on this subject states: 'the decision to administer such a preparation should be carefully considered as it may result in either a positive drug test or a prolonged lay-off time.'

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- Delayed absorption and excretion may occur following intramuscular injection. Since absorption depends on vascularity and lipid solubility, inadvertent injection into fatty tissue or between fascial planes may result in prolonged excretion.
- Lipid-soluble substances, such as corticosteroids and local anaesthetics, may be well absorbed following, for example, intra-articular injection and may be detectable in urine. Topical non-steroidal anti-inflammatory drugs (NSAIDs) may be absorbed through the intact skin, leaving detectable residues in urine.

Generally, the amount of a substance found in a sample of urine or blood taken from a competing Greyhound is irrelevant in determining whether or not there has been a breach of the 'Rules of Racing', the detection of a prohibited substance in any quantity being likely to initiate a Stewards' Inquiry.

Summary

In summary, when prescribing for racing Greyhounds, the attending veterinary surgeon should:

- Adhere strictly to datasheet recommendations as far as possible
- Follow the prescribing cascade if this is not possible
- Advise owners and trainers not to race dogs for at least 7 days after treatment, or longer if deemed necessary.

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Dart guns

Dart guns and blowpipes are categorized as firearms in the UK. For the sake of clarity, from hereon all types of blowpipe and dart gun are described under the term 'dart gun'.

Courtesy of Nick Masters and John Lewis (IZVG).

- Dart guns are commonly used in the chemical capture and/or medical treatment of wild or dangerous animals, especially in zoo situations, or for escaped animals such as cows.
- The practical applications of dart gun use need careful consideration. Repeat injections using a dart gun are not practical, unless the animal is restrained in a confined area. Similarly, using a dart gun for the chemical capture of animals, such as rogue dogs, is not practical because in the time it takes for the drugs to work, the animal could well have disappeared over the horizon.
- Prior to purchase, careful thought should be given as to whether a dart gun is really required. If it is, then further consideration should be given to the size and type of darts needed, as this will determine the specifications of the dart gun. It is logical to ensure that the dart gun purchased is not only powerful enough for the job, but also one that will be able to fire darts of a sufficient size. A larger gun is needed for firing darts carrying 10 ml of a drug.
- There should be training for individuals in how to use dart guns safely: this may be provided by the supplier of the dart gun.
- It is an offence to purchase a dart without having a licence, so the first step in getting a dart gun is to get a firearms licence.

Firearms licences

Firearms licences are obtained from the local police force, under the Firearms Act of 1968. The licence needs to be renewed every 3 years. In general, police forces will require the following:

- **The gun cabinet.** The dart gun will need to be kept in a gun cabinet. For the cabinet to be acceptable it will need to be manufactured and kite marked to British Standard BS 7558:1992. The cabinet should be kept in a protected part of the premises and hidden from public view. The keys should be available only to those people who have a firearms licence
- Proof of identity and photographs of licence holder
- **Ammunition.** In this case meaning the darts, needles and sleeves, should be kept in a locked cabinet, either within the gun cabinet or in a separate cabinet
- It is important to remember that only those people with a firearms licence can have access to the gun cabinet contents. If there are a number of people involved it is sensible to appoint a firearms officer, who is in charge of the whole process
- If a number of dart guns or other firearms are to be kept, then consideration should be given to having an alarm system.

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Drugs used in dart guns

- Any drug can be used in a dart gun; however, the viscosity of the drug and the volume of the drug needed should be taken into account in the decision-making process. The dart gun supplier will supply notes on the correct procedure for loading, priming and cleaning of the darts. They will also advise on the pressures required for firing darts of different weights and over varying distances.
- Many drugs used in darts are anaesthetics, and can be very dangerous. Suitable standard operating procedures (SOPs) should be developed for the loading, firing and cleaning of darts. For example, LA Immobilon is still commonly used in darts for anaesthetizing escaped cattle or large zoo animals. In these cases, handling such a dangerous drug in a loaded dart should be done with extreme care, with antidotes available and drawn up in a syringe ready to use. **Note:** it has been suggested that darts that have contained LA Immobilon should not be cleaned for re-use but placed into a sharps bin as soon as they have been retrieved.
- Apart from veterinary use of dart guns, there are a number of other establishments and groups that use dart guns and may request drugs. Most commonly this is either zoos, when the drugs are being used under the direct direction of a veterinary surgeon, or private individuals. In these cases, it is often LA Immobilon that is being requested, e.g. for use on deer farms or for escaped beasts. Before dispensing drugs, the veterinary surgeon should check the legality and correct procedure with reference to the **Royal College of Veterinary Surgeons (RCVS) (www.rcvs.org.uk)** Guide to Professional Conduct.

Standard operating procedures

Safety

Use of a dart gun (and all other firearms) is restricted to people who have been approved to use them by the Firearms Officer at the local police station, who will ensure compliance with the UK Firearms policy. No one else is allowed access to or use of a dart gun.

Nitrile gloves and suitable eye protection must be worn when charging/uncharging the darts.

