Good practice guide on veterinary medicines

The Veterinary Medicines Directorate supports this Good practice guide on veterinary medicines written and published by the British Veterinary Association.
Legal requirements and provisions affect which medicines may be administered to animals or incorporated in the feedingstuffs of food-producing animals. Most of the legal requirements are captured within the Veterinary Medicines Regulations (VMR). These Regulations are revoked and remade each October following a consultation period with all stakeholders during the preceding months. It is important to be aware of the changes that are likely to be made annually. The most current information on legislation is available on the Veterinary Medicines Directorate (VMD) website at www.vmd.gov.uk
A ‘veterinary medicinal product’ (VMP) means any substance or combination of substances presented for treating or preventing disease in animals — that is, all animals other than man and including birds, reptiles, fish, molluscs, crustaceans and bees (‘medicinal by presentation’); or which may be used in or be administered to animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in animals by exerting a pharmacological, immunological or metabolic action (‘medicinal by effect’).

This classification defines those who may prescribe and those who may supply the VMP. Information on other substances such as specified feed additives, homeopathic remedies, small animal exemption scheme products, and nutritional supplements that are not supplied for a medicinal purpose is also provided in this text.

**AUTHORISED VETERINARY MEDICINE—GENERAL SALES LIST (AVM–GSL)**

The current list of AVM–GSL products authorised in the UK is available at www.vmd.gov.uk/ProductInfo/AuthMed/categories.htm. There are no restrictions on the supply of these medicines. A veterinarian can sell these to anyone, whether a client or not.

**NON-FOOD ANIMAL—VETERINARIAN, PHARMACIST, SUITABLY QUALIFIED PERSON (NFA–VPS)**

The current list of NFA–VPS products authorised in the UK is available at www.vmd.gov.uk/ProductInfo/AuthMed/categories.htm. These medicines may be supplied without prescription but only by a Registered Qualified Person (RQP). Before supplying the product, the RQP must be satisfied that the person who will use the product is competent to do so safely and intends to use the product for the purpose for which it is authorised.

**Safe administration**

At the time of supply, advice must be given on the safe administration of the product and any necessary warnings or contraindications on the label or package leaflet. The minimum amount required for treatment must be supplied, except if the product does not exist in a smaller container and the supplier is not authorised to break open the package before supply.

An RQP is a registered veterinarian, a registered pharmacist or a registered suitably qualified person (SQP). Their registration status is within the control of their individual registration bodies: the veterinarian with the Royal College of Veterinary Surgeons (RCVS), the pharmacist with the Royal Pharmaceutical Society of Great Britain (RPSGB), and the SQP with a body which has been recognised as suitable for this purpose such as the Animal Medicines Training Regulatory Authority (AMTRA) (see page 35 for contact details). The SQP must be suitably trained and hold qualifications that are accredited in a national framework of education. Registered veterinary nurses may also be registered as SQPs if they have gained the necessary qualifications. For further information, see Veterinary Medicinal Products – Qualified Persons, VMD Veterinary Medicines Guidance Note No 20.
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and the supplier is not authorised to break open the package before supply.

It can be supplied by a veterinarian, a pharmacist or an SQP in accordance with a prescription from one of those persons, which may be written or oral. At the time of supply, advice must be given on the safe administration of the product and any necessary warnings or contraindications on the label or package leaflet.

**Prescription Only (POM–V)**

The current list of POM–V products authorised in the UK is available at www.vmd.gov.uk/ProductInfo/AuthMed/categories.htm. They may be prescribed by a veterinarian after carrying out a clinical assessment of the animal under his/her care. Before prescribing the product, the veterinarian must be satisfied that the person who will use the product is competent to do so safely and intends to use the product for the purpose for which it is authorised.

**Supplying POM–V medicines**

POM–V medicines may be supplied by a veterinarian or a pharmacist and must be supplied in accordance with a veterinarian’s written prescription. A veterinarian need not be present when the product is handed over but must authorise each transaction individually before the product is supplied and must be satisfied that the person handing over the product is competent to do so. The minimum amount required for treatment must be prescribed, except if the product does not exist in a smaller container and the supplier is not authorised to break open the package before supply. At the time of supply, advice must be given on the safe administration of the product and any necessary warnings or contraindications on the label or package leaflet.

The RCVS Guide to Professional Conduct indicates that veterinarians must provide adequate information on medicine prices to clients including the correct prices for the ten POM–V medicines most commonly prescribed during a recent and typical three-month period in order to give clients a fair and representative illustration of the practice’s medicines’ prices.

**Written Prescription**

A prescription may be verbal or in writing but, if oral, the veterinary medicinal product must be supplied by the person prescribing it.

A written prescription is required when:

- The veterinary medicinal product is to be supplied by an RQP working at a different business or at another site from where the product was prescribed by another RQP
- Prescribing a veterinary medicinal product for incorporation into feedingstuffs
- Prescribing a medicinal product within the terms of administration under the cascade
- It is a repeatable prescription.

A written prescription is not required when:

- Both the prescribing and the supplying RQPs are not working in a different business or at another site
- NFA–VPS and AVM–GSL veterinary medicinal products are to be supplied
- Prescribing a medicinal product within the terms of administration under the cascade if the prescribing veterinary surgeon supplies and administers the product himself to the animal.

There are legal requirements for written prescriptions for POM–V and POM–VPS products and controlled drug (CD) products. A medicated feedingstuffs prescription (MFSp) is used for veterinary medicinal products incorporated into feed (see pages 5 to 6).

To avoid ambiguity it is good practice to write all prescriptions legally in a standard manner. The following recommendations should be noted:

- Quantities of 1 gram or more should be written as 1 g, etc
- Quantities of less than 1 gram should be written in milligrams, for example 500 mg, not 0.5 g
- Quantities of less than 1 milligram should be written in micrograms, for example 100 micrograms, not 0.1 mg
- When decimals are unavoidable a zero should be written in front of the decimal point where there is no other figure, for example 0.5 ml, not .5 ml
- The terms ‘micrograms’, ‘nanograms’ or ‘units’ should not be abbreviated
- ‘Millilitre’ (mL or ml) is used for veterinary medicine and pharmacy in preference to cubic centimetre, cc or cm³.

Names of drugs and preparations should be written clearly and not abbreviated. Wherever possible an authorised veterinary medicinal product should be specified. Where this is not possible and an active substance is prescribed, only approved titles should be used. These must be International Nonproprietary Names (INNs). In most cases, the British Approved Names (BANs) and INNs are identical. Where they differ, the INN must be used. A comprehensive list of INNs for pharmaceutical substances with reference to BANs is available from the World Health Organization (WHO) (International Nonproprietary Names [INN] for Pharmaceutical Substances: Names for Radicals & Groups WHO 2004).

Directions should preferably be in English without abbreviation. It is recognised that some Latin
abbreviations, as follows, are used when prescribing:

- Once daily: **qid** or **qid** (Note: use of **od** may be confusing because this is used as an abbreviation for oculus dexter or ‘right eye’)
- Twice daily: **bid** or **bd**
- Three times daily: **tid** or **tids**
- Four times daily: **qid** or **qids**

Prescriptions must be in ink or be otherwise indelible. A sample veterinary prescription form is available for BVA members to download from www.bva.co.uk

A written prescription must include:

- The name, address and telephone number of the prescriber, which may be printed on practice forms
- The name and address of the owner or keeper
- The identification (including species) of the animal or group of animals
- The premises at which the animals are kept if this is different from the address of the owner or keeper
- The date of the prescription
- The name(s) and amount of product prescribed. Usually this will be a pre-prepared formulation.

Medicines may be prescribed using the generic name or by specifying a proprietary preparation but only the product specified may be supplied. The formulation of any preparation that needs to be extemporaneously prepared should be included.

- The dosage and administration instructions
- Any necessary warnings
- The withdrawal period, if relevant
- A statement that the product is prescribed under the cascade, if applicable
- The prescriber’s name, usual signature (or other authentication) and authority to prescribe; that is, the letters ‘MRCVS’ or ‘FRCVS’. It is recommended that the veterinarian’s RCVS registration number be appended. Other authentication means a written or electronic signature, or a stamp or sticker incorporating the veterinarian’s RCVS registration number and the name and address of the practice.
- The qualifications of the person prescribing the product.

It is also advisable to include:

- The words: ‘For an animal under my care’
- A direction on whether the prescription may or may not be repeated and the number of times the prescription may be repeated, as appropriate.

A veterinarian is allowed to supply medicines on prescription of another veterinarian (POM–V and POM–VPS products), a prescribing pharmacist or a prescribing SQP (POM–VPS products). A veterinarian supplying a product under a written prescription must take all reasonable steps to ensure that the prescription is genuine and has been written and signed by a person entitled to prescribe the product, and that the product is supplied to the person named in the prescription. The supplying veterinarian should use their knowledge to check that the prescription accords with their own understanding of the product. Any concerns should be raised with the prescriber before supplying the medicine. It is open to any supplier to refuse to supply against a prescription should they wish.

**Electronic prescriptions**

Electronically transmitted and faxed prescriptions are permitted. Such prescriptions must comply with the above requirements. The RPSGB advises that it is possible to fax a prescription many times and the supplier is advised to ensure that a system is put in place to check that the prescription has only been filled once.

A written prescription is valid for six months or less as may be specified in the prescription.

The prescription must not be repeated unless it contains a specific direction for further supply. If a prescription contains a direction that it is to be repeated without specifying the number of times, it shall not be supplied on more than two (2) occasions; that is, it may only be repeated once. When a prescription is to be dispensed in instalments, the

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**VETERINARIANS ARE PROHIBITED** from charging clients fees for prescriptions for POM–V veterinary medicinal products until 30 October 2008, by which time it is expected the situation will have been reviewed and any change to the legislation will have been notified. Veterinarians may choose to pass on to clients the costs of making the decision whether or not to provide a veterinary medicinal product, of providing the instructions and warnings to the owner or keeper of the animal(s) and any other costs, but in doing so they must not discriminate between those who are given prescriptions and those who are not. The veterinarian must ensure that clients are able to obtain prescriptions, as appropriate and are advised that prescriptions are available by way of notices in the waiting room or other appropriate area (as indicated in the RCVS Guide to Professional Conduct). Medicated feedingstuffs prescriptions are exempt from the charging prohibition and fees may still be charged. A sample prescription form is available for BVA members to download from www.bva.co.uk
number of instalments and intervals to be observed when supplying must be specified along with the amount of drug in the instalment, and the total amount of drug to be supplied. Exact information on the permission to issue and provisions of repeat prescriptions for a particular animal should be included in the patient’s record by the veterinarian who has the animal under his/her care. This is to allow a veterinary colleague in the same practice to provide a repeat prescription if necessary.

The period of time that the veterinarian may allow repeat prescriptions without re-examining the patient will be variable and be dependent on the patient, the condition, the client, the medicine prescribed and the necessity to monitor clinical signs and side-effects by, eg, monitoring blood parameters or hepatic function. For guidance, some authorities suggest a time interval of three months (shorter for, eg, cytotoxic drugs and perhaps longer for, eg, mild cardiac disease therapy) between re-examinations. Each practice should decide general protocols for each drug; these may need to be varied in individual cases.

Controlled drugs (CDs) for use in animals may only be supplied on a prescription from a veterinarian and supplied by a veterinarian or a pharmacist in accordance with that prescription.

These drugs are capable of being abused and many lead to addiction. In addition to there being strict controls on the use of these drugs in animals, veterinarians may themselves be vulnerable to self-use of addictive drugs. The veterinary profession operates confidential helplines, the Vet Helpline and the Veterinary Surgeons’ Health Support Programme (VSHSP) (see page 35 for contact details). The Vet Helpline provides practical advice and information on coping with problems such as depression, alcohol or drug abuse, financial worries or employment issues. The VSHSP helps veterinarians suffering problems of alcohol or drug abuse who contact the group or who are referred to them to combat their addiction by assisting them and arranging adequate professional treatment.

In The Misuse of Drugs Regulations 2001, the drugs are classified in five Schedules according to different levels of control.

Schedule 1
Schedule 1 includes cannabis and hallucinogenic drugs such as LSD, which are not commonly used therapeutically. Veterinarians have no general authority to possess or prescribe them.

Schedule 2
Schedule 2 includes some drugs that may be used in veterinary practice such as etorphine, fentanyl, morphine, pethidine, methadone, the amphetamines, and secobarbital (quinalbarbitone). These drugs are subject to particular requirements for prescriptions, requisition, record keeping, safe custody (except secobarbital [quinalbarbitone]), and disposal of unwanted medicines.

Schedule 2 CDs, except secobarbital (quinalbarbitone), must be stored in a locked and permanently secured receptacle, which can be opened only by a veterinarian or a person authorised by a veterinarian to do so. Schedule 2 CDs may not be destroyed except in the presence of a person authorised by the Secretary of State (see Disposal of medicines, pages 30 to 31).

Schedule 3 CDs
Schedule 3 includes buprenorphine, butorbin (butorbarbitone), pentazocine, pentobarbital (pentobarbionate), phenobarbital (phenobarbionate) and some minor stimulant drugs. These drugs are subject to prescription (see Schedule 2 above) and requisition requirements, but transactions do not have to be recorded in a Controlled Drugs Register. A requisition in writing must be obtained by a supplier before delivery of a Schedule 3 drug (see page 5). Temazepam, diethylpropion and buprenorphine must be kept in a locked receptacle, which can be opened only by a veterinarian or a person authorised by a veterinarian to do so; this condition does not apply to other Schedule 3 CDs.

Schedule 4
Schedule 4 includes anabolic substances (Part II), and the benzodiazepines and ketamine (Part I). They are exempt from all CD requirements pertaining to veterinary practice other than the need to keep relevant invoices for two years. However, ketamine may be used as a drug of abuse and the RCVS recommends that it is stored in the CDs cabinet and its use recorded in an informal Register.

Schedule 5
Schedule 5 includes preparations of certain CDs, eg, cocaine, codeine and morphine, which are exempt from full control when present in low strength medicinal products. They are exempt from all CD requirements pertaining to veterinary practice other than the need to keep relevant invoices for two years.

