PEER REVIEWED

Animal Medicines: Regulation and Supply

It is acknowledged by any professional involved with the dispensing and supply of animal medicines that there is considerable confusion and lack of understanding of the legal regulations governing this by owners of both large and small animals. The purpose of this article is to clarify some of the misunderstandings currently displayed by animal owners, e.g. a farmer or small animal pet owner with regard to how an animal medicine might be legally and appropriately supplied by a member of either the veterinary or pharmaceutical professions.

There is a significant and ongoing problem with veterinary surgeons sending large animal and pet owners to pharmacies with recommendations for them to purchase products not licensed for veterinary use to treat their animals. Examples I, personally, have come across are:

Benylin® cough mixture for treating a dog cough Lacrilube® eye drops and eye ointment for treating a dog with dry eyes Phenergan® an antihistamine containing promethazine formulated as both tablets and syrup to give their animals around Bonfire Night to calm them down Ibuprofen to treat arthritis Aspirin for a dog who has had a transient ischaemic attack (TIA) or stroke.

There are, without doubt, more examples which could be cited by other pharmacists who have had to deal with angry owners that do not understand that it is illegal to sell products to treat their animals which are not appropriately licensed for animal use: even if the relevant veterinary surgeon has recommended that they do purchase these medicines for administration to their animals. They generally consider that the advice of the veterinary surgeon should be enough and the staff are being uncooperative and making waves when their requests are refused. If the veterinary surgeon considers that an unlicensed product is the correct material to treat the condition, then they are obliged to provide the owner with a relevant prescription complying with the veterinary medicines cascade regulations.

A veterinary medicinal product (VMP) is legally defined[1] as:

1. any substance or combination of substances presented as having properties for treating or preventing disease in animals
2. any substance or combination of substances that may be used in, or administered to, animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

This means that a product may be a VMP if it is:

- medicinal by presentation and gives the averagely well-informed person the impression that the product treats or prevents disease
- medicinal by function.

VMPs are generally classed as either pharmaceutical or biological in origin.

A biological substance is produced or extracted from a biological source. The manufacturer needs to submit, for confirmation of its characterisation and determination of quality, a combination of physiochemical-biological testing results as well as a description of the production process and its control.

The following are considered to be biological veterinary medicines[1]:

1. An immunological veterinary medicine. This is a product administered to animals to produce active or passive immunity, or to diagnose the state of immunity to desensitise against allergens, or to produce an effect based on interaction of antigens with specific antibodies
2. A veterinary medicine derived from blood and plasma.

Pharmaceutical veterinary medicines are comprised of formulations used to treat other large and small animal conditions.

Legal Classification of Veterinary Medicines

The existing legal classifications for veterinary medicines in the UK are:

POM-V: Prescription-only medicine. These may only be prescribed by a veterinary surgeon and supplied by a veterinary surgeon or a pharmacist with a written prescription

POM-VPS: Medicines falling within this category are prescription-only medicines which may be prescribed and supplied by a veterinary surgeon, pharmacist or suitably qualified person (SQP) on an oral or written prescription. A written prescription is only required if the supplier is not the prescriber

Non-prescription medicines

NFA-VPS: These are medicines which can be supplied without prescription to treat a non-food animal. These medicines can be supplied by a veterinary surgeon, pharmacist, or suitably qualified person

AVM-GSL: This category applies to authorised veterinary medicines which are available on general sale.

The highest level of control is the POM-V category. This includes veterinary medicines containing controlled drugs and those intended for administration following diagnosis and clinical assessment by a veterinary surgeon.

Medicines in the POM-VPS category must also be prescribed, but this can be by a pharmacist, SQP or a veterinary surgeon, whereas NFA-VPS products do not require a prescription. Products in these categories must be provided with appropriate advice at point of sale in order to ensure that the products will be properly administered.

Medicines intended for use in food-producing animals would normally be classified as POM-VPS. The NFA-VPS category contains many of the dog and cat worm and flea control products.