Dart gun safety

- The dart gun must be kept locked in a secure place unless its imminent use is expected or required.
- The dart gun (whether loaded or not) should never be deliberately pointed at anyone, or anything that is not intended to be shot.
- When the dart gun is being carried, it should be done in a way that will not alarm people, i.e. it should be kept pointed at the ground or sky with the bolt (if fitted) clearly open so people can see that it is not in a 'ready-to-fire' state.
- The dart gun should not be loaded with a dart until the target has been identified and is in range, and it has been deemed safe to shoot with respect to the area around and behind the target. Thought must also be given to the possible occurrence of ricochets from objects around and from the chosen target.

Dart safety

- Charged darts should be kept in a purpose-designed container and not carried in a pocket or loose in a bag.
- If available, the safety cap must always be kept on the needle of charged darts and only removed when the dart is being loaded into the chamber of the dart gun.
- After use, the darts should be recovered as soon as is practical.

Materials

- Dart gun (e.g. Dan-Inject)
- Darts appropriate for species
- Gun cabinet (this must be securely attached to a solid wall with bolts)
- Anaesthetic or other drug
- Bound dart gun usage book.

Procedure

Preparation prior to use: Before the dart gun can be used, the darts are made ready with the desired quantity of anaesthetic for the animal. The choice of anaesthetic will be determined by the availability of drugs and other factors decided by the veterinary surgeon (and the scientist in charge of the study where appropriate).

Charging the dart

1. Remove the hypodermic needle from the protective case (if applicable). Slide the green/red silicone sleeve on to the needle so that the injection holes are located at the centre of the sleeve. This can be achieved by rotating the needle whilst exerting pressure on the sleeve. The green/red silicone sleeve must only be used once.
2. Remove the red stabilizer from the dart; if necessary, using a venting pin, release any retained air from the dart syringe air chamber.
3. Hold the dart with the air chamber uppermost. Using an air-filler syringe fitted with a coupling adapter connected to the drug chamber, position the black plunger at the rear of the chamber.
4. Reverse the dart so that the drug chamber is now uppermost. Using a suitable syringe filled with the required drug, slowly inject the drug into the chamber. Ensure that a sufficiently small gauge needle is used to allow air from the drug chamber to be expelled without displacing the drug.
5. Mount the hypodermic needle on to the dart syringe boss using pliers and locate it firmly by rotating it slightly whilst applying pressure.
6. If available, apply a safety cap over the needle and seat it firmly on the dart.

Pressurising the dart

1. Hold the dart horizontally with the needle/protection cap uppermost. Mount the coupling adapter on to a clean, dry syringe of suitable size to charge the dart in a single go. Introduce the correct amount of air into the syringe (see below). Connect the syringe securely to the air chamber of the dart and with a smooth continuous action, inject the air into the dart air chamber.
2. Now the same amount of air is let in to the syringe though the coupling. The red plunger will act as a non-return valve and retain the air, under compression, within the dart.

   WARNING: the dart is now pressurised and extreme caution must be exercised at all times.

3. Place the red stabilizer firmly on the rear of the dart.

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Correct air pressures for dart types

Dart type	Drug volume (ml)	Volume of air injected (ml)
S 150	1.5	10–12
S 300	3.0	12–14
S 500	5.0	15
S 10	10.0	20

Procedure after use

Discharging an unfired dart:

1. Remove the red stabilizer from the dart.
2. Holding the dart vertically, depress the red plunger to release air pressure using the venting pin.
3. Remove the protection cap from the dart.
4. If using proprietary medication/drug bottles with rubberized seals, insert a plain hypodermic needle, directed away from the operator, into the seal before proceeding to the next step. This will allow excess air pressure to vent from the bottle.
5. Holding the dart with the needle pointing downwards, insert the needle into a suitable receptacle as far as possible. The silicon sleeve will slide along the needle shaft exposing the injection ports.
6. Hold the dart with the attached bottle. Using a coupling adapter on an air-filler syringe, steadily and smoothly insert 12 ml of air into the dart air chamber. The air pressure will slowly force the black plunger forwards and inject the drug into the bottle.

Note: drugs must not be kept in dart syringes for prolonged periods. The extreme pH of most drug formulations will adversely affect the plunger and dart barrel after 3–4 days.

Cleaning the syringe:

After releasing any remaining air from the air chamber, hold the dart vertically with the black plunger upwards. Fit a coupling adapter to a filler syringe and flush the drug chamber with warm water. Repeat several times.

Note: syringes must not be sterilized by steam or have heat applied to them.

Cleaning the needle:

1. Remove the green/red silicone sleeve from the needle and disgard it.
2. Remove the needle from the syringe using pliers. Removing the needle after use can prolong the serviceability of the dart, as the mounting hub will remain in better condition and retain its shape for longer.
3. Rinse the needle by passing warm water through it several times (giving free passage), so that the two injection ports are free from debris and foreign material.
4. Sterilize the needle by a suitable method.

Note: it has been suggested that darts that have contained LA Immobilon should not be cleaned but discarded directly into a sharps bin.