A veterinarian acting in a professional capacity has authority to supply Schedule 2, 3, 4 and 5 CDs. The veterinarian may administer the drug or direct any other persons to administer such drugs to patients under the veterinarian’s care.

Prescriptions for Schedule 2 and Schedule 3 CDs must conform to particular requirements in addition to those mentioned above under written prescription. The prescription must be signed by the veterinarian and may not instead be authenticated. The retail supplier should be satisfied that the prescription is genuine.

The prescription must also include:

- The address of the prescriber, which must be in the UK
- The form and strength of drug(s) to be dispensed, eg, Pethidine Tablets, 50 mg
- Either the total quantity (in both words and figures) of the preparation, eg, Pethidine Tablets, 50 mg. Send 10 (ten); or the number (in both words
A separate Register must be kept for each premises where CDs are stored. A separate part of the Register must be used for each class of drug, which must be specified at the head of each page of the Register. A class is any drug specified in Schedule 2 together with its salts, stereoisomers and any preparation in which it is contained; eg, a separate part of the Register must be kept for each of pethidine, morphine, and etorphine. The layout of Registers is stipulated in the legislation. 

The form in which received: 
- The date on which received 
- The name and address of person or supplier from whom obtained 
- The amount received 
- The form in which received 
  (eg, Hypnorm injection).

For each CD supplied the following must be recorded: 
- The date on which the supply was made 
- The name and address of the person to whom supplied 
- The authority of the person supplied to be in possession 
  (eg, direct administration) 
- The amount supplied (eg, 50 mg, 1 ml) 
- The form in which supplied 
  (eg, pethidine injection).

Entries must be indelible in the Controlled Drugs Register in the form of a bound book (not a loose-leaf book) or held in a computerised form. Entries must be made in chronological order and must not be amended; if corrections are necessary they must be made by means of a marginal note or footnote and specify the date the correction was made. Safeguards must be incorporated into the software to ensure that the author of each entry is identifiable, entries cannot be altered at a later date, and a log of all data entered is kept and can be recalled for audit purposes. The Controlled Drugs Register should include a running total. Access control systems should be in place to minimise the risk of unauthorised or unnecessary access to the data in the computerised Register. Adequate backups must be made of a computerised Register. The Register must be kept for two years from the date of the last entry, but all other records relating to the VMR must be kept for five years and therefore the same condition is recommended here.
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- The date of the prescription
- The signature or other authentication of the person prescribing the product
- The name and amount of the product prescribed
- The exact dosage (as directed is not acceptable) and administration instructions
- Any necessary warnings
- The name and address of the manufacturer or distributor (who must be a person registered with the Animal Medicines Inspectorate [AMI] of the VMD or the Department of Agriculture and Rural Development [DARD] in Northern Ireland)
- The name, type and quantity of the feedingstuff to be used
- A statement that if the validity of the prescription exceeds one month, not more than 31 days supply may be provided at any time
- The withdrawal period, if relevant. (If a veterinary medicine is to be incorporated in accordance with the marketing authorisation, the withdrawal period shown must be that on the Summary of Product Characteristics (SPC) of the product. When prescribing an MFS outwith the recommendations specified on the current SPC (under the cascade) or if the SPC does not specify a withdrawal period, the statutory minimum withdrawal periods must be applied (see Drug residues and withdrawal periods, pages 28 to 29.)
- The inclusion rate of the veterinary medicinal product and the resulting inclusion rate of the active substance
- Any special instructions to the stock keeper
- The percentage of the prescribed feedingstuffs to be added to the daily ration.

MFS prescriptions
Three copies of an MFS prescription are required: one for the person incorporating the VMP or the distributor; one for the stock keeper and one for the veterinarian. The MFSp must be kept for a period of five years and be available for inspection.

The MFSp should be personally signed or authenticated and dated by the veterinarian, in respect of animals under his/her care.

The MFSp is valid for a period of up to three months from the date of the veterinarian’s signature but only for one course of treatment. For animals on farms under the veterinarian’s care where there are regular occurrences of chronic or recurring disease, which could require repeat in-feed medication, it is essential, at regular but not prolonged intervals, to reassess the need for continuing the in-feed medication. This should be based on clinical examination and/or post-mortem findings supported by laboratory or other diagnostic tests.

An MFSp can be used to obtain more than 31 days of feed where treatment exceeds one month; however, only one month’s supply at a time may be purchased against the prescription.

The veterinarian (or in the case of a wormer, the veterinarian, pharmacist or SQP) must prescribe the medicated feedingstuffs only in such quantities as necessary for one course of treatment for the number of animals stated on the MFSp and for the duration and frequency of treatment. The quantities must be within the maximum limits laid down in the marketing authorisation.

Incorporating VMPs
A veterinary medicinal product must be incorporated into a feedingstuff or premixture in accordance with the SPC, marketing authorisation (unless prescribed under the cascade) and the prescription. It is important to know of any additives that are already incorporated into the feed. Interactions listed in the SPC must be taken into account. The legal requirement is that it is necessary to indicate MFS products on the MFSp but it is recommended that other feed additives already contained in the feedingstuff should also be listed. The signatory veterinarian (or in the case of a wormer, the veterinarian, pharmacist or SQP) must be satisfied that there is no undesirable interaction between the veterinary medicinal product and any feed additive used in the feedingstuff.

The veterinary medicinal product must not contain the same active ingredient as any other additive in the feedingstuff or premixture. A veterinarian may, at his/her discretion and under his/her own responsibility, authorise combinations of medicinal feed additives unless they are specifically prohibited in the data sheet.

Approved premises
The premises of all manufacturers who add medicines to feeds and all distributors of premixtures and medicated feeds are required to be approved. The appropriate authority is the AMI or DARD (see page 35 for contact details). Approval does not apply to incorporation of a veterinary medicinal product into feedingstuffs on domestic premises for feeding on those premises of non-food producing animals or food-producing animals kept purely for domestic consumption.

SMALL ANIMAL EXEMPTION SCHEME

Some veterinary medicines may be marketed, imported or administered without a marketing authorisation under the Small Animal Exemption Scheme. These are medicines for use in certain animals kept exclusively as pets (aquarium fish, cage birds, ferrets, homing pigeons, rabbits, small rodents and...
terrarium animals), the active ingredients of which do not require veterinary control. The active substance is approved and the approval specifies the species for which it is approved and how the product is to be used. These products are exempt from the requirement for a marketing authorisation and are not therefore required to prove safety, quality or efficacy but must be manufactured to the same standards as authorised medicines and are subject to pharmacovigilance reporting.

FEED ADDITIVES

Feed additives are substances used to maintain animals in good health or favourably affect their performance. The use of feed additives in animal nutrition is controlled and authorised under Regulation 1831/2003/EC. Each product is authorised by its own EC Regulation, which includes conditions of use; there is no provision for incorporation in any way that does not accord with the entry, eg, at higher concentrations or for different species. Controls of feed additives with the categories of coccidiostats, histomonostats and ‘other’ zootechnical feed additives are set out in the VMR and are the responsibility of the VMD. Antibiotics used to promote growth have not been permitted since 1 January 2006. All other additives are covered by separate legislation and guidance by the Food Standards Agency (FSA) at www.foodstandards.gov.uk

HOMEOPATHIC PRODUCTS

A homeopathic remedy is any veterinary medicinal product prepared from homeopathic stocks in accordance with homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in the EU member states. It must not be an immunological product (eg, a nosode). A registered homeopathic remedy is classified as any other veterinary medicinal product. The active substance of a homeopathic remedy used in food-producing animals must be listed in Annex II Regulation 2377/90/EC and therefore the withdrawal period is zero. A homeopathic remedy for human use or a homeopathic remedy extemporaneously prepared by a veterinarian or a person holding a suitable manufacturing authorisation may be administered by a veterinarian or under his/her responsibility.

PROBIOTICS AND ENZYMES

Probiotics are cultures of live microorganisms in a vegetative or arrested state which, when administered in feed, have a positive effect on the health of the animal and thereby help increase productivity. Enzymes enhance the digestibility of certain feed ingredients. The addition of enzymes to feed can significantly improve digestion of carbohydrate fractions in the feed that result in increased viscosity in the gastrointestinal tract of the animal, which impairs digestion. Probiotics and enzymes are controlled under Regulation 1831/2003/EC.

TRADITIONAL REMEDIES AND CHEMICALS

Traditional remedies and chemicals such as Epsom salts, liquid paraffin and Stockholm tar are freely available and would not normally be considered as veterinary medicines. However, once a veterinarian supplies them for a medicinal purpose (ie, ‘medicinal by effect’), they become veterinary medicines. They may be prescribed under the VMR as extemporaneously prepared products, and as such the standard minimum withdrawal periods are applicable.
Any VMP administered to an animal in the UK must have either a UK marketing authorisation or have been imported into the UK under an approved scheme. The administration must be in accordance with that marketing authorisation unless the product is administered under the cascade (see below and pages 9 to 11) or the product is administered for research purposes in accordance with an Animal Test Certificate (ATC) or a licence issued under the Animals (Scientific Procedures) Act 1986.

A veterinarian prescribing a POM–V medicine must prescribe for an animal under his/her care, and after having carried out a clinical assessment.

There is no definition in the legislation of ‘animals under his/her care’. The RCVS has interpreted the meaning of the term in the RCVS Guide to Professional Conduct as follows:

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

What amounts to ‘recent enough’ must be a matter for the professional judgement of the veterinary surgeon in the individual case.

The RCVS advice is offered for professional and ethical purposes. In a number of cases, the courts have also followed this guidance.

There is no definition in the legislation of ‘clinical assessment’. The RCVS indicates that clinical assessment means assessment of relevant clinical information, which may include an examination of the animal under the veterinarian’s care.

In an emergency situation, a veterinarian may prescribe medicines that are part of an animal’s routine medicinal therapy although the animal is not usually under the care of the veterinarian (e.g. owners on holiday with their animals). The veterinarian should examine the animal and make every attempt to contact the animal’s usual veterinarian to obtain the relevant case history. Only sufficient quantity of drug for the animal’s immediate use should be prescribed. Written records thereof should be kept.

Where a client is served by more than one veterinarian, or two or more veterinarians are each concerned with the same group of animals, each may properly prescribe and supply medicines to be administered to animals as part of the services provided. In order to avoid adverse reactions arising from unsuitable combinations of products, each veterinarian must keep the other(s) informed about the products he/she prescribes.

The veterinarian must prescribe only the minimum amount of medicine required for treatment, which is a matter for the professional judgement of the veterinarian in the individual case.

A written prescription is required if another veterinarian or pharmacist would be expected to supply the POM–V or POM–VPS medicine.

Veterinarians may prescribe POM–VPS medicines in circumstances where there has been no prior clinical assessment of the animals and the animals are not under his/her care. In these circumstances veterinarians should prescribe responsibly and with due regard to the health and welfare of the animals.

It is an offence to administer (or cause or permit to be administered) any veterinary medicine to an animal unless the product has been granted a marketing authorisation (or product licence) in the UK for treatment of the particular condition in the species being treated at the manufacturer’s indicated dosage and route of administration.

There are important specific exceptions to this rule outlined in the ‘cascade’ method of prescribing and in relation to the importation of medicines for use in exceptional circumstances.

A VETERINARIAN PRESCRIBING A POM–V medicine must prescribe for an animal under his/her care, and after having carried out a clinical assessment.
may exercise professional judgement according to the ‘cascade’, whereby he/she selects in the following order:

(1) A veterinary medicine authorised in the UK for use in another animal species or for another condition in the same species (‘off-label use’), or

(2) If, and only if, there is no such product that is suitable, either (i) a medicinal product authorised in the UK for human use, or (ii) a veterinary medicinal product not authorised in the UK but authorised in another EU member state for use with any animal species. An import certificate is required (see page 11), or

(3) If, and only if, there is no such product that is suitable, a product prepared extemporaneously (ie, made up at the time of need) by an authorised person in accordance with a veterinary prescription. In the UK, such medicines may be prepared by a veterinary, a pharmacist or the holder of an appropriate manufacturer’s authorisation. Extemporaneously prepared products are those that are not commercially available such as preparations containing common ingredients in an unusual formulation or unusual drug concentration, or others that are preservative, excipient or additive free. They may be obtained from specialised authorised manufacturers. Where an authorised product is available, the authorised preparation must be used in preference unless a specific formulation is required.

Horses declared non-food producing under the horse passport scheme are regarded as non-food producing animals for the purposes of these provisions.

Where the cascade options are used, the veterinarian should advise the owner that he/she intends to administer to the animal an authorised veterinary preparation outwith its data sheet recommendations, an authorised human medicinal preparation or a medicine extemporaneously prepared such as a ‘magistral formula’ (any medicinal product prepared in a pharmacy in accordance with a veterinary prescription for an individual animal or a small group of animals) or an ‘offical formula’ (any medicinal product prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and is intended to be supplied directly to the end-user). The client’s written consent should be obtained (see Consent forms, pages 32 to 33).

The veterinarian should prescribe from knowledge based on current best practice. Advice may be sought from clinical specialists, pharmaceutical companies and/or consultants and such information recorded and retained. A veterinary medicinal product for use under the cascade must be prescribed by a veterinarian and may only be supplied by a veterinarian or pharmacist. Unless the product is administered by the veterinarian, it must be correctly labelled (see page 17).

The VMD advises that it is likely that [the Regulations] will be interpreted in the light of how a competent and professional veterinary surgeon would reasonably act in pursuance of the aims in a particular set of circumstances.

The aims of the administration provisions are to ensure that unauthorised medicines are used only when no product is authorised for the condition and species concerned, and, in the cases of food-producing animals, to ensure that potentially harmful residues of veterinary medicines do not enter the food chain.

However circumstances may arise … where a veterinarian exercising his or her professional expertise and judgement in the interests of the animals concerned may consider that there is no authorised treatment in the UK for the condition or species to be treated. For example, a product may be authorised for a condition in a particular species but be considered inappropriate or even ineffective for the animal(s) presented. Such instances may arise, eg, due to bacterial resistance to antimicrobials and chronic infections, inadequacy of the recommended dosage, the age and known sensitivities of the individual animal, complex conditions requiring concurrent drug treatment, unavailability of a product within a reasonable time, or if owner compliance considerations provide that a formulation of an authorised product would be inappropriate.

The legislation does not allow the cost of the medicine to be taken into account when deciding which medicine to use. It is not permissible to use a medicinal product authorised for human use solely because it is cheaper. Any use of such a human medicinal product instead of the authorised veterinary medicinal product for the condition and species concerned must be justified by the veterinarian on clinical grounds alone.

For further information, see Controls on the Administration of Veterinary Medicines, Veterinary Medicines Guidance Note (VMGN) No 15, available at www.vmd.gov.uk.

**UNDER THE VMR, where no authorised veterinary medicine exists in the UK for a condition in a particular species, in order to avoid unacceptable suffering, a veterinarian responsible for the animal may exercise his/her professional judgement according to the ‘cascade’.”

**FOOD-PRODUCING ANIMALS**

A food-producing animal is an animal whose flesh or products are intended for human consumption.

Under the Regulations, where no authorised veterinary medicine exists in the UK for a condition in the animal, in order to avoid unacceptable suffering, a
veterinarian responsible for the animal may exercise their clinical judgement according to the ‘cascade’, whereby they select in the following order:

1. A veterinary medicine authorised in the UK for use in another animal species or for another condition in the same species (‘off-label use’), or

2. If, and only if, there is no such product that is suitable, either (i) a medicinal product authorised in the UK for human use, or (ii) a veterinary medicinal product not authorised in the UK but authorised in another EU member state for use with any animal species that is a food-producing species. An import certificate is required (see page 11), or

3. If, and only if, there is no such product suitable, a product prepared extemporaneously (ie, made up at the time of need) by an authorised person in accordance with a veterinary prescription.

In addition to the above legislation, if the animal is a food-producing animal, the treatment in any particular case is restricted to a single holding. Veterinarians should keep adequate case records, including details of medicines used for the treatment of animals and the circumstances, including justifications, of their use. The Regulations require that records must be kept when prescribing, administering and supplying medicines for food-producing animals under the cascade (see Record keeping, pages 19 to 21). The veterinarian must specify an appropriate withdrawal period (see Drug residues and withdrawal periods, pages 28 to 29).

The veterinarian or person acting under his/her direction may only administer a product that contains substances found in a product authorised for use in food-producing animals. This applies whichever tier of the cascade is used, ie, veterinary, human or extemporaneously prepared medicines. Any medicine imported from another EU member state must be authorised for use in food-producing species in that country. Any pharmacologically active substance included in a medicinal product administered to a food-producing animal under the cascade must be listed in Annex I, II, or III of Regulation 2377/90/EEC (see pages 28 to 29).

Pharmacologically active substances which are not contained in products currently authorised for food-producing species, including those in products that have been withdrawn, or the active ingredient has been entered into Annex IV or for which there is no Annex entry under Regulation 2377/90/EEC, must not be administered to food-producing animals under the cascade.

**EQUIDAE**

Under European legislation, Equidae (including horses, ponies, donkeys, mules or cross breeds of these species – the term ‘horse’ will be used in this text) are regarded as food-producing animals unless the individual animal has been declared as not intended for slaughter for human consumption on its passport. For horses that are declared as not intended for food production, derogations within the legislation have been made that allow use of some products without established maximum residue limits (MRLs). Under the horse passports legislation, all equids are required to have a passport. When a veterinary medicinal product is to be administered, prescribed or dispensed for a horse, the passport should be made available. The veterinarian or person administering the product must ensure that the horse is the one described in the passport. Section IX of the passport deals with medicinal treatment.

In Section IX, Part II, the owner or representative of the owner can make a declaration that the horse is not intended for slaughter for human consumption. Alternatively, in Section IX, Part II A, the owner or representative can make a declaration that the horse is intended for human consumption. In England (not Scotland, Wales or Northern Ireland), an owner may elect not to sign the declaration until such time as medication is required. In this case the horse must be treated as if intended for human consumption as far as medicines administration and recording are concerned.

**Horses not for human consumption**

Horses declared as not intended for human consumption in the passport can be treated with veterinary medicinal products authorised for horses and other medicines under the cascade as for non-food animals. These horses can be treated with products containing substances listed in Annexes I, II, III or IV and other substances (see lists under Authorised Medicines available at www.vmd.gov.uk). Recording the treatment in Section IX, Part IIIB, by the person administering the product is optional. The horse must never be slaughtered for human consumption if an Annex IV substance is used for treatment.

Horses declared in the passport as intended for human consumption (or in England the declaration is unsigned) can be treated with veterinary medicines.

**THE LEGISLATION DOES NOT allow the cost of the medicine to be taken into account when deciding which medicine to use. It is not permissible to use a medicinal product authorised for human use solely because it is cheaper. Any use of such a human medicinal product instead of the authorised veterinary medicinal product for the condition and species concerned must be justified by the veterinarian on clinical grounds alone.**
medicines authorised for horses or under the cascade for food-producing animals with substances listed in Annex I, II or III of Regulation 2377/90/EEC and other substances but not those listed in Annex IV of that Regulation. Substances in Annex I, II or III of Regulation 2377/90/EEC need not be recorded in the passport but the horse owner must keep records if the horse is intended as a food-producing animal or if no declaration has been signed in the passport. Recording of the medicines allows the specific product withdrawal period to be applied; otherwise the statutory six-month withdrawal period applies. The list of Essential Substances given in Annex of Regulation 1950/2006/EC (see under Authorised Medicines at www.vmd.gov.uk) may also be used to treat horses intended for human consumption. The statutory six-month withdrawal period applies and the treatment must be recorded in the passport.

The administration of all equine vaccines must be recorded by the veterinarian in the relevant section of the passport: equine influenza vaccinations must be entered in Section V; all other vaccinations must be recorded in Section VI.

Further information on horse medicines is available on the VMD website at www.vmd.gov.uk

IMPORTATION OF VETERINARY MEDICINES

A veterinarian may import a veterinary medicinal product authorised in another EU member state if it is for the purpose of administration by him or under his supervision under the cascade or administration in exceptional circumstances and in accordance with a Special Import Certificate (SIC).

Where the health situation so requires, and where there is no suitable veterinary product available either as an authorised product in the UK or another EU member state or under the cascade, a veterinarian responsible for one or more animals may treat an animal with a veterinary medicinal product authorised in a non-member state if he/she has obtained a Special Treatment Certificate (STC) permitting importation and certainly before treating the animal. In this circumstance, the disease or condition must be such that the veterinary medicinal product is likely to be needed as a matter of urgency for the treatment of the animal and delay in administering the product will seriously affect the health or welfare of the animal. An STC is required for importation of a medicinal product authorised for human use irrespective of whether from a EU member or non-member state.

Is there a UK-authorised product?

An SIC or STC will not be granted if a suitable UK authorised product is available for the treatment of the specified animal for which the application is made. For STCs, the VMD must be satisfied that the benefits of using the product will outweigh any risks and will not pose a threat to human or animal health or the environment. For these reasons, there may not be a suitable way of obtaining products to treat food-producing animals or for the importation and use of vaccines (Import Certificate Schemes, VMGN No 7, October 2006 available at www.vmd.gov.uk). There are no restrictions on the importation of authorised AVM–GSL veterinary products.

Application forms for SICs and STCs are available at www.vmd.gov.uk; for completion online or submission by post to Special Treatment/Imports Certificates, Licensing Services Section, Veterinary Medicines Directorate, New Haw, Addlestone, Surrey KT15 3NB. The veterinarian’s RCVS membership number must be quoted on all applications.

Responsibility of the vet

The prescribing veterinarian is fully responsible for the importation and use of the product under the cascade. The product cited on the certificate may only be sold or supplied by the certificate holder for administration to the animal(s) specified in the certificate. The product must be administered by the veterinarian named in the application or a person acting in accordance with their directions and under their responsibility. The veterinarian must indicate the withdrawal period, which should not be less than the standard withdrawal periods (see pages 28 to 29). Any contraindications, safety warnings, etc. should be observed. Any adverse reactions to the product must be recorded and reported to the VMD within 15 days.

The holder of the certificate must keep the following records for each product imported:

- The date of sale or supply
- The name of the product
- The quantity supplied
- The name and address of the recipient and the identification of the animal treated
- The justification for using the product under the cascade
- Any adverse reactions.

Further information in Import Certificate Schemes, VMGN No 7, October 2006, available at www.vmd.gov.uk

PRESCRIBING BY VETERINARIANS ESTABLISHED IN EEA STATES OTHER THAN THE UK

Veterinarians established in EEA states other than the UK (EU countries plus Iceland, Liechtenstein, Norway) but whose practices extend into the UK may carry with them and administer small quantities of medicines (other than immunologicals) not authorised in the UK provided such medicines are authorised in the member state in which the veterinarian is established. A veterinarian who practises in both the UK and another EU member country may hold veterinary medicinal products authorised in another member country.

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provided that the amount held is proportionate to the amount expected to be used in that member country. For further information, see Controls on the Administration of Veterinary Medicines, VMGN No 15, available at www.vmd.gov.uk.

PRESCRIBING MEDICINES FOR USE IN DART GUNS

The possession of weapons and ammunition designed for tranquillising and treating animals and kept for that purpose is governed by the Firearms (Amendment) Act 1997. The legislation affects veterinarians who possess tranquillising dart guns in order to treat animals, and who prescribe medicines for use in dart guns or blow pipes. Drugs such as etorphine and ketamine are POM–V medicines and, in addition, are not authorised for use in food-producing animals and treated animals cannot be used for human consumption.

RCVS guidance indicates that the veterinarian and the dart gun licence holder should sign a written agreement before supply of the veterinary product and a signed receipt for each supply of medicines used for restraint. The agreement should include the following:

- Details of the dart gun licence holder’s firearms licence with expiry date
- Recognition that a veterinarian cannot supply medicines to a dart gun licence holder per se, but can supply only for animals under the veterinarian’s care
- Recognition that medicines will be supplied only to the dart gun licence holder in person, and only in sufficient quantities for immediate use
- Confirmation that only the dart gun licence holder will handle the medicines after he or she has received them and when not being used they will be kept in a nominated locked place
- That the veterinarian will require a signed receipt for each supply of medicines used for restraint, such as etorphine (Immobilon). The signed receipt to be retained together with the written agreement for at least two years from the date of the last supply
- Confirmation that the dart gun licence holder has been instructed in the use of the gun and medicines
- Confirmation that the dart gun licence holder has been told what to do in an emergency, eg, a person being struck by a dart. There should be details in the written agreement on the use of specified antagonists to the tranquiliser or similar product and on appropriate resuscitative and first-aid measures
- Confirmation that the dart gun licence holder will keep records of medicines used for restraint in each animal per year.

Where a specific antagonist is available, the veterinarian should also ensure that the antagonist is available for use by the dart gun licence holder in an emergency. Arrangements should be made for the veterinarian to visit the area where the animals are kept to check on their general health and condition and ensure appropriate numbers of animals are marked permanently.

The dart gun licence holder will keep records of the owner of the animals, the number of animals of each species on each holding administered with medicines not authorised for food-producing animals and the medicines used for each identifiable animal, which are to be reviewed at least yearly by the veterinarian. The veterinarian should keep a copy of the agreement, supply receipts and animal records.

Animals treated with products not authorised for use in food-producing animals must be marked permanently in each ear with a Ketchum ‘EAT NOT’ tag (available from the Veterinary Deer Society, see page 35 for contact details), if relevant, or the carcass disposed of to ensure, as far as practicable, that such animals will not enter the human food chain.

Further information and a copy of a letter from the Food Standards Agency (FSA) published in The Veterinary Record 6 December 2003, is given in the RCVS Guide to Professional Conduct, under Part 3, Annex h. Medicines (dart guns), available at www.rcvs.org.uk. A copy of the FSA’s letter should form part of the agreement detailed above.
Supplying medicines

Any VMP supplied by a wholesaler or a retailer must have a marketing authorisation and must not be past its expiry date. Additionally, the product must be a veterinary medicinal product or a medicinal product authorised for human use for administration to an animal as prescribed by a veterinarian under the cascade (see pages 8 to 10) or a product supplied in accordance with an import certificate.

POM–V veterinary medicinal products or other medicinal products for use under the cascade must be prescribed by a veterinarian and may only be supplied by a veterinarian or a pharmacist in accordance with a prescription from a veterinarian. A POM–VPS medicine may only be supplied by a veterinarian, pharmacist or an SQP in accordance with a prescription from one of those persons. An NFA–VPS product may be supplied without a prescription but only by a veterinarian, pharmacist or SQP. There are no restrictions on the supply of AVM–GSL products.

A veterinarian supplying a VMP, other than an AVM–GSL product, must authorise each supply individually, but the supply of a POM–V medicine may be carried out by a competent person (see example SOP 08: The sanction of the veterinarians, page 25) in the absence of the supplying veterinarian. Veterinarians may supply POM–V medicines on the prescription of another veterinarian (ie, for animals not under the care of the supplying veterinarian). When supplying Schedule 2 CDs against a prescription from another veterinarian, it is good practice to seek to properly identify the person who collects the drug (requesting written evidence if necessary) and record the identification of that person in the Controlled Drugs Register.

When supplying POM–V, POM–VPS or NFA–VPS medicines, the veterinarian must always advise on the safe handling and administration of the veterinary medicinal product and any warnings or contraindications on the label or package leaflet, and be satisfied that the person who will use the product is competent to use it safely, and intends to use it for a use for which it is authorised. Veterinary medicinal products must be supplied in appropriate containers and with appropriate labelling.

SQPs can supply POM–VPS and NFA–VPS medicines only from premises approved by the VMD for the purpose. Pharmacists can supply POM–V, POM–VPS and NFA–VPS products only from premises registered and approved by the RPSGB. From 1 April 2009, veterinarians will be allowed to supply POM–V, POM–VPS and NFA–VPS medicines only from registered premises.