Useful contacts

Wildpharm (suppliers of dart guns)
PO Box 255, Taunton, Somerset, TA4 1YX
Telephone: 01984 623462

Health and safety in the dispensary

Management of health and safety at work

The **Health and Safety Executive (HSE) (www.hse.gov.uk)** asks businesses to:

- Assess risks in the workplace
- Consult with and involve employees
- Take suitable precautions to avoid risk
- Review and revise risk assessments as necessary.

Risk assessment

A risk assessment should be performed for any potentially hazardous procedure and should:

- Identify the hazard
- Identify who is at risk as a result of the hazard
- Classify the seriousness of the risk: insignificant, minor or major
- Assess the probability of the hazard occurring: unlikely, likely or very likely
- Assess any risk to health
- Assess any risk to the environment
- Identify who is responsible for the task or area
- Identify what control measures are already in place
- Identify what protective clothing or equipment is used
- Assess whether any special procedures are needed for first aid, fire, spillage or storage
- Assess whether current control measures are satisfactory
- If not, identify what additional controls are needed
- Identify when and by whom these control measures will be implemented and the date of the next review.

The areas of risk that need to be assessed in the dispensary include:

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

A risk assessment should be carried out for each of these activities, preferably by the staff directly involved, and reviewed annually. As a result of the risk assessment, standard operating procedures (SOPs) should be drawn up and staff trained in their use.

Control of substances hazardous to health

Under the Control of Substances Hazardous to Health (COSHH) Regulations 2002, practices should assess the risk to health and safety from veterinary medicines and other substances used in the practice.

Drugs and substances should be classified according to risk:

- Low
- Medium
- High.

British Small Animal Veterinary Association
Woodrow House, 1 Telford Way, Waterwells Business Park, Quedgeley, Gloucester GL2 2AB
Tel: 01452 726700 Fax: 01452 726701 Email: administration@bsava.com Web: www.bsava.com

Low- and medium-risk substances

Low- and medium-risk substances can be grouped by therapeutic group, type or route of administration. Standard measures to control exposure can be used for the whole group; examples of groups include:

- Antibiotics
- Vaccines
- Injectable anaesthetics
- Inhalation anaesthetics
- Steroids
- Disinfectants.

Any specific risks within the groups must be identified (e.g. allergy to penicillin).

High-risk substances

High-risk substances must have an individual detailed assessment. These substances include:

- Oil-based vaccines
- Cytotoxic drugs
- Glutaraldehyde disinfectants
- Hormones
- Tilmicosin.

Measures to control exposure to these high-risk substances must be explained to staff.

Summaries of product characteristics

- Safety data must be available for all drugs stocked. Drug companies no longer have to supply safety datasheets but many manufacturers still do and some can be found in the NOAH datasheet compendium available from The National Office of Animal Health or online at **www.noahcompendium.co.uk**
- All veterinary authorized products have a summary of product characteristics (SPC). These are available on the Veterinary Medicines Directorate website at **www.vmd.gov.uk**. The product database (**www.vmd.gov.uk/ProductInformationDatabase**) is arranged alphabetically and clicking on the chosen product brings up a link to its SPC. All veterinary medicinal products currently authorized in the UK plus homeopathic products and specified feed additives, and a list of suspended or recently expired products are included in this database.
- For non-veterinary authorized drugs (e.g. human prescription-only medicines) used under the prescribing cascade, SPCs can be found online at **www.emc.medicines.org.uk** or in copies of the ABPI compendium of datasheets, which are supplied to doctors, pharmacists and nurses and can be purchased from **www.medicines.org.uk**
- Disinfectants and cleaning chemicals need to have material safety datasheets (MSDS) under the Chemicals (Hazard Information and Packaging for Supply) (CHIP) Regulations 2009 known as CHIP4. These Regulations require manufacturers to give information about the hazards to their customers. Suppliers generally provide this information on the package itself, usually on the label. Safety datasheets laws have been transferred to the European Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulations, and manufacturers no longer have to provide a safety datasheet if there is sufficient safety information available to the user supplied with the product.

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Medicine waste disposal

The relevant legislation pertinent to medicine waste disposal is the Waste Framework Directive (WFD) (2006/12/EC). To help explain the Directive, there is a Department of Health guidance booklet entitled **Environment and Sustainability Health Technical Memorandum 07-01: Safe management of healthcare waste (www.dh.gov.uk/en/PublicationsandStatistics/Publications/PublicationsPolicyAndGuidance/DH_063274)**.

More specific to the veterinary sector are the **British Veterinary Association (BVA) Waste Guidelines 2008 (www.bva.co.uk/public/documents/hw_poster.pdf)**.

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 BVA or waste contractor should be sought.

Whole pharmaceuticals

These are made up of the following:

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

Returned stock: Client returns of unused medicines: whilst there is no legal duty to accept dispensed medicines back into the practice, there is often pressure from the client to do so. Veterinary surgeons may wish to take into consideration the practice's standard operating procedure (SOP) for advising clients on medicine returns. It is not permissible to reuse returned medicines and there is a cost involved in their disposal. Disposal legislation is far more onerous for the veterinary practice than it is for domestic disposal. 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. The only consistency is the inability to reuse the medicine once it is returned to the practice.

Out-of-date stock: Out-of-date medicines should always be disposed of due to the inherent danger of using out-of-date stock. This category includes all injectable medicines, 28 days after the broaching of a multidose vial.