ADVERTISING VETERINARY MEDICINAL PRODUCTS

As a general rule, veterinary medicinal products available on prescription, MPAH-IU and particularly those medicines containing psychotropic drugs or narcotics must not be advertised. ‘Advertising’ means the provision of any detail, as well as prices, of the product and includes the provision of summary of product characteristics (SPC) leaflets, data files and Electronic Data Interchange (EDI) from wholesale dealers and manufacturers, through advertisements in journals, newsletters and magazines, and materials provided by manufacturers’ representatives. However, in exceptional circumstances for POM–V products, this does not apply to price lists displayed in veterinary surgeries or to advertisements aimed at veterinarians, veterinary nurses, pharmacists or professional keepers of animals (eg, stock farmers).

Exceptions

In the case of POM–VPS products, this does not apply to price lists displayed in veterinary surgeries or to advertisements aimed at veterinarians, pharmacists, SQPs, other healthcare professionals (including veterinary nurses), professional keepers of animals, or owners or keepers of horses. It is accepted that specialist journals, magazines, newsletters and other media (eg, websites) will be read by people other than the target audience. Provided the advertisement is included in a journal or website aimed at a group who are allowed to receive such advertising then it may continue to be distributed.

The publication of material produced primarily for health education is not considered advertising provided there is no specific promotion of a product other than the use of a ‘strap line’ identifying a company and product name. Therefore it is possible to provide information to the public about a disease, its symptoms and how to prevent or treat it without the material being classified as advertising. Material that is not directly aimed at selling the product (eg vaccine reminders, health education leaflets or posters) is allowed. The legislation does not prohibit a veterinarian from providing his/her clients with product information during the course of a consultation. There are no restrictions of the advertising of NFA–VPS or AVM–GSL products.

SUPPLY VIA THE INTERNET

Veterinarians involved in the supply of veterinary medicinal products via the
Supplies medicines

internet must ensure that clients with prescriptions know who is the supplier and the nature of their duty of care for treated animals; this is essentially whether the veterinarian is acting as a responsible supplier of medicines or as a general practitioner. The RCVS provides the following guidance:

A veterinary surgeon who communicates with clients via the internet about animals that he/she has already examined and which are his/her patients should remember that the professional conduct and legal position is essentially no different to communication with clients by telephone or letter. It should be clear in each case whether an animal is under the care of a veterinary surgeon and a clinical assessment has been carried out . . . such that a minimum amount of . . . POM–V (products) may be supplied for the treatment of that animal.

**PREMISES**

Premises at which medicines are stored should be a building, or part of a building, of a permanent nature. Areas used for supply or storage of medicines should not be any residential part of a dwellinghouse. Premises should be kept well maintained, clean and vermin proof. Premises should be divided into areas to which the public has access (waiting rooms, consulting rooms, etc) and ‘staff only’ areas where public access is not allowed or is controlled. There must be no smoking, eating or storage of food for human consumption in areas where medicines are stored or supplied. There should be notices in place to inform staff and clients accordingly.

Premises in which medicines are stored and supplied should be capable of being secured so as to deter unlawful entry. Insurers may require that the premises be fitted with a security alarm. Storage within the premises must also be secure and meet storage conditions set out in each product’s marketing authorisation. Ideally, no other activity should be allowed in storage areas. Refrigerated space must be provided for products with specific temperature requirements. POM–VPS and NFA–VPS veterinary products should be stored in an area to which members of the public do not have access. POM–VPS and NFA–VPS products should not be displayed for customer self-service. Controlled drugs and injection materials present an attractive target not only to addicts but also to professional criminals aware of profits to be made from illicit drug sales. Advice should be obtained from the local crime prevention officer on the suitability of premises, receptacles, etc, for CDs.

**Consulting room**

Medicines kept in consulting rooms to which the public has access should be kept to a minimum, should not be drugs capable of abuse, and should be kept in cupboards and drawers not readily to hand or secured against clients’ access. Only the minimum necessary quantities of medicines should be carried by car or in a small animal visit container or case.

Premises are taken to mean all veterinary premises, which should be of a permanent construction, some or potentially all veterinary practice vehicles, and any other places where medicines are ‘stored’. Veterinary premises are required to be registered premises under the VMR by 1 April 2009.

**Emergency numbers**

A list of key telephone numbers (doctor, hospital, fire service, poisons centre, local police, etc) should be prominently displayed. Suitable fire-fighting equipment should be available (of the types, number and at locations as recommended by professional equipment installers) and staff should have adequate training in prevention and control of fire and fire drills (on the basis of a fire-officer’s advice). Emergency exits should be clearly marked and clear access maintained. Appropriate safety equipment must be available due to the differing natures of products stored.

The Control of Substances Hazardous to Health Regulations 1999 (COSH–H) must be observed (contact the BVA or the Environment Agency for further information. See page 35 for details.)

**THE MEDICINES STORE**

Great care should be taken to ensure safe storage of all medicines. Medicines should be stored in accordance with instructions specified in the Summary of Product Characteristics (SPC) or the same information that is contained within the NOAH Compendium of Data Sheets for Animal Medicines.

Medicines should be protected from damage arising from extremes of environmental conditions, such as direct sunlight, temperature and humidity in the medicines supply area. Blinds, as necessary, should cover windows. Light-sensitive products should be protected from direct light by, for instance, leaving them in their outer protective containers. Hot water sterilisers or autoclaves should not be sited in the medicines’ store because they are likely to adversely affect the humidity of the room. Ventilation must be adequate. In order to avoid contamination, stocks of medicines to be supplied to clients must not be stored in toilets, laboratories, or places where animals are kept, such as kennels.

**Storage temperature**

Particular attention should be taken to ensure that products are stored at the correct temperature. Products to be stored above 8°C and below 25°C are not required to be refrigerated and may be stored at what is termed ambient room temperature. Storage of products at ambient temperature should be monitored during periods when the environmental temperature is outside the ambient temperature range or remains high or low for longer periods than usual.

Refrigerated space must be provided for products such as vaccines, antisera, insulin and some recombinant antibiotic solutions with specific low temperature storage requirements. Vaccines, etc, should be removed from their delivery cool chain protection as soon as received and refrigerated and only removed thereafter for immediate use. Biological samples, food, bacteriological media, etc, should not be stored here but in specifically designated refrigerators. Particular care must be taken to avoid freezing or
prolonged exposure to inappropriately high temperatures. Refrigerators must be maintained at 2°C to 8°C and should be fitted with a means of regular daily monitoring and the recording of temperatures, such as a minimum/maximum thermometer and dedicated log book. An electronic device can be used to measure and record temperatures. A named person should check at least daily the temperature records of each refrigerator. In-car refrigeration units are now available. Regular servicing, cleaning and stock control should be maintained for refrigerators as for other storage areas.

Flammable products must be stored in appropriate cabinets specifically designed for the purpose. Well designed shelving and fittings should be installed to reduce the possibility of breakage, spillage and stock misplacement.

Stock control
A named person should be responsible for stock control. It is good practice to affix a practice label to each item before it is placed in stock. The date of first usage on multi-dose vials and the date at which the vial is to be discarded should be indicated. Multi-dose vials with an in-use shelf life now have a suitably labelled space for the user to insert the date for discarding the opened container. In general, medicines should be stored in the outer packaging with its package leaflet, or in the inner or immediate packaging and an SPC or product leaflet should accompany each, for example, vial. Dates of deliveries from manufacturers or wholesalers should be recorded, unless this information from the manufacturer or wholesaler is on the invoice or delivery note, which is retained. Batches of the same product should be kept separate and older stock should be issued before new stock, i.e., careful stock rotation should be maintained (eg, FIFO: first in first out, or LIFO: last in last out). Packs with defaced or damaged labels, damaged packs or those that are date expired should be stored separately before being disposed of. It is an offence to supply out-of-date products or to obscure the expiry date. Once stock has been supplied, it should not be accepted back into the medicines store.

Stock returns
No returned goods should be offered for resale because they may have been subject to improper storage conditions beyond the veterinarian’s control. Although stock that has to be returned to a manufacturer or wholesaler (eg, supplied in error) should be returned without delay, there are also restrictions relating to returned stock to wholesalers and other suppliers. Because of the absence of absolute guarantees over storage of the products, they are usually taken back and then destroyed (ie, not resold).

The following example standard operating procedures (SOPs) are given on pages 22 to 25:

- **SOP 02**: Placing an order with the supplier
- **SOP 03**: Receiving an order into the practice
- **SOP 04**: Storage of medicinal products in permanent premises
- **SOP 06**: The medicines’ supply area
- **SOP 07**: Spillage of hazardous substances.

Only medicines used frequently and then only sufficient for immediate case treatment should be carried routinely in vehicles. It is good practice to carry a minimum amount of preparations in a car because the temperature within the car may fluctuate greatly and the efficacy of the products may be affected. An insulated container will provide short-term storage for some temperature-sensitive items. Precautions against theft from vehicles must be taken which may include not storing medicinal products in the vehicle for long periods and not overnight. (See example **SOP 05**: Storage of medicinal products in veterinarians’ vehicles, pages 23 to 24).

Veterinarians should attempt to ensure that owners and keepers of animals store medicines appropriately and that preparations are not used beyond their expiry dates or the broadened vial usage periods (see Working with clients, page 18).

Very strict requirements operate for the storage of CDs. Security is essential. Only the minimum quantity of CDs should be stored consistent with routine needs and emergencies of the practice. Schedule 2 and some Schedule 3 CDs must be kept in an appropriately designed locked receptacle, secured against removal to the fabric of the building that can only be opened by the veterinarian or by a person authorised by the veterinarian to do so. This is best implemented by having not more than one key per veterinarian to the CD cabinet. The keys should be kept on the person. A locked car and/or a locked glove compartment are not considered to be such a receptacle within the meaning of the **Misure of Drugs (Safe Custody) Regulations 1973**, and as such veterinarians are advised to provide additional locked units within any vehicles (being secured to the vehicles’ structure to prevent their removal) used for the transport of such medicines.

Sheep dip concentrate must be stored in a properly constructed farm chemical store or approved steel cabinet. A VMP for incorporation into a feedingstuff or a premixture containing a VMP must be stored in a suitable locked storage area or an appropriate hermetic container.

**PERSONNEL**

In all practices there must be a Responsible Person (preferably a veterinarian) who is delegated to seeing that the requirements of this Guide are observed. It would be convenient for the same person also to be responsible for the practice complying with COSHH regulations.
requirements and waste disposal regulations. A practice manual (or SOPs) should be prepared which provides staff with detailed specific instructions on practice policy including supplying medicines (see pages 22 to 25).

Anyone involved in medicines’ supply activity must be suitably trained.

Medicines should be handled and administered only by someone competent to do so or who is under the supervision and responsibility of the veterinarian. Competence testing in the safe use of veterinary medicines is available from the National Proficiency Tests Council (NPTC) (see page 35 for contact details).

All persons engaged in medicines’ supply should observe high standards of personal cleanliness. Frequent hand washing is paramount. Protective clothing should be used and worn, and ideally be of the disposable type, or if not, regularly and frequently cleaned. Staff must report infections and skin lesions to the responsible person. No person with open lesions or skin infections should be engaged in the medicines’ supply process. But, if specifically permitted, all such persons should keep any cut or abrasion on any exposed part of their person covered with a suitable waterproof dressing. Direct contact between the operator’s hands and the dispensed products should be avoided, eg by wearing disposable gloves or, for instance, by using a tablet counting device. This is to prevent both contamination of the medicinal product and any potential idiosyncratic reaction on the part of the handler.

SUPPLY OF SHEEP DIPS

The supply of a sheep dip can only be to a person (or a person acting on their behalf) who holds a Certificate of Competence in the Safe Use of Sheep Dips issued by the NPTC. The supplier must make a record of the Certificate number as soon as reasonably practicable and these records must be kept for three years.

If the active ingredient of the sheep dip is an organophosphorus compound, the supplier must give the purchaser an A4 double-sided clear laminate safety sheet (available from the marketing authorisation holder) and two pairs of protective gloves as stipulated in the legislation. For further information see the HSE leaflet Sheep dipping: advice for farmers and others involved in dipping sheep, available at www.hse.gov.uk/pubns/as29.pdf.

SUPPLY OF HUMAN MEDICINAL PRODUCTS FOR ANIMALS

A veterinarian may supply a medicinal product authorised for human use (MPsAHU) under the cascade or a person under his/her direction may supply a medicine authorised for human use for use in a particular animal (see Administration and prescribing of medicines, pages 8 to 12) in accordance with a written prescription under the cascade. That the medicine is prescribed under the cascade must be noted on the prescription. A veterinarian should advise the owner that he/she intends to administer a medicine authorised for human use to the animal and ideally obtain the client’s written consent (see Consent forms, pages 32 to 33).

A veterinarian may have in his/her possession MPsAHU for administration to animals under the cascade but proportionate to the amount expected to be used under the cascade, ie, consistent with past or extrapolated usage.

CONTAINERS

The RPSGB recommends that when medicines are repacked from bulk or prepared extemporaneously they must be packed in containers that are appropriate for the product dispensed and the user: All containers intended for medicinal products must be protected and free from contamination.

It is recommended that preparations be dispensed as proprietary products in containers supplied by the manufacturer wherever possible. In general, all solid dose and all oral and external preparations should be dispensed in the manufacturer’s original pack, such as blister-packed medicines, or a reclosable child-proof container. Sachets and manufacturers’ strip or blister-packed medicines should be dispensed in paper board cartons or wallets, or paper envelopes.

Child-proof containers

Discretion may be exercised in the use of child-proof containers. There are occasions when they are clearly inappropriate (aged and infirm clients, large-animal formulations, no suitable child-resistant container exists for a particular liquid preparation, etc). A notice should be displayed in the waiting room indicating that tablets and capsules will normally be dispensed in child-proof containers but that plain containers can be supplied on request. Advice must be given to keep all medicines out of reach of children and that the medicinal products supplied are for animal treatment only.

Preventing contamination

Tablets, capsules and powders are often adversely affected by moisture and should be stored in the original sealed container until required in order to protect the medicine against breakage, crushing, moisture ingress, contamination and deterioration, with the lid being properly replaced after use. In addition, adequate labelling and stock rotation should be taken into account when repackaging tablets ready for dispensing. Paper envelopes and plastic bags are unacceptable as the sole container for veterinary medicines.