Damaged stock: Damaged stock includes any in-transit damages or spillages and breakages. For spilled drugs, 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

The medicines should be collected into a leak-proof storage container. **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.

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The contents of the bin must be recorded and the record made available to the disposal contractor. It is good practice to create a client file on the practice management system, be that computerized or manual, for this purpose. The date, type and amount of medicine can then be recorded. Computerized practices will then automatically 'de-stock'. A printout or photocopy of the record is then 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 audit.

Controlled Drugs: Controlled Drugs require additional recording and action before disposal. All Schedule 2 medicines must be effectively denatured before disposal. This applies to out-of-date whole medicines; it is not necessary to apply denaturing to residual amounts left in used vials, syringes or needles. It is permitted to open packaging and de-blister to aid denaturing. Denaturing kits are available from veterinary wholesalers. When denaturing Schedule 2 medicines, a witness must be present and sign that the procedure has been carried out. The record of disposal should be entered into the Controlled Drugs Register so that purchase, use and disposal appear in one single record. An authorized witness list is regulated by the **Royal Pharmaceutical Society of Great Britain (www.rpsgb.org)**. However, for small volumes it is acceptable for a veterinary colleague to sign the witness section.

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 Controlled Drug. Schedule 3, 4 and 5 Controlled Drugs 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.

Cytotoxic and cytostatic drugs: This is a special category of medicines that has been introduced under the Disposal of Healthcare Waste Regulations. These medicines are deemed to be Hazardous Waste and will carry variable hazard codes. They all fall under the generic European Waste Catalogue (EWC) coding system of 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, residue in used vials, contaminated syringes, needles, cannulae and contaminated protective clothing. It is important that the medicines are defined by their particular hazardous properties, which may include the following:

- H6 Toxic teratogenic
- H7 Carcinogenic
- H9 Infectious
- H10 Toxic for reproduction
- H11 Mutagenic.

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

- Cancer chemotherapeutics: including vincristine, pharmarubicin, methotrexate and all similar classes of tumour toxic medicines
- Antiviral medicines: including aciclovir (Zovirax) ophthalmic ointment
- Ciclosporin medicines in any form
- Certain hormonal preparations: including prostaglandins and androgens (e.g. Tardak, Alizin and Mesalin).

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These wastes must be segregated into purple flagged containers (i.e. the separate sharps bin should have a purple top, the separate pharmaceutical waste bin should have a purple lid or label and the yellow waste bag should be purple labelled). In addition, the EWC code and the H 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 (for example, 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 drugs can also be added, provided they are listed and mixing precautions (see above) are observed. Where other contaminated items are produced, e.g. giving sets, canullae, gloves, etc., 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. If large volumes of soft, cytotoxic contaminated waste is produced, these can be disposed via a yellow and purple striped bag.

Residue pharmaceuticals

Used vials of injectable medicines

This type of waste includes all empty multidose bottles, vaccine vials and contaminated tablet pots. These are best collected into a pharmaceutical waste bin separate from whole medicines. A detailed list is not required as these are classified as non-hazardous waste. If Hazardous Waste (e.g. cytotoxic drugs) are added, the whole bin has to be classified as Hazardous Waste and subject to rigorous (and expensive) disposal. Some contractors are now happy for residue and whole pharmaceuticals to be placed in the same bin. It is still important to ensure that details of the whole pharmaceuticals are recorded, and again hazardous and non-hazardous waste must be segregated. Items allowed in these bins include:

- Vaccines bottles
- Empty injection bottles
- Syringes.

It should be ensured that all syringes placed in the bin have been fully discharged of content. Snap-top vials should not be placed in these bins, unless they conform to the British Standard for ‘sharps’. Snap-top glass should be placed in the sharps bin.

Needles

There is some controversy surrounding the disposal of ‘sharps’. The Environment Agency have insisted that all ‘sharps’ are *de facto* Hazardous Waste. The BVA guidelines state this clearly. 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’. If this advice is followed, there is no need to segregate cytotoxic drugs, but the correct H codes must be applied to the bin. Larger sharps containers are available. 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 proprietary sharps container. These must comply with British Standard 7320:1990. If cytotoxic/cytostatic contaminated needles are segregated, the needle can be deemed non-hazardous.

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To dispose of 'sharps' as non-hazardous:

1. Ensure the waste contractor has facilities to transport and dispose of non-hazardous 'sharps'. The NHS has made the decision to classify all 'sharps' as hazardous to avoid the segregation requirements.
2. Prepare a proper risk assessment for separating 'sharps' from syringes.
3. Make sure staff are properly trained.
4. Place hypodermic syringe needles in a British Standard sharps bin. The non-hazardous white-topped bin is now not available due to low demand. A yellow-topped bin is acceptable, but ensure that the hazardous transportation label (diamond symbol with a '6' code with in it) has been blanked out.
5. Apply the EWC code 18 02 01 to denote the waste as 'sharps'.
6. Ensure that there is no addition of needles contaminated with cytotoxic/cytostatic medicines.
7. Ensure that there is no contamination with H9 waste (infectious; see Hazardous Waste guidelines).