Under the legislation, certain liquid medicinal products for external use should be dispensed in fluted bottles so that they are recognisable by touch. This requirement does not apply to containers of a capacity greater than 1.14 litres or to eye or ear drops supplied in plastic containers. However, fluted bottles may be difficult to obtain. Creams, dusting powders, granules, ointments, pessaries, powders, suppositories, semi-solids, etc.
should be dispensed in wide-mouthed jars made of glass or plastic. Medicinal products for external use should be labelled as such. Medicines sensitive to light should be dispensed in an opaque or appropriately coloured container. It is good practice to supply, for example, injectable antibacterials for administration by farmers, in 20 ml or 40 ml vials available from manufacturers.

**Clear instructions**
The supplier has a duty to ensure that the owner or animal keeper understands any instructions on the label (see below) and knows how to use the product safely. The owner or keeper of the animal or herd should be warned to keep all medicines out of the reach of children. The RPSGB has extended this advice to keep all medicines out of reach and sight of children.

**Labelling of supplied medicines**
All medicines sold or supplied by an RQP in accordance with a prescription, are by definition ‘retail supplied medicines’ and as such must be labelled correctly.

Unless the veterinarian who prescribed the veterinary medicinal product supplies or administers it him/herself to the animal, the person supplying the product must label it or ensure that it is properly labelled according to the written prescription. The administration of the medicinal product, if not by the prescribing veterinarian, under the cascade remains the responsibility of the prescribing veterinarian.

The label should be in mechanically printed lettering (ie, computer generated) or labels must be indelibly and legibly printed or written in accordance with statutory requirements. Biro, ballpoint or felt-tip pens are acceptable for labelling; non-permanent ink and pencil are not. The legal requirements for VMPs supplied under the cascade state that the label must include:

- The name and address of the animal owner
- The name and address of the pharmacy or veterinary surgery supplying the veterinary medicinal product
- The name of the prescribing veterinarian
- The identification (including species) of the animal or group of animals
- The date of supply
- The expiry date of the product, if applicable
- The name or description of the product which should include at least the name and quantity of active ingredient(s)
- Dosage and administration instructions
- Any special storage precautions
- Any necessary warnings for the user, target species, administration or disposal of the product, eg, it is good practice to supply the operator with, for instance disposable gloves when dispensing griseofulvin-containing powder or granules
- The withdrawal period, if relevant. The withdrawal period, even if it is zero, should be indicated
- And if not already contained within the wording of the marketing authorisation (MA) label on the immediate packaging or container, the words: ‘Keep out of reach of children’ and ‘For animal treatment only’. This requirement will apply particularly to medicinal products for use under the cascade and is less likely to apply to VMPs within immediate packaging specified in the MA. However, should the VMP be supplied in a container outwith the MA immediate packaging then this requirement would apply.

And in the instructions to the owner/keeper it is good practice to provide:

- Any specific handling instructions for the medicinal product, such as ‘shake the bottle’, ‘for external use only’, ‘avoid self-injection’, etc.

If a product is supplied in a container other than that specified in the marketing authorisation, sufficient written information (eg, an SPC or product information leaflet) must be supplied to enable the product to be used safely.

SPCs are available at www.vmd.gov.uk and SPCs or datasheets at www.noahcompendium.co.uk

A product must not be supplied if any information on the outer packaging (or immediate packaging if no outer packaging) is not clearly visible or has been changed in any way, except if a label is amended by a veterinarian or a pharmacist in accordance with a prescription from a veterinarian, provided the unamended information remains clearly visible.

Apart from complying with the legislation, instructions on labels should be aimed at creating a greater awareness on the part of the end user as to the manner in which animal medicines should be stored, handled and administered. The supplier or dispenser should bring the owner’s attention to the instructions, provide clarification, and answer any questions. Product information leaflets are often supplied by the manufacturer within the outer packaging to supplement the information on the container and immediate packaging. This additional information may prove useful to the end user and product information sheets, package inserts or leaflets should be supplied with the product, where available.

**Sending medicines by post**
Pharmaceutical companies occasionally send medicines directly to a veterinary practice by post, and wholesalers frequently use this means to forward medicines to remote practices and when small items are required urgently. Veterinarians may send medicines by post to clients whose animals are under the veterinarian’s care provided the medicines are not potentially hazardous to the public, are in child-proof or the manufacturer’s original containers, and have been safely packed. Safe packaging is especially important for liquid medicines and the veterinarian must ensure that there should be no leakage outside the packaging if the inner container breaks; the inner container...
Suppling medicines

must be enclosed in polythene, with absorbent material, etc. The Home Office does not recommend that controlled drugs be sent via the postal service. However, if there is no alternative, it is recommended that a recognised postal/package carrier be used, that the package is at least sent by recorded delivery and there is a clear audit trail from the beginning to end of the journey that is capable of identifying where any loss has occurred.

WORKING WITH CLIENTS

Under the VMR there is a requirement for the supplier to ensure that the user of the product is competent to do so. Under the COSHH Regulations the veterinarian has a duty of care to ensure that an owner knows how to use a product safely and that this information is made known to the person actually using the product. The veterinarian may assist farmers with their COSHH assessments. For further information on using animal medicines safely, with particular reference to the COSHH Regulations, refer to the HSE leaflet Veterinary medicines: Safe use by farmers and other animal handlers, available at www.hse.gov.uk/pubs/nsa31.pdf.

The veterinarian should ensure that only sufficient quantities of medicines are prescribed or supplied to the owner for the individual or group of animals being treated. In particular cases, it will be reasonable to allow selected clients to hold a small reserve of some preparations provided the veterinarian recognises a recurring need for the use and is satisfied that the client has demonstrated his/her reliability in all aspects of using medicines.

Clients should be advised that instructions provided should be read carefully before administering any medicine and to check any warning statement and guidance given about how a medicine should not be used, in particular whether it can be used concurrently with any other medicines given to the animal. Clear and concise advice should be given to clients on the safe storage and use of medicines supplied or prescribed. Clients should be advised to store medicines correctly and in accordance with the instructions on the label. Medicines should be stored securely and should be kept out of reach of children or animals. Where medicated feed is stored on farm, the feed bins should be clearly labelled with a description of the contents and their expiry date. Some drugs such as prostaglandins, tranquillisers, certain antifungals, and anabolic steroids may pose a risk when handled and communicated with the client may include information about any special restrictions on who, in terms of gender, age or competence is permitted to handle the drug and how it is handled. Any specific instructions about the administration of the drug should be included in an advice note and a copy kept for future reference in the case records.

Part-used packs of injectable preparations should be discarded safely at the end of each daily operation or use and not reused on subsequent days if the data sheet specifies such a reusage of opened packs in not permitted. The date of first usage on multi-dose vials and the date at which the vial should be discarded should be indicated. Multi-dose vials with an in-use shelf life now have a suitably labelled space for the user to insert the date for discarding the opened container. The expiry date on the label should be checked and the medicines should not be used past that date. It is good practice to make a note of the date after which the medicated feed or medicine in the opened container is not to be used.

Clients should be reminded to use medicines only on animals recommended on the label or leaflet, unless the veterinarian has otherwise directed. The result of giving a medicine to an animal for which it is not recommended is unpredictable and may endanger the animal and may be illegal.

Written SOPs should be designed by the veterinarian attending food-producing animals to cover medicines that are used regularly on a farm. The SOPs should be under the direct supervision of the veterinarian. The reason for the use of the medicine, the dosage regimen, instructions on correct administration, storage requirements and identification of withdrawal periods should be specified. The veterinarian should provide additional information on exactly how the withdrawal period must be followed.

During farm visits, a detailed appraisal of medicines’ storage, handling and usage on the farm should be undertaken. It is good practice to discuss with the stockpersons who carry out the routine day-to-day tasks to ensure that the correct procedures are in use. In addition, line management on the enterprise should be observed with the owner or manager kept fully informed.

The livestock farmer has a statutory obligation to keep records (see Record keeping, pages 19 to 21). A veterinarian has legal and ethical obligations to help the client keep such records. Client education plays a vital role in ensuring that medicines are used correctly. There is a Code of Practice on the Responsible Use of Animal Medicines on the Farm agreed by a number of organisations; this is included in the NOAH/AHDA Animal Medicines Record Book and is also available at www.vmd.gov.uk/General/VMR/RUCOP.pdf. Regular newsletters or presentations giving clients information on issues such as legislation affecting the manner in which veterinarians prescribe and supply medicines, will help clients to understand any restrictions placed upon them. Practice open days and other clients’ meetings also allow clients to be informed about and observe working practices.
It is imperative that veterinarians and all personnel involved in administration and supply of medicines keep permanent records. Record keeping relates to both receipt and supply of prescription products in the practice. Most of the necessary details of receipt are usually provided automatically on the wholesaler’s or manufacturer’s invoice or delivery list. The exact process of information logging should be checked with each supplier to ensure the law is complied with at practice level. These records must be kept for five years. The reasons for record keeping are to enable effective recall of an individual product and/or batch(es) of a product if this becomes necessary and provide traceability in the use of medicines in food-producing animals, whilst guarding against abuse/misuse of medicines. Current recalls are reported on the VMD website at www.vmd.gov.uk/ProductInfo/BatchRecall/batch.htm

Additional records
In addition to specific legal requirements for record keeping, it may be necessary to record reasons for prescribing. Under legislation, the record keeping requirements apply to administration, supply and retail sale for food-producing animals, including horses unless the specified animal has been declared as not intended for human consumption in the horse passport (see pages 10 to 11). However, veterinarians are expected to maintain records of administration and supply of veterinary medicines for pets or other non-food animals, particularly to achieve product recall should the need arise.

All necessary records should be in writing, durable, permanent and available for inspection and kept in a readily retrievable manner (e.g., a handbook, files, or in a computerised data-file). Where a computer is used there must be adequate precautions against inadvertent loss of data by a suitable back-up system that is used daily or at other appropriate intervals. Any discrepancies must be entered into the records.

Prescribing cards have been used as an aid for accurate record keeping, and control over supply. Most practices, having a small animal patient element, are likely to keep this information as part of normal case recording.

For each animal or group of food-producing and non-food producing animals, a detailed record should be kept showing which medicines are authorised to be supplied, in what quantities on each occasion, and what actual supply has occurred. A limit on the total supply should be set and no further supply should be made without the authority of a veterinarian in the practice. The prescribing cards should be checked periodically to ensure that the information is current. Whatever procedure from prescription to supply is undertaken at practice level, supervision by the veterinarian is required at the time the medicinal product is handed over; alternatively, in his/her absence, each supply transaction must be personally authorised. It is suggested that to ensure both the actuality and the spirit of the law are obeyed, a standard operating procedure (see pages 22 to 25) is created and is readily available for staff at the point of supply and that they are trained to the required level of competency.

Records should be kept for at least five years to comply with the VMR. However, they should be retained for at least six years in case a civil action for damages ensues.

**THE VETERINARIAN: SUPPLY OR RETAIL SALE OF MEDICINES BY THE VETERINARIAN**

Veterinarians must keep records for products supplied on prescription (POM-V and POM-VPS products) for each incoming transaction concerning products received from wholesalers, manufacturers, etc, along with each outgoing transaction involving the retail supply of products to clients. Information retained for each incoming or outgoing transaction made by a veterinary practice must include:

- The date and nature of the transaction
- The precise identity of the veterinary medicinal product and the manufacturer’s batch number
- The quantity received or supplied
- The 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.

**RECORD KEEPING RELATES TO BOTH RECEIPT AND SUPPLY OF PRESCRIPTION PRODUCTS IN THE PRACTICE. MOST OF THE NECESSARY DETAILS OF RECEIPT ARE USUALLY PROVIDED AUTOMATICALLY ON THE WHOLESALER’S OR MANUFACTURER’S INVOICE OR DELIVERY LIST. THESE RECORDS MUST BE KEPT FOR FIVE YEARS.**
Record keeping

As a derogation for non-food animal prescription products, record keeping means that, instead of batch number recording at every usage of the product, the batch number can either be recorded when the batch is received or when the product is first used. Client and animal records must be maintained such that the product when used can definitively be matched to the owner supplied for the treated animal. See example SOP 09: Batch recall process, page 25.

If the documents do not include all of the above information, a record of the missing information must be made as soon as reasonably practicable after the transaction. For further information on practical application of the requirements, see Record-Keeping Requirements for Veterinary Medicinal Products, VMGN No 16, available at www.vmd.gov.uk. Records must be kept for at least five years.

In addition, at least once a year a detailed audit of all receipt and supply transactions must be carried out. The number and nature of all incoming and outgoing prescription products should be reconciled with those held in stock and any discrepancies recorded. In order to perform a detailed medicines’ audit it is good practice to account for breakages and spillages, items used as consumables such as in the operating theatre or animal treatment areas, other disposables, residues lost and the disposal of out-of-date stock. If discrepancies have occurred, eg, from unrecorded spillage or breakage it is for the practice concerned to consider whether any or each discrepancy is acceptable or whether further action may be required. Further information is provided in example SOP 10: Stock audit, page 25 and in Record-Keeping Requirements for Veterinary Medicinal Products, VMGN No 16, available at www.vmd.gov.uk

Under The Misuse of Drugs Regulations 2001, veterinarians must record the purchase and administration or supply of all Schedule 2 CDs in a Controlled Drugs Register within 24 hours of the transaction (see pages 4 to 5).

ADMINISTRATION OF A VETERINARY MEDICINAL PRODUCT TO A FOOD-PRODUCING ANIMAL UNDER THE CASCADE

If there is no authorised medicinal product in the UK for a condition affecting a food-producing animal the veterinarian responsible for it may either administer the product himself or permit another under his responsibility to treat an animal following the cascade provision in the VMR (see pages 9 to 10).

A veterinarian must enter into the permanent records as soon as reasonably practicable after the administration:

- The date of examination of the animals
- The name and address of the owner

THE REASONS FOR RECORD KEEPING are to enable effective recall of an individual product and/or batch(es) of a product if this becomes necessary and provide traceability in the use of medicines in food-producing animals, whilst guarding against abuse/misuse of medicines.
The identification and number of animals treated
The results of the veterinarian’s clinical assessment
The proprietary (trade) name(s) of the product(s), if there is one
The manufacturer’s batch number shown on the product, if there is one
The name and quantity of the active substances
The doses administered or supplied
The duration of treatment
The withdrawal period.

The records must be kept and be available for inspection for at least five years.

OWNER/KEEPER OF FOOD-PRODUCING ANIMAL:

ACQUISITION OF A VETERINARY MEDICINAL PRODUCT BY THE OWNER OR KEEPER OF A FOOD-PRODUCING ANIMAL

The owner or keeper of a food-producing animal must keep proof of purchase of all VMPs acquired for the animal. If the products were not bought, documentary evidence of how they were acquired must be retained. Records must be made at the time of:

- The date of each acquisition
- The name of the product and batch number
- The quantity acquired
- The name/address of the supplier of the veterinary medicinal product.

ADMINISTRATION OF A VETERINARY MEDICINAL PRODUCT BY THE OWNER OR KEEPER TO A FOOD-PRODUCING ANIMAL

At the time of administration by the owner or keeper, the following must be recorded by him/her and in the owner’s or keeper’s records:

- The name of the product
- The date of administration of the product
- The quantity of product administered
- The identification of the animal or group of animals treated
- The withdrawal period.

If the administration is by the veterinarian, in addition to the above details the name of the veterinarian and the batch number of the product must also be recorded. The veterinarian must either enter the information himself in the keeper’s records or give it to the keeper in writing in order that the keeper records the information.

When dipping, showering, jetting or spraying sheep, it is advisable to also record the time and place where the sheep were treated. This will provide useful evidence in the event of a pollution incident being investigated.

DISPOSAL OF A VETERINARY MEDICINAL PRODUCT BY THE OWNER OR KEEPER OF A FOOD-PRODUCING ANIMAL

Disposal other than by treating an animal must be recorded with details of:

- The date of disposal
- The quantity of product involved
- How and where disposal was effected.

In order to complete this report, it may be in the farmer’s interest to record the dates on which the treatment finished and any required withdrawal period for meat, milk, or any other animal product.

Records must be kept for at least five years following VMP acquisition, administration or disposal, even if the animals concerned have been slaughtered or have died during that period.

It is a condition of the Groundwater Regulations 1998 that records are kept of the type of substances contained in sheep dips disposed of and as to volumes, dates, and location of disposal.

The veterinarian may assist clients to keep good records by, eg, supplying a medicines’ record book. The National Office of Animal Health (NOAH) in conjunction with the Animal Health Distributors Association (AHDA) produce an Animal Medicine Record Book, which is available from the AHDA. The Pig Veterinary Society also produces a Veterinary Medicines Record of Administration Booklet. The NTF Medication Book is available from the National Trainers Federation (NTF) to assist trainers in recording the medical treatment of horses in training (see page 35 for contact details).

As a matter of good practice, the veterinarian should regularly examine the medicines’ record book to provide confirmation of the diseases and conditions requiring medication on the farm, whether the dose and regimen was as recommended, and that detailed withdrawal periods were adhered to.

The VMD has produced guidance in Record-Keeping Requirements for Veterinary Medicinal Products, VMGN No 16, available at www.vmd.gov.uk

Sheep dips disposed of and as to volumes, dates, and location of disposal.

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The VMD has produced guidance in Record-Keeping Requirements for Veterinary Medicinal Products, VMGN No 16, available at www.vmd.gov.uk
Standard operating procedures

Standard operating procedures (SOPs) should be provided for staff members and be readily available to them and the content be regularly reviewed covering all functions performed by them in the handling and supply of VMPs and MPs AHU. Evidence and use of the SOP may be taken, alongside a relevant training programme and continuing professional development, as sufficient evidence that staff are regarded as being ‘competent’ under the requirements of the VMR.

Written SOPs should be designed by the veterinarian attending food-producing animals to cover medicines that are used regularly on a farm. The SOPs should be under the direct supervision of the veterinarian. The reason for the use of the medicine, the dosage regimen, instructions on correct administration, storage requirements and identification of withdrawal periods should be specified. The veterinarian should provide additional information on exactly how the withdrawal period must be followed.

Ten example SOPs (see box below) follow. These are illustrative and should be adapted according to practice policy.

**SOP 01: Medicines’ handling**

Members of staff must:

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

Members of staff must not:

- Eat, drink or smoke in medicines’ handling or storage areas
- Take medicines from the storage areas for their own use or make such medicines available to other persons
- Handle any product 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 product if they know or think that to do so will put them at increased risk
- Handle either cytotoxic medicines or CDs unless as a veterinarian or upon the instructions of a veterinarian.
Members of staff should be familiar with the order process:

- Orders may be placed by fax, telephone or by electronic means (e.g., through the practice management system), however the last method (EDI) is preferred because of the greater speed of ordering, its accuracy and ease of processing.
- Whichever method is used care must be taken to ensure that the products are correctly identified in terms of:
  1. The precise name
  2. The pack size
  3. The product strength, if applicable
  4. The quantity required, i.e., of the immediate or outer packaging
  5. The wholesaler product code.
- Where a product requires specific authorisation (Schedule 2 and Schedule 3 CDs), the order must be correctly completed and signed.
- Agreement should be reached before supply that if a substitution for a non-available product is to be made, how exactly that substitution is to be carried out.
- The order is made by a principal competent member of staff under the responsibility of the veterinarian and the ordering must have been authorised by him/her.

**SOP 03: RECEIVING AN ORDER INTO THE PRACTICE**

Members of staff should ensure that:

- The delivery person has adequate access to the premises and to areas where the order will not conflict with the movements of personnel or animals.
- The delivery boxes, totes or pallets have been counted against the delivery note and any discrepancies, damage or inconsistencies are noted on the driver’s copy of the delivery note.
- Medicines, particularly biologicals, are unpacked and put away as soon as is practicable into their relevant storage areas.
- The whole order is checked against the delivery note or enclosed invoice within a clear area (e.g., away from people traffic and to prevent improper product removal before GRNS – goods received not stored) and not directly associated with currently stocked medicines’ storage areas.
- Once the whole order has been unpacked any delivery errors or omissions are notified as soon as possible to the wholesaler or other supplier.
- If possible, all items are labelled with the delivery date before being put away as an aid to stock rotation and potential product recall under the VMR.
- If a product is heavy or awkward in shape or size, help is sought or the packaging is broken down into its component parts.

**SOP 02: PLACING AN ORDER WITH THE SUPPLIER**

*(i.e., wholesale dealer)*

Members of staff should ensure that:

- Medicines must be stored:
  1. In a secure permanent building or designated area thereof.
  2. Separate from raw ingredients.
  3. Separate from animals.
  4. Separate from pet foods.
  5. At the correct temperature, monitored by a max/min thermometer.
- Medicines must not be stored:
  1. In inappropriate areas such as laboratories, staff rooms, food storage areas, toilets, etc.
  2. In any residential part of a dwelling house.
- Display:
  1. POM-V products should not be displayed to the public.
  2. POM-VPS and NFA-VPS products may only be displayed in a locked cabinet.

**SOP 04: STORAGE OF MEDICINAL PRODUCTS IN VETERINARIANS’ VEHICLES**

Members of staff should be familiar with the following:

- All professional staff must ensure that medicinal products are secure against theft and out of sight of the public.
- Vehicles should be kept in a clean and hygienic state and are left locked at all times – however a locked car is not deemed to be a secure container for CDs.
- Medicinal products, chemicals, etc., should be kept in a secure container bearing on the outside a ‘Harmful Substance’ warning label.
- Only medicinal products used frequently should be carried routinely in vehicles and those carried should be referred to in a list attached to the container.
- Medicinal products must be stored according to manufacturers’ instructions and protected against temperature, light or humidity extremes.
- Medicinal products requiring storage between +2°C and +8°C must be refrigerated storage.

**SOP 05: STORAGE OF MEDICINAL PRODUCTS IN PERMANENT PREMISES**

Members of staff should be familiar with the following:

- The storage area must be:
  1. Maintained in a clean and dry state.
  2. Well lit and adequately ventilated.
  3. Free from temperature fluctuations.
  4. Vermin proof.
  5. Protected against theft and vandalism.
- Refrigerated storage must:
  1. Be available for the storage of biologicals (i.e., vaccines) requiring a storage temperature between +2°C and +8°C.
  2. Have temperatures monitored and capable of being recorded daily, and the records retained for subsequent inspection.
  3. Not be used for food or drink for human consumption.
Standard operating procedures

SO P 06: THE MEDICINES’ SUPPLY AREA

Members of staff should be familiar with the following:

- A separate room of a part of it should be designated for the supply of medicines
- Ideally access to the area should be restricted to authorised staff only
- The handling of open products, drug mixes and their preparation should only be carried out in this area
- The area should have adequate light and ventilation
- A separate sink and washing facilities should be provided within this area
- Disposable gloves should be worn when handling open products
- Protective clothing, eye shields and face masks should be available
- A spillage kit should be available in case of spillage or breakage
- A first-aid kit and eye wash facilities should be readily available
- Eating, drinking and smoking should be strictly prohibited in this area
- Practice rules for the supply of medicines should be prominently displayed.

SO P 07: SPILLAGE OF HAZARDOUS SUBSTANCES

Members of staff should be familiar with the following:

- Appropriate facilities should be available for use in medicines’ supply areas where spillage of hazardous substances might occur:
  (i) Inert, absorbent granules for large volumes of liquids
  (ii) Absorbent pads for small volumes of liquids
  (ii) Hazardous waste disposal bags

Medicinal products must be properly labelled at the time of supply, ideally prior to storage within the vehicle
- Medicinal products must be protected from contamination by chemicals, dirty protective clothing and animal restraint devices
- Medicinal products must be stored separately from clinical waste. The carrying of a sharps’ container and receptacles specifically for waste is recommended
- Vehicles should be cleaned regularly both inside and on the outside and the contents reviewed, removed and restocked as appropriate
- A travelling first-aid kit and fire extinguisher should be carried in the vehicle and be readily to hand.

Medicinal products once opened/broached should bear the time and date of first opening
- Medicinal products must be completely used that day

Carried in a cool box and be

© Gill Harris BVA
(iv) Disposable waterproof gloves  
(v) Dust masks for use in the event of powder spillage.

■ Mechanical ventilation is recommended for such areas to ensure that hazardous dust or vapour can be extracted and does not spread to adjacent areas.

Product safety data sheets must be available and be consulted for specific advice on dealing with any spillage and the first aid required in the event of personal exposure to the product. See also Disposal of medicines, pages 30 to 31.

**SOP 08: THE SANCTION OF THE VETERINARIAN**

Members of staff should be familiar with the following:

The VMR state that a veterinarian supplying a VMP (other than one classified as AVM-GSL) must be present when it is handed over unless he/she authorises each transaction individually before the product is supplied, and he/she has satisfied him/herself that the person handing it over is competent to do so.

■ The name of the authorising veterinarian is to be included in the records at the time of supply
■ Repeat prescriptions may be supplied on the written authority of a ‘permitted medicines’ register maintained for that purpose on:  
(i) Prescribing cards  
(ii) A register of food-producing animal clients  
(ii) A computer data file.
■ The register should include details of:  
(i) The specific identity of medicines authorised for supply  
(ii) The quantity permitted to be supplied  
(iii) The frequency of the permitted supply  
(iv) The limit on the total amount to be supplied without further authorisation  
(v) The limit on the period of time that must not be exceeded without further authorisation

■ All labelling and packaging requirements must be fulfilled for the supply of each medicinal product on every occasion
■ Medicinal products may only be supplied to clients provided that:  
(i) The authorisation of a veterinarian has first been obtained  
(ii) The product is correctly packaged  
(iii) The product is correctly labelled  
(iv) Further verbal advice about administration and other warnings is given.

**SOP 09: BATCH RECALL PROCESS**

The objective of a batch recall is to remove from the market place a product that is unsafe (to the animals, humans or environment) or inefficacious.

As a mark of the practice’s ability to recall a product the following questions should all be answered in the affirmative.

If the practice is given the name of a product and its batch number would my record keeping system and my recall plan, within a reasonable time, be able:

■ To show that it has or has not been received from the supplier  
■ To show how much was received and when  
■ To show to which clients it has been supplied, when and in what quantities  
■ To show how much of the product with that batch number remains within the practice, branches or vehicles and where  
■ To show sufficient information within the system to be able to institute a recall process from clients if that was required?

**SOP 10: STOCK AUDIT**

Members of staff should be familiar with the following:

■ Make allowances for:  
(i) Bonus goods received (eg, BOGOFs – buy one get one free)  
(ii) Products on invoice subsequently returned or about to be returned to the wholesaler or other supplier  
(ii) Out of date (OOD) stock and disposed OOD stock  
(iv) Quarantined products  
(v) Part used products where containers have been disposed of to clinical waste  
(vi) Breakages, spillages, damaged or defaced stock.
■ Reconcile discrepancies between invoiced receipts and invoiced sales, products used internally in the practice and stock on hand (SOH). This process gives the audit check required by the VMR, and against abuse and theft of product or use greater than expectation.

■ Regularly, ideally on a monthly basis (on a legal basis: annually), carry out a physical count of all stock, including that in all practice cars.

BVA GOOD PRACTICE GUIDE ON VETERINARY MEDICINES 25
Suspected Adverse Reaction Surveillance Scheme

The Suspected Adverse Reaction Surveillance Scheme (SARSS) is a national surveillance scheme run by the VMD to record and monitor reports of suspected adverse reactions to veterinary medicines in both animal species and humans. The scheme also records lack of efficacy, adverse environmental effects, and suspected residues in milk and meat.

Adverse reactions
A suspected adverse reaction is a harmful and unintended reaction to a veterinary medicine (or lack of expected effect) when administered to an animal at its recommended dosage and route of administration. Any veterinary medicine, whether a drug or vaccine, may be associated with adverse reactions in animals. A reaction may occur in an animal undergoing treatment or in an untreated animal in the same household or holding. Suspected adverse reactions in human operators may also occur in a person administering a veterinary medicinal product, or a person exposed to a treated animal.

Ethical obligation
All veterinarians should accept as a serious ethical obligation the reporting of suspected adverse reactions to authorised veterinary medicines in animals or humans. Adverse reactions resulting from the use of medicinal products authorised for human use (MPSAHU) under the cascade should also be reported. Any observation that might lead to suspicion of an adverse reaction should be treated with careful professional judgement because of the implications for the manufacturer/supplier; the future of the product in the marketplace, and animals or humans.