Practices are advised to make sure that their waste contractor is licensed for disposal of this type of waste.

Post script

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 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.

Variations in legislation for Scotland

These 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) (www.sepa.org.uk)**.

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Standard operating procedures

A standard operating procedure (SOP) is a written document describing routine procedures carried out in veterinary practice. They 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:

- Assures of the quality of the service
- Ensures the achievement of good practice
- Enables veterinary surgeons to delegate and so free time up for other duties
- Avoids confusion over who does what
- Provides advice and guidance to locums and part-time staff
- Provides a useful tool for training new staff members
- Contributes to the audit process
- Provides financial benefits
- Most importantly, SOPs protect staff and clients.

How to write a standard operating procedure:

1. Decide the purpose, e.g. how to receive a drug from a wholesaler.
2. Decide on the author. This should be someone who performs the task regularly.
3. Draft the content. Various styles can be used such as bullet points, flow charts or detailed information. There should be logical steps that are easy to read and understand.
4. Consult others. Ideally, input from someone new to the task should be sought to ensure the information is clear and detailed enough, and someone who knows the task well in case anything has 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. SOPs should be reviewed regularly.

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

Waste medicines returned by clients

1. Greet the client and ask if there are any 'sharps' (i.e. hypodermic needles or syringes) or Controlled Drugs in the returned waste. Carefully accept the returned waste from the client, holding the bag by the handles (if it has any) to avoid potential needle stick injuries.
2. Remove any Schedule 2 and 3 Controlled Drugs from the returned waste immediately and store in the Controlled Drugs cupboard, clearly separated from other stock until they are denatured.

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3. Place the remaining waste in a designated area for sorting at a suitable time. The designated area must be chosen to prevent contamination or mixing with dispensary stock (e.g. stock room bench).
4. Put on protective clothing before handling.
5. Tip out the contents of the bag into a returns tray in the waste designated area – this avoids contact with cytotoxic/cytostatic substances or 'sharps'.
6. Labels with patient details must be removed from containers and disposed of as confidential waste. Remove blister strips from the outer carton. To comply with waste regulations, do not remove medication from blisters or decant from containers (except Controlled Drugs).
7. Store the waste in a secure location and then wash your hands. Do not store waste in excess of 5 m^3 or for longer than 6 months.
8. After waste collection, file the collection dockets issued by the waste contractor and retain for 5 years.
9. A summary consignment note listing all the collections made in the past 3 months will be sent to the practice by the contractor. This should be filed and retained for 5 years and may be audited by the Environment Agency (Scottish Environment Protection Agency (SEPA) and Animal Health in Scotland) at any time or at the annual notification of waste collection.

Using ampoules

1. Injectable drugs 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, choose the closest volume ampoule for dispensing.
2. Draw up the correct volume and empty the remainder of the ampoule into a 'sharps' bin. If it is a Controlled Drug, this must be witnessed.
3. Place the empty ampoule in the 'sharps' bin.
4. If the medicine is a Schedule 2 Controlled Drug, a record must be made in the Controlled Drugs Register. Note the amount used and the amount discarded, for example if 0.5 ml was used from a 1 ml ampoule, the register should read '0.5 ml given and 0.5 ml wasted.'
5. Label the sharps bin as 'mixed pharmaceutical waste and sharps – for incineration' when it is sent for destruction.

Date-checking the dispensary

1. Develop practice-specific date-checking matrices.
2. Take care to include all dispensary stock on the matrices, e.g. fridge, liquids, Controlled Drugs and injectables. Ideally distribute the workload evenly by dividing the dispensary into equal parts on the matrix and planning throughout the month.
3. Date-check all dispensary stock every 3 months, following the date-checking matrices. Ideally, each area should be date-checked regularly by the same team member.
4. As each area is date-checked, move the stock with the shortest expiry date to the front and the stock with the longest expiry date to the back of the shelf. Identify stock with <4 months shelf-life and record short-dated items in a book used for this purpose. Highlight short-dated stock with short-dated stickers.
5. 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 the rest of the date-checking is completed.