The following categories of suspected adverse reactions are important to detect and record for all species:

- Unexpected suspected adverse reaction associated with the use of an authorised product
- Suspected adverse reaction mentioned in the data sheet but occurring more frequently than expected
- Any suspected adverse reaction to a new product within the first year of the marketing authorisation
- Any suspected adverse reaction to an authorised veterinary medicine used outwith the data sheet (‘off-label’)
- Lack of efficacy, such as unexpected antimicrobial or antiparasitidal resistance
- All suspected adverse reactions in humans possibly associated with the use of a veterinary medicine in an animal
- Unexpected effects of use of MPSAHUs in animals
- Suspected meat and milk drug residue problems
- Validity of withdrawal periods, eg, MRLs outwith expectation
- Effects of veterinary medicines on the environment.

A veterinarian may prescribe for use an authorised product outwith the data sheet or an MPSAHU following the prescribing cascade when he/she concludes that an authorised product does not exist in a particular case, because a lack of efficacy is suspected or there are likely to be unacceptable side-effects by the authorised product. Such suspicions should be (and should have been) reported to the VMD, where they will be recorded and monitored against further findings. The VMD will then assess the incidence and severity of side-effects and the efficacy of the products and act as necessary to have the product literature or the product marketing authorisation amended.

Under the wider scope of pharmacovigilance, the VMD collects information on incidents involving the provisional detection of antibiotic residues in milk of dairy cows that have received lactating or dry cow therapy to treat or prevent mastitis. Problems in individual dairy cows or with bulk tank residues may have been reported. The individual animal should be identified and the treatment undertaken noted. In addition, information on the milking regimen used on the farm, such as type and service history of the milking machine, teat-dipping protocols, the frequency of milking, and herd lactation yield, should be given.

Suspected adverse reactions in animals or humans should be reported on yellow Form MLA 252A, suspected antibiotic residues in milk reported on Form MLA 2, and suspected environmental incidents on Form MLA 1 to:

Veterinary Medicines Directorate
FREEPOST KT 4503
Woodham Lane, New Haw
Addlestone, Surrey KT15 3BR.

Copies of these forms are available on request from the VMD (see page 35 for contact details). They are also available for download from the VMD website www.vmd.gov.uk under ‘Adverse Reactions’. Tear-out copies of the yellow form are included in the NOAH Compendium of Data Sheets for Animal Medicines, The Veterinary Formulary, and the BSAVA Small Animal Formulary.

Identification of the product marketing authorisation number is a vital
part of the validation of a suspected adverse reaction to a VMP, environmental incident, or suspected antibiotic residues in milk report. Details to be provided on the reporting form include the product authorisation number preceded by the PL, MA, Vm or EU prefix; the product batch number; and any relevant information such as post-mortem or laboratory reports, and perhaps photographs. Suspected adverse reactions involving use of medicines subject to Animal Test Certificates should be recorded and reported in the same way as for authorised products. It is important to report a suspected adverse reaction to a medicinal product, environmental incident, or suspected antibiotic residues in milk to the marketing authorisation holder so that appropriate steps can be taken to investigate the alleged problem. Where a serious suspected adverse reaction occurs (particularly death), the report should be sent to the VMD and the pharmaceutical company holding the marketing authorisation for the product as soon as possible and, in any case, within 15 days of occurrence.

Guidance on pharmacovigilance is available in Marketing Authorisations for Veterinary Medicinal Products — Supplementary Guidance on Pharmacovigilance, VMGN No 13; SARSS: Guidance for Veterinary Surgeons; and SARSS: Antimicrobial Resistance Monitoring, all available at www.vmd.gov.uk.
When treating food-producing animals, veterinarians may only use medicines comprising ingredients that are contained in a product authorised for use in food-producing animals. This is to ensure that residue implications have been properly and fully evaluated.

Residues of veterinary medicines are defined as pharmacologically active substances (whether active principles, excipients or degradation products) and their metabolites that remain in foodstuffs obtained from animals which have been administered the veterinary medicine in question.

Regulation 2377/90/EEC establishes Maximum Residue Limits (MRLs) for pharmacologically active substances used in food-producing animals. The MRL is defined as the maximum concentration of residue resulting from administration of a veterinary medicine that is legally permitted in the Community or recognised as acceptable in or on a food. Substances may be listed in one of the four Annexes to the Regulation as indicated below:

**Annex I** – substances for which a full MRL has been fixed
**Annex II** – substances for which an MRL is not required
**Annex III** – substances for which a provisional MRL has been fixed
**Annex IV** – substances for which no MRL can be fixed

The substances listed in Annex IV are Aristolochia spp. and preparations thereof, chloramphenicol, chlороform, chlorpromazine, colchicine, dapsone, dimetridazole, metronidazole, nitrofurans (including furazolidone) and ronidazole. These substances are banned from use in food-producing animals. In addition, substances that do not have an Annex entry (ie, I, II, III) may not be used in food-producing animals. Special provisions apply to horses under the horse passport scheme (see Equidae, pages 10 to 11).

Further information on MRLs may be found on the European Medicines Evaluation Agency (EMEA) website www.emea.europa.eu and on the VMD website www.vmd.gov.uk. Details of the Annexes to Regulation 2377/90/EEC and a consolidated list, which is periodically updated, are available on the European Commission website http://ec.europa.eu/enterprise/pharmaceuticals/mrl/index.htm

MRLs established under these procedures are adopted in the UK and...
Drug residues and withdrawal periods

Northern Ireland (NI) for surveillance and enforcement purposes under The Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (Amendment) Regulations 2006 and equivalent regulations in NI.

A person may not sell or supply for slaughter any animal for human consumption if the withdrawal period of any authorised veterinary product, which has been administered to the animal, has not expired. The withdrawal period is the time interval after cessation of treatment and before the animal or any of its products can be used as human food (the concentration of residues in tissues such as muscle, liver, kidney, skin and fat, or products such as milk, eggs and honey must be lower than or equal to the MRL).

A veterinarian administering a VMP to a food-producing animal under the cascade must specify an appropriate withdrawal period. If no withdrawal period for the species concerned is indicated on the product, the veterinarian must specify a standard minimum withdrawal period of not less than the following:

- Seven days for eggs
- Seven days for milk
- 28 days for meat from poultry and mammals (but see below for horses)
- 500° days for meat from fish (where degree days is the cumulative sum of mean daily water temperatures in degrees Celsius following the last treatment).

Horses declared in the passport as intended for human consumption (or in England, the declaration is unsigned) may be treated with veterinary medicines authorised for horses or under the cascade for food-producing animals with substances listed in Annex I, II or III of Regulation 2377/90/EEC and other substances but not those listed in Annex IV of that Regulation. Substances in Annex I, II or III of Regulation 2377/90/EEC need not be recorded in the passport but recording of the medicines allows the specific product withdrawal period to be applied, otherwise the statutory six-month withdrawal period applies. The list of Essential Substances given in Annex of Regulation 1950/2006/EC may also be used to treat horses intended for human consumption. The statutory six-month withdrawal period applies and the treatment must be recorded in the passport.

Homeopathic remedies for food-producing animals contain active principles listed in Annex II to Regulation 2377/90/EEC and a zero withdrawal period applies.

Observing withdrawal periods

Whenever medicines are treated or otherwise supplied or administered to food-producing animals, an assessment must first be made to ensure that the appropriate withdrawal period can be observed on the farm. The importance of observing a withdrawal period and its duration for the product used should be fully and clearly explained to the owner/keeper.

The UK has in place a rigorous system of statutory and non-statutory surveillance for veterinary residues in animal products at slaughterhouses, on farms, at border inspection posts and at retail outlets. Both these programmes play a central role in ensuring that the consumer is protected against harmful levels of residues of veterinary medicines.

National surveillance

The National Surveillance Scheme for residues in a range of animals and animal products, including red meat, poultry, farmed fish (salmon and trout), milk, eggs, honey, and wild and farmed game, is a statutory programme designed to monitor whether residues of veterinary medicines are passing into food for human consumption in unacceptable concentrations and fulfils the UK’s obligations under Council Directive 96/23/EC and Commission Decision 97/747/EC. Authorised officers may collect samples from farms, slaughterhouses and egg packing stations. Where confirmed residues of authorised substances are found above the MRL, a veterinary officer of the State Veterinary Service carries out an investigation at the farm of origin to establish the source of the residue. For residues detected in fish an officer from the Centre for Environment, Fisheries and Aquaculture Science in England and Wales or the Fisheries Research Services in Scotland will undertake the follow-up investigation. The stock-owner/keeper will be advised on how to ensure that residues do not enter the food chain. Prosecution will be considered if serious shortcomings or deliberate misuse are found. Where unauthorised substances or high concentrations of authorised substances are detected, an Investigation Officer from the Department for Environment, Food and Rural Affairs (DEFRA) legal division will undertake an investigation.

The VMD’s non-statutory programme supplements the statutory programme and covers mainly imported produce and some home-produced food that is not part of the National Surveillance Scheme.

Stock owner/keeper education plays a vital role in a successful residue prevention programme. The programme should not only involve the owner and his management, but also his staff and particularly the stockpersons. This can be achieved by regular farm visits, newsletters, clients’ events and discussion groups.

Product withdrawal periods are subject to change. Information such as Withdrawal Periods for Animal Medicines included in the current NOAH Compendium of Data Sheets for Animal Medicines can be made available to the stockfarmer. However, some of the information may be outdated and it is important to check the current product data sheets for the appropriate withdrawal periods and ensure that the farmer is advised. Product information leaflets or the Summary of Product Characteristics (SPCs) may be left with the stock-owner/keeper.
Disposal of medicines

Disposal of veterinary medicines is regulated under many Acts and Regulations. Under the legislation the waste producer has a duty of care and, if any part of the disposal chain fails, the initial producer can be held responsible. Waste from medicines may be classified as clinical waste, pharmaceutical waste or hazardous waste.

Clinical waste is defined as ‘any waste which consists wholly or partly of animal tissue, blood or other body fluids, excretions, drugs, pharmaceutical products, swabs or dressings, syringes, needles or other sharp instruments, or any other waste arising from veterinary practice, investigation, treatment, care, teaching, or research’. Most drugs or pharmaceutical products such as tablets, capsules, creams, ointments, ampoules, syringes and needles, including those containing a small amount of medicinal residue, are classified as clinical waste. Clinical waste may be hazardous if it is infectious.

Hazardous waste includes some pharmaceuticals such as cytotoxic and cytostatic medicines and, for instance, infectious/contaminated materials and radiography processing chemicals.

Cytotoxic and cytostatic medicines are defined as any medicinal product that has one or more of the following hazardous properties: toxic, carcinogenic, mutagenic and toxic for reproduction. Examples from human medicine include antineoplastic agents, many hormonal drugs, some antivirals, immunosuppressants, and others.

As producers of, on average, more than 200 kg of hazardous waste per year, veterinarians must classify waste, and notify (register) their premises to the Environment Agency (see pages 35 for contact details) on an annual basis, or through the waste carrier used by the veterinarian. A Hazardous Waste Transfer Notice must be completed for each consignment of hazardous waste. It is advisable to use an authorised waste carrier as listed at www.environment-agency.gov.uk and to check with the waste disposal site used by the contractor to ensure waste has been delivered, since the responsibility for the waste’s disposal remains with the producer until final disposal.

Hazardous waste and non-hazardous waste must be kept segregated and sharps containers and dump-bins (Disposal of Old Pharmaceuticals, DOOP) containers will be required for ‘cytotoxic and cytostatic waste’ and another for ‘Non cytotoxic and cytostatic waste’. Waste should be segregated into coloured bags or containers.

For further information, see BVA Guidelines on the Hazardous Waste Regulations available to members at www.bva.co.uk/members/advice/hw_guidelines.asp

HAZARDOUS WASTE is waste with one or more properties that are hazardous to health or the environment. Hazardous waste includes some pharmaceuticals such as cytotoxic and cytostatic medicines and, for instance, infectious/contaminated materials and radiography processing chemicals.

CLINICAL WASTE is defined as ‘any waste which consists wholly or partly of animal tissue, blood or other body fluids, excretions, drugs, pharmaceutical products, swabs or dressings, syringes, needles or other sharp instruments, or any other waste arising from veterinary practice, investigation, treatment, care, teaching, or research’. Clinical waste may be hazardous if it is infectious.

CONTROLLED DRUGS

No person required to keep a Register of transactions for CDs may destroy a Schedule 2 CD except in the presence of a person authorised by the Secretary of State such as a police officer or an inspector of the Home Office Drug Office. A record must be made of the date of destruction and the quantity destroyed, which the authorised person must sign. Home Office legal advice indicates that destruction is taken to mean ‘denatured or made not readily recoverable’. Schedule 2 CDs returned by the client can be denatured (destroyed) without formality and their destruction need not be entered in the Controlled Drugs Register. The RPSGB recommends that such destruction is documented and witnessed by another responsible member of staff. A commercially available Controlled Drugs Destruction Kit should be used wherever possible. Alternative methods to denature CDs should be used to protect the environment and people.

The RPSGB provides the following guidance on denaturing CDs:

- Solid dose forms should be deblistered
- Ampoules should be opened, the
liquid poured into the resin kit and the ampoule itself be put in the sharps bin

- An ampoule that contains powder can have water added to it to dissolve the powder; and the resulting mixture can be poured into the CD denaturing kit.

- For fentanyl patches, the backing should be removed and the patch folded over itself.

CDs should be denatured and disposed of with other pharmaceutical waste (using a resin kit), according to local agreements with waste disposers. The destruction of Schedule 3, 4 and 5 CDs does not require to be witnessed by an authorised person.

In some instances, such as when an animal dies or the results of diagnostic tests lead to a change in treatment, medicines may be returned. Medicines returned to the surgery should not be re-used because the conditions under which the medicines have been stored will be largely unknown. Once a product has reached the final user; the legislation affecting disposal no longer applies. However, a professional responsibility still exists when advising clients as to the proper disposal of supplied medicines.