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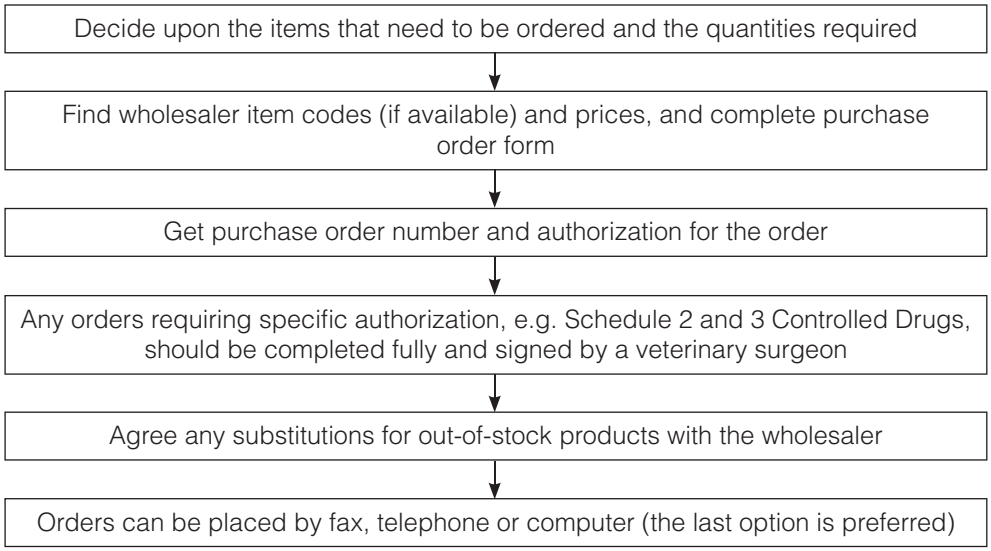
6. Record quantities and values of out-of-date medicines for accounts purposes and the annual audit, and dispose of this stock appropriately in a yellow pharmaceutical waste bin.
7. Record completion of date-checking of each area on the matrices by initialling and writing the date of completion in the relevant box. Every 4 weeks, check the short-dated stock book and remove any stock that is within 1 month of its expiry date.
8. Retain matrices for 6 months. The matrices must be available for inspection by authorized persons.

Receiving a Schedule 2 or 3 Controlled Drug

1. Check that any packages received are intact and not damaged. If the stock received is damaged or incorrect, notify the supplier immediately.
2. Immediately open the package(s) containing the Controlled Drug(s) and check the stock received against the invoice and delivery note or the request made to another pharmacy. Check the product name, strength, dosage form, pack size, expiry date and that the manufacturer's tamper-evident seal is intact.
3. If the medicine received is a Schedule 2 Controlled Drug, record the amount received in the relevant section of the Controlled Drugs Register. 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. If the Controlled Drug 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 Controlled Drugs requiring safe custody in the Controlled Drugs cupboard. Damaged stock should be stored in the Controlled Drugs 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 Controlled Drugs Register.
6. It is good practice to keep invoices for all Controlled Drugs for 5 years.

Placing an order with a wholesaler

The stock order should be placed by a competent member of staff with the authorization of the veterinary surgeon.



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Disposing of out-of-date Controlled Drugs

1. Identify any Schedule 2 and 3 Controlled Drugs that have been returned by a client or that are obsolete, expired or unwanted.
2. Record the details of any Schedule 2 Controlled Drugs returned by the client in the client returns register. This information should include: the date of return of the Controlled Drugs; name, quantity, strength and form of the Controlled Drugs; the role of the person who returned the Controlled Drugs (if known); name and signature of the person in the practice who received the Controlled Drugs; and owner's name and address and animal name (if known). This is a legal requirement.
3. If it is not possible to denature them immediately, store the Controlled Drugs in a sealed bag, clearly marked as 'Patient Returns – Not for Use' or 'Out-of-Date Stock – Not For Use' and lock the bag in the Controlled Drugs cupboard.
4. Make sure that an authorized person is present to witness the destruction of the Controlled Drugs (this can be the veterinary surgeon for patient returns. For stock Controlled Drugs, the witness must be either a member of the Animal Medicines Inspectorate, an inspector of the RCVS Practice Standards Scheme, a veterinary surgeon who is independent of the practice, or a police officer (such as a Controlled Drugs Liaison Officer – a list can be found at **www.vmd.gov.uk/VetSQP/pcdl_officers.pdf**).
5. Put on gloves, apron and goggles if required.
6. Denature the Controlled Drugs by crushing in a tablet crusher or mortal and pestle.
7. Place the denatured Controlled Drugs in to the Controlled Drugs denaturing kit or waste container.
8. Update the records with details of any client-returned Schedule 2 Controlled Drugs that have been destroyed: the name, position and signature of the person who destroyed the drugs and the witness, and the date of destruction, should be added to the record. The information recorded should include: the drug name, form and strength; quantity being destroyed; date of destruction; signature of the authorized person and the signature of the witness.
9. Record the destruction of any stock Schedule 2 Controlled Drugs (i.e. non-client returns) in the relevant section of the Controlled Drugs Register. All stock of the Schedule 2 Controlled Drug in question must be counted manually to ensure that the amount of stock held corresponds to the balance in the stock record.
10. Store the waste in a secure location and then wash your hands. Do not store waste in quantities in excess of 5 m^3 or for longer than 6 months.
11. After waste collection, file the collection dockets issued by the waste contractor and retain for 5 years. A summary consignment note listing all the collections made in the past 3 months will be sent to the practice. This should be filed and retained for 5 years and may be audited by the Environment Agency (SEPA and Animal Health in Scotland) at any time or at the annual notification of waste collection.

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Hazardous Waste spillages

All members of staff should be aware of where the spillage clean up kit is stored.

When a hazardous spillage is noticed, inform another member of staff and ask them to wait near the spillage until a hazard sign has been put in place

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Check whether any staff member has been in direct contact with the spillage and arrange for a first aider if required

↓

Check the Control of Substances Hazardous to Health (COSHH) assessment in the pharmacy manual for the required safety precautions

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Collect the spillage kit, which should include absorbent granules, absorbent pads, Hazardous Waste disposal bags, disposable gloves, aprons, masks and goggles

↓

Clean up the spillage using the required safety precautions

↓

Ventilate the area to prevent contamination from dusts or vapours in adjacent areas

Handling medicines

Members of staff must:

- Treat all medicinal products as potentially harmful; direct contact with and inhaling dust or vapours should be avoided
- Be aware of the hazards associated with the medicines to be handled and the safety measures required to minimize any risks to health; staff must 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
- Use additional protective clothing and equipment as and when specified in the practice rules, other SOPs or medicine safety data
- Be familiar with the type, position and operation of safety equipment (e.g. fire extinguishers, spillage kits, eye wash and first aid kits)
- Deal with any accidental spillage of medicines immediately and refer to the medicine safety datasheets or seek advice from the health and safety officer
- Inform a senior member of staff in the event of any accident
- Inform the health and safety officer if they are or expect to become pregnant, or if they suffer from asthma or any known allergy or any condition that they consider may put them at increased risk
- Inform the health and safety officer if they experience any adverse effects thought to be caused or made worse by the handling of/and exposure to veterinary medicine products (VMPs)
- Wash their hands after handling medicines, even if disposable gloves have been worn.

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Members of staff must not:

- Eat, drink or smoke in the medicines handling or storage areas
- Take medicines from the storage area for their own use or make such medicines available to other persons
- Handle any medicine unless they are familiar with the relevant safety data and know the hazards, safety precautions and spillage procedures, and the first aid requirements if exposed
- Handle any medicine if they know or think that to do so will put them at risk
- Handle either cytotoxic medicines or Controlled Drugs unless as a veterinary surgeon or pharmacist, or on the instructions of a veterinary surgeon or pharmacist.

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Pharmacovigilance

Pharmacovigilance is the monitoring of unwanted or adverse reactions to medicines and vaccines. For veterinary surgeons, veterinary nurses and animal owners, this monitoring is done through the Suspected Adverse Reactions Surveillance Scheme (SARSS). The reporting of reactions is not currently mandatory in the UK for these groups, but there are legal obligations on medicines manufacturers and distributors (see **Veterinary Medicines Regulations (VMR) Part 8 at www.opsi.gov.uk/si/si2007/uksi_20072539_en_12**).

The reporting of suspected adverse reactions is a key part of the process of ensuring the safety of medicines, and also plays a part in keeping existing medicines on the market and available.

Who can report an adverse reaction?

Suspected adverse reaction reports can be filed by anyone. In practice, most are submitted by veterinary surgeons. Reports should be sent to the Veterinary Medicines Directorate (VMD) and also to the manufacturer or distributor of the medicine where this is known. Where the manufacturer is a member of the National Office of Animal Health (NOAH) and authorizes further investigation of an incident, they will meet the costs involved.

What is an adverse reaction?

Adverse reactions are harmful and unintended reactions to a medicine when administered to an animal at its recommended dosage and route of administration. Adverse reactions in animals that should be reported include:

- Lack of expected efficacy, including resistance to antibiotic or antiparasitic agents
- Reactions not mentioned in the datasheet
- Reactions mentioned in the datasheet, but occurring more frequently or more severely
- Reactions arising during clinical use of a new medicine under development (Animal Test Certificate)
- Any reaction to a medicine which has been authorized for less than a year
- Reactions arising during 'off-label' use (i.e. under the prescribing cascade)
- Environmental problems.

The VMD and manufacturers will categorize the reaction as minor or serious. Examples of reactions which would be regarded as serious are listed in the **VMD Veterinary Medicine Guidance Note, number 13 (www.vmd.gov.uk/General/VMR/vmgn08/VMGNote13.pdf)**.

Reactions in animals to human medicines

Veterinary surgeons may use medicines authorized for use in humans under the prescribing cascade. The number of **reactions reported (www.vmd.gov.uk/Publications/SARSS/Letter_Cascade.pdf)** following such use is low. The VMD encourages veterinary surgeons to be on the look out for such reactions and to report them in the usual way.

Adverse reactions in humans

There may also be adverse reactions in humans following exposure to a veterinary medicine. The legal definition of a Human Adverse Reaction (HAR) is 'a reaction that is noxious and unintended and that occurs in a human being following exposure to a veterinary medicine'.

British Small Animal Veterinary Association
Woodrow House, 1 Telford Way, Waterwells Business Park, Quedgeley, Gloucester GL2 2AB
Tel: 01452 726700 Fax: 01452 726701 Email: administration@bsava.com Web: www.bsava.com

There is a questionnaire that should be completed when reporting such **reactions (www.vmd.gov.uk/General/Adverse/HumanSARvetmeds.pdf)** or in the case of **accidental injection (www.vmd.gov.uk/General/Adverse/HumanSARinj.pdf)** and sent to the VMD at the address below.

How to report

For most reactions, a SARSS form (Form MLA 252A) should be completed. Copies can be found in the *BSAVA Small Animal Formulary* or in the *NOAH Datasheet Compendium*. Copies can also be **downloaded (www.vmd.gov.uk/General/Adverse/mal252.pdf)**. If the reaction is a result of the animal being exposed after environmental contamination with a veterinary medicine, then a **separate form (www.vmd.gov.uk/General/Adverse/MLA1.PDF)** is used (MLA 1 (A5)).