**SHEEP DIPS**

Stock-owners/keepers are also subject to the regulations for the disposal of both pharmaceutical and clinical waste. Veterinarians are exempt from the need to register as carriers, provided they are carrying waste produced in the course of their business. Veterinarians should be aware that solutions such as spent sheep dips or pesticides should not be disposed of so as to contaminate water courses, including ponds, ditches, ground and surface water, public sewers or drains. The disposal of used or spent dips onto land must be in accordance with a Groundwater Regulations authorisation obtained from the Environment Agency.

Records of the types of substances disposed of, volumes, dates, and location of disposal must be kept.

When dipping, showering, jetting, or spraying sheep, farmers and sheep dipping contractors should ensure this accords with good environmental practice (see codes of practice available from DEFRA and the Scottish Environment Protection Agency [SEPA]). Spent dip should be disposed of by a licensed waste disposal contractor or applied to a suitable area of land. The Environment Agency or SEPA should be contacted for advice. Dip concentrate should not be disposed of on the farm but should be disposed of by a licensed waste disposal contractor. Farmers can contact the Environmental Services Association for advice on reputable waste disposal contractors. Empty dip containers should be made safe against re-use. They may be thoroughly rinsed out and then disposed of at registered disposal sites. Rinsings should be handled as for spent sheep dips.

**MEDICATED FEEDINGSTUFFS**

The Environment Agency is responsible for the Regulations relating to disposal of medicated feed products. Guidance is available at www.environment-agency.gov.uk or telephone 08708 506506. The local Waste Regulation Authority can advise on safe disposal of any unused product and empty containers.

FOR FURTHER INFORMATION see BVA Guidelines on the Hazardous Waste Regulations available to members at www.bva.co.uk/members/advice/hw_guidelines.asp
Consent forms should be completed for all animal patients where veterinary medicines are prescribed outwith the data sheet, or are prescribed MPsAHU, or for animals undergoing euthanasia, likely to require an anaesthetic (local or general) or surgery (minor or major) unless delay would adversely affect the animal’s welfare. In order to give informed consent, it is essential that the client is advised about the significance and risks involved with options for treatment being given before being asked to sign a consent form. Common risks and adverse effects should be discussed appropriate to the patient’s health and circumstances. Costs or whether a member of support staff may perform any procedure may also be relevant to the client’s decision process.

Notwithstanding written information available for or presented to the owner or keeper of the animal to be treated, if the client’s consent is in any way limited or qualified or specifically withheld, the preference of the veterinarian cannot override the client’s specific wishes other than on exceptional welfare grounds.

CONSENT FOR MEDICAL TREATMENT

Under the prescribing cascade, a veterinarian may prescribe a VMP outwith the data sheet recommendations (‘off-label’), an MPsAHU, a specially prepared unauthorised medicine, extemporaneous or ‘magistral product’ or a medicine imported from another country under an import certificate under certain circumstances. A veterinarian should explain to the owner that he/she intends...
to administer such a preparation to the animal and ideally obtain the client’s written consent.

When treating ‘small animals’ or ‘exempt species’ such as rabbits and rodents, reptiles and exotic birds, for which there are limited or no authorised products, it may be necessary to use MPsAHU or veterinary medicinal products outwith their data sheet recommendations or specially prepared unauthorised medicines or medicines imported from another country under an import certificate. In order to avoid the owners having to complete a consent form for each procedure or therapeutic course, the Veterinary Defence Society (VDS) has produced a form to ensure consent of the owner for such treatment while the animal is under the care of the veterinary practice.

Consent forms for use of medicines used ‘off-label’ are available on request from the Veterinary Defence Society (VDS) (see page 35 for contact details).

**CONSENT FOR ANAESTHESIA AND SURGERY**

Veterinarians may find it prudent to present a written fee estimate at the same time as obtaining written consent for, particularly, anaesthesia and surgical procedures. The consent form and written estimate may be included in the same document but it is advisable to obtain a separate signature for each section. When deciding on the wording, lay-out and degree to which a particular fee estimate should be itemised, the veterinarian will need to take into account the following: the animal’s welfare and the need to attend promptly to an emergency; the time available for discussion with the client; the type of case, eg, acute or chronic, elective surgery or routine treatment, complex investigation followed by extensive surgery, treatment, or both; the changing profile of many disease processes; the possibility that complications may arise; the likelihood that owners will not understand the difference between an estimate and a quotation; and the need to inform owners that where cases are likely to be protracted regular updates of the fee estimate may be necessary.

The importance of maintaining good communications with clients throughout the management of a case cannot be overemphasised. To this effect, staff should straight away inform the owner of any contemplated change in the treatment plan for the case and particularly where such change is likely to change any estimated costing given. The difference between ‘estimate’ and ‘quotation’ in terms of the practice’s commitment to a declared cost should be well understood by staff.

In order to avoid unnecessarily long forms, clients may be made aware of various protocols in other ways such as by practice brochures or notices in the waiting room. Such information could include the standard of supervision for in-patients, the level of care given, and practice policy on performance of procedures by a veterinary student, a veterinary nurse or other support staff.

A Microsoft Word version of the RCVS Specimen Form of Consent for Anaesthesia and Surgical Procedures is provided in Part 3 Annex e (Consent form specimens) of the RCVS Guide to Professional Conduct at www.rcvs.org.uk.

**CONSENT FOR EUTHANASIA**

It is recommended that a separate consent form for euthanasia is made available. It is important that the client understands the term ‘euthanasia’ and that there is no misunderstanding. For instance, the use of the phrase ‘put to sleep’ or similar wording may not mean euthanasia to the distressed client. The decision to euthanise an animal may be difficult for both the veterinarian and the client. Guidance on euthanasia of a healthy animal or the client’s refusal for euthanasia where an animal’s immediate welfare is compromised is given in the RCVS Guide to Professional Conduct.

Under the Animal Welfare Act 2006, a veterinarian may certify that the condition of a domesticated animal is such that it should in its own interests be destroyed. An inspector or constable may destroy the animal where it is or take it to another place and destroy it there or make arrangements to this effect. An inspector or constable may act without the certificate of a veterinarian if it appears to him that the condition of the animal is such that there is no reasonable alternative to destroying it, and that the need for action is such that it is not reasonably practicable to wait for a veterinarian.

The court may order the destruction of an animal in relation to an offence committed if it is satisfied, on the basis of evidence given by the veterinarian, that it is appropriate to do so in the interests of the animal. The court may not make a deprivation or seizure order that involves the destruction of an animal unless it is satisfied, on evidence provided (orally or in writing) by a veterinarian, that destruction would be in the interests of the animal. The veterinarian should make full records of all the circumstances supporting a decision to euthanise without the owner’s consent in case of subsequent challenge.

Where the veterinarian is asked to destroy an animal injured in a sporting event, the opinion of a professional colleague, if available, should be sought before doing so. Further guidance is provided in the RCVS Guide to Professional Conduct.

Under the Dangerous Dogs Act 1991, as amended, and the Dangerous Dogs (Northern Ireland) Order 1991, a destruction order may be made by the Court, a Justice of the Peace, or the police and usually involves euthanasia of an apparently healthy dog. The veterinarian should request a written and signed destruction order from one of the appropriate statutory authorities before or, if this is not possible and there is a genuine threat to human safety, immediately afterwards.

A Sample Consent Form of Request for Euthanasia is given in Part 3 Annex e (Consent form specimens) of the RCVS Guide to Professional Conduct (as above).
Recommendations for prescribing, dispensing, and safe use of medicinal products for animals may be found in the following sources, some of which are periodically updated.

- Veterinary Pharmacy courses organised by the BVA and its specialist divisions. For details contact the BVA, 7 Mansfield Street, London, W1G 9NQ, telephone 020 7636 6541, fax 020 7908 6349, email bvahq@bva.co.uk
- National Office of Animal Health (NOAH) Compendium of Data Sheets for Animal Medicines. NOAH, 3 Crossfield Chambers, Gladbeck Way, Enfield, Middlesex EN2 7HF, telephone 020 8367 3131, fax 020 8363 1155, e-mail noah@noah.co.uk
- Royal College of Veterinary Surgeons RCVS Guide to Professional Conduct. Available at www.rcvs.org.uk
- Royal Pharmaceutical Society of Great Britain (RPSGB) Medicines, Ethics, and Practice: A guide for pharmacists. Available at www.rpsgb.org.uk
- Responsible Use of Medicines in Agriculture Alliance (RUMA) Responsible Use of Antimicrobials in Poultry Production, Responsible Use of Antimicrobials in Pig Production, Responsible Use of Antimicrobials in Dairy and Beef Production, Responsible Use of Antimicrobials in Sheep Production, Responsible Use of Antimicrobials in Fish Production, Responsible Use of Vaccines and Vaccination in Farm Animals. All available at www.ruma.org.uk
- Tennant B. BSAVA Small Animal Formulary, 5th ed. BSAVA, 2005
- Veterinary Medicines Directorate (VMD) Marketing Authorisations for Veterinary Medicinal Products – Qualiﬁed Persons, VMGN No 20, revised October 2006. Medicated Feedingstuff Prescriptions, VMGN No 21, revised October 2006. Medicated Feedstuffs and Specified Feed Additives, VMGN No 22, revised October 2006. All available at www.vmd.gov.uk

**LEGISLATION**

The legislation implementing the law relating to the administration, supply, and management of medicines in veterinary practice is extensive. The main Acts and Regulations include:

- Animal Welfare Act 2006
- Animals and Animal Products (Examination for Residues and Maximum Residue Limits) Regulations 1997 (and amendments)
- Animals (Scientific Procedures) Act 1986
- Control of Substances Hazardous to Health Regulations 1999 (COSHH)
- The Controlled Waste Regulations 1992
- Environmental Protection Act 1990
- Firearms (Amendment) Act 1997
- Groundwater Regulations 1998
- The Hazardous Waste (England and Wales) Regulations 2005 (and others)
- Health and Safety at Work etc Act 1974
- Health and Safety (First-Aid) Regulations 1981
- The Horse Passports (England) Regulations 2004 (and others)
- The Medicines Labelling Regulations 1976 (and amendments)
- The Misuse of Drugs Regulations 2001
- The Misuse of Drugs (Safe Custody) Regulations 1973 (and amendments)
- Offices, Shops and Railway Premises Act 1963 (OSRPA)
- Poisons Act 1972
- The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR)
- The Supply of Relevant Veterinary Medicinal Products Order 2005 (2205 No. 2751)
- Veterinary Medicines Regulations (re-enacted annually)
- Water Environment (Controlled Activities) (Scotland) Regulations (CAR) 2005 (and others)
USEFUL CONTACTS

Animal Health Distributors Association
Belmesthorpe Grange, Newstead Lane, Stamford PE9 4JJ
Tel: 01780 767757 Fax: 01780 767221
Email: mail@ahda.org.uk
Website: www.ahda.org.uk

Animal Medicines Inspectorate
National Agricultural Centre, Stoneleigh Park CV8 2LZ
Tel: 024 7684 9260 Fax: 024 7684 9261
Email: enquiries@ami.gov.uk
Website: www.vmd.gov.uk

Animal Medicines Training Regulatory Authority
Gable Court, Parsons Hill, Hollesley, Woodbridge IP12 3RB
Tel: 01394 41010 Fax: 01394 410455
Email: info@amtra.org.uk
Website: www.amtra.org.uk

British Veterinary Association
7 Mansfield Street, London W1G 9NQ
Tel: 020 7636 6541 Fax: 020 7908 6349
Email: bvahq@bva.co.uk
Website: www.bva.co.uk

Environment Agency
PO Box 544, Rotherham S60 1BY
Tel: 0870 502 858
Website: www.environment-agency.gov.uk

Environmental Services Association
154 Buckingham Palace Road, London SW1W 9TR
Tel: 020 7824 8882 Fax: 020 7824 8753
Email: info@esauk.org
Website: www.esauk.org

Department of Agriculture and Rural Development in Northern Ireland (DARD)
Dundonald House, Upper Newtownards Road, Belfast BT4 3SB
Tel: 028 9052 4999
Email: dardhelpline@dardni.gov.uk
Website: www.dardni.gov.uk

National Office of Animal Health (NOAH) Ltd
3 Crossfield Chambers, Gladbeck Way, Enfield EN2 7HF
Tel: 020 8367 3131 Fax: 020 8363 1155
Email: noah@noah.co.uk
Website: www.noah.co.uk

National Proficiency Tests Council (NPTC)
Stoneleigh Park, Stoneleigh, CV8 2LG
Tel: 024 7685 7300 Fax: 024 7699 6128
Email: information@nptc.org.uk
Website: www.nptc.org.uk

National Trainers Federation (NTF)
9 High Street, Lambourn, Hungerford RG17 8XN
Tel: 01488 71719 Fax: 01488 73005
Email: info@racehorsetrainers.org
Website: racehorsetrainers.org

Pig Veterinary Society
Southview, East Tytherton, Chippenham SN15 4LX
Tel: 01249 740380 Fax: 01249 740380
Email: office@pigvetsoc.org
Website: www.pigvetsoc.org.uk

Ten Alps Publishing
9 Savoy Street, London WC2E 7HR
Tel: 020 7878 2300 Fax: 020 7379 7118
Email: info@tenalpspublishing.com
Website: www.tenalpspublishing.com

Veterinary Deer Society
Email: julian@arthurlodge.co.uk
Website: www.the-veterinary-deer-society.org

Veterinary Defence Society
4 Haig Court, Parkgate Estate, Knutsford WA16 8XZ
Tel: 01565 652737
Email: admin@veterinarydefencesociety.co.uk
Website: www.veterinarydefencesociety.co.uk

Vet Helpline
7 Mansfield Street, London W1G 9NQ
Tel: 07659 811118 (local call rates apply)
Website: www.vetlife.org.uk

Veterinary Medicines Directorate (VMD)
Woodham Lane, New Haw, Addlestone KT15 3LS
Tel: 01932 336911 Fax: 01932 336618
Email: postmaster@vmd.defra.gsi.gov.uk
Website: www.vmd.gov.uk

Veterinary Surgeons’ Health Support Programme
7 Mansfield Street, London W1G 9NQ
Tel: 07946 634220
Website: www.vetlife.org.uk

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