Completed forms should be sent to:
The Veterinary Medicines Directorate
FREEPOST KT 4503
New Haw
Addlestone
Surrey KT15 3BR

Where the manufacturer or distributor of the medicine which caused the reaction is known, they should also be contacted. Contact details are listed in the *NOAH Datasheet Compendium* or on the medicine package. It is a legal requirement for each company to have a designated member of staff responsible for pharmacovigilance.

What happens to the report?

Reports are collated by the manufacturer and used as part of the ongoing safety monitoring of all medicines. Information on serious adverse reactions and reactions in humans to veterinary medicines must be reported to the VMD within 15 days. Reports are classified under the ABON system:

- A The medicine probably caused the reaction observed
- B The medicine possibly caused the reaction observed
- O There is insufficient information to judge if the medicine caused the reaction observed
- N The medicine probably did not cause the reaction observed.

Reports from all European Union countries are collated by the European Commission. Quarterly summaries of the reports received are published in the *Veterinary Record* and in the VMD journal *MAVIS*.

Useful websites

BVA Good Practice Guide on Veterinary Medicines (www.bva.co.uk)

European Veterinary Pharmacovigilance (eudravigilance.emea.europa.eu/veterinary/index.html)

NOAH – Pharmacovigilance (www.noah.co.uk/issues/pharmacovigilance.htm)

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Statutory prescription notices for practices

Following the Department of Trade and Industry (DTI) and the Office of Fair Trading (OFT) investigations into veterinary drug sales in 2005, there has been the requirement for practices to be more transparent in the pricing and dispensing of veterinary medicines. This has been incorporated into the **Royal College of Veterinary Surgeons (RCVS) Guide to Professional Conduct (www.rcvs.org.uk)**.

- Veterinary surgeons must supply clients with prescriptions for veterinary medicines where appropriate (in the case of emergencies or hospitalized animals this may not be appropriate).
- A veterinary surgeon can only prescribe a POM-V medicine following a clinical assessment of the animal under their care.
- Itemized invoices showing the price of individual veterinary medicinal products (VMPs), separate from other charges, must be provided.
- Practices must give clients information on medicine prices when requested and display a list of the ten most commonly dispensed VMPs (with prices) during a recent 3-month period.
- Veterinary surgeons should also advise clients of the frequency of, and charges for, check ups to allow further prescriptions to be issued.
- This information should be provided on a large and prominently displayed sign in the waiting room of the practice.

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Abbreviations and useful links

ADR	Adverse drug reaction
AMI	Animal Medicines Inspectorate
ATC	Animal Test Certificate
AVM-GSL	Authorized veterinary medicine – general sales list
CD	Controlled Drug
HSAR	Human suspected adverse reaction
MA	Marketing authorization
MPsAHU	Medicinal product authorized for human use
NFA-VPS	Non-food animal medicine – veterinarian, pharmacist, SQP
POM-V	Prescription-only medicine – veterinarian
POM-VPS	Prescription-only medicine – veterinarian, pharmacist, SQP
PSUR	Periodic safety update report
RQP	Registered qualified person
SIC	Special Import Certificate
SQP	Suitably qualified person
STC	Special Treatment Certificate
VMP	Veterinary medicinal product

AMTRA
Animal Medicines Training Regulatory Authority (**www.amtra.org.uk**)

ABPI
Association of the British Pharmaceutical Industry (**www.abpi.org.uk**)

BP
British Pharmacopoeia (**www.pharmacopoeia.co.uk**)

BVA
British Veterinary Association (**www.bva.co.uk**)

EMA
European Medicines Agency (**www.ema.europa.eu**)

NOAH
National Office of Animal Health (**www.noah.co.uk**)

PSS
Practice Standards Scheme (**www.rcvs.org.uk/Templates/Internal.asp?NodeID=93186**)

RCVS
Royal College of Veterinary Surgeons (**www.rcvs.org.uk**)

RPSGB
Royal Pharmaceutical Society of Great Britain (**www.rpsgb.org.uk**)

SAES
Small Animal Exemption Scheme (**www.vmd.gov.uk/General/VMR/vmgn/VMGNote14.pdf**)

SARSS
Suspected Adverse Reaction Surveillance Scheme (**www.vmd.gov.uk/General/Adverse/adverse.htm**)

SPC
Summary of Product Characteristics (**ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/eudralex/index_en.htm**)

VMD
Veterinary Medicines Directorate (**www.vmd.gov.uk**)

VMR
Veterinary Medicines Regulations (**www.opsi.gov.uk/si/si2007/uksi_20072539_en_1**)

VMRGN
Veterinary Medicines Regulations Guidance Notes (**www.vmd.gov.uk/General/VMR/VMG07notes.htm**)

VPIS
Veterinary Poisons Information Services
London: 020 7635 9195
vpis@gstt.sthames.nhs.uk
Leeds: 0113 245 0530
medicines.information@leedsth.nhs.uk

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BSAVA BRITISH SMALL ANIMAL VETERINARY ASSOCIATION