Medicines in the AVM-GSL category may be supplied by any retailer without any restrictions, or provision of advice.

Veterinary surgeons, pharmacists and suitably qualified persons (SQPs) are collectively known as registered qualified persons (RQPs) and are entitled to prescribe veterinary medicinal products.

An RQP may only prescribe and/or supply the products that fall within the scope of the qualification and registration they hold. It is the duty of the RQP to ensure that they comply with the statutory requirements in respect of the prescription and/or supply of POM-V, POM-VPS and NFA-VPS.

There is an additional category of veterinary medicines in relation to products intended solely for use in small, non-food-producing animals (e.g. cage birds, small rodents, aquarium animals, etc). These are known as Small Animal Exemption Scheme (SAES) products. They are not market authorised (so they have not been assessed for quality, safety or efficacy) but may be legally sold and administered according to the instructions on their labelling1.

Prescribing, Dispensing, Supply
Only veterinary surgeons can diagnose clinical conditions in animals. However, the prescribing, dispensing and supply of veterinary medicines is permitted as follows:

Veterinary surgeons can:
Prescribe and supply all categories of authorised veterinary medicines and also human medicines for veterinary use (under the prescribing cascade[2] – see further information below), extemporaneously prepared medicines and SAES products[1].

Distribution Categories of Veterinary Medicines
Distribution categories provide controls for the supply of veterinary medicines to help ensure that appropriate advice is given at the point of sale to enable products to be used safely and effectively.

The distribution category of a veterinary medicine is decided by the Veterinary Medicines Directorate (VMD) following evaluation of scientific data submitted by the marketing authorisation holder or applicant for a marketing authorisation. The distribution category also defines a 'registered qualified person' in order to ensure the correct supply of the medication.

A registered qualified person may be defined as:
- a UK registered veterinary surgeon
- a UK registered pharmacist (operating from registered pharmacy premises)
- a UK registered suitably qualified person (SQP).
- An SQP is an individual who must be suitably trained and qualified and is included on the SQP register of the Animal Medicines Training Regulatory Authority (AMTRA). This category may include veterinary nurses, agricultural merchants, pet shop personnel and internet retailers.

Regulation of Veterinary Medicines in the UK
Veterinary Medicines Regulations (VMR) govern the UK controls on veterinary medicines, including their manufacture, advertising, marketing, supply and administration. It is the responsibility of anyone engaged in these activities to comply with the relevant VMR[1].

The VMD, an Executive Agency of the Department for Environment, Food & Rural Affairs (Defra), is responsible for the granting of marketing authorisations (MA) for veterinary medicines in the UK and for monitoring these medicines following authorisation.

The VMR prohibit the administration of a veterinary medicine unless:

- it is the subject of an MA
- it has been registered under the scheme for homeopathic remedies, or has been notified to the VMD for inclusion on the "grandfather rights" list
- it is exempt from the requirements of an MA under the small pet animal exemption scheme
- it has been imported by a vet or his agent for the purpose of administration under the cascade.
- Further restrictions apply in the case of food-producing animals.
- Exceptions are provided for products administered for research purposes in accordance with a certificate granted by the Secretary of State (SoS) or administered in accordance with the provisions of the VMR (including the cascade).

As stated above, before a veterinary medicine can be placed on the UK market, it is required that any manufacturer obtains a MA for its sale and supply. The authorisation of veterinary medicines is subject to similar controls to those for human medicines in that a large quantity of scientific data related to the product's formulation, doseage and stability, undergoes rigorous assessment to ensure that the benefits of using the product outweigh the risks and the medicine meets recognised standards for quality, safety and efficacy. An MA must be renewed five years following initial authorisation.

The data on quality has to provide evidence that the veterinary medicine has been formulated appropriately and will be consistently manufactured to required standards. The veterinary medicine must be shown to retain appropriate strength, efficacy and safety over the entire shelf life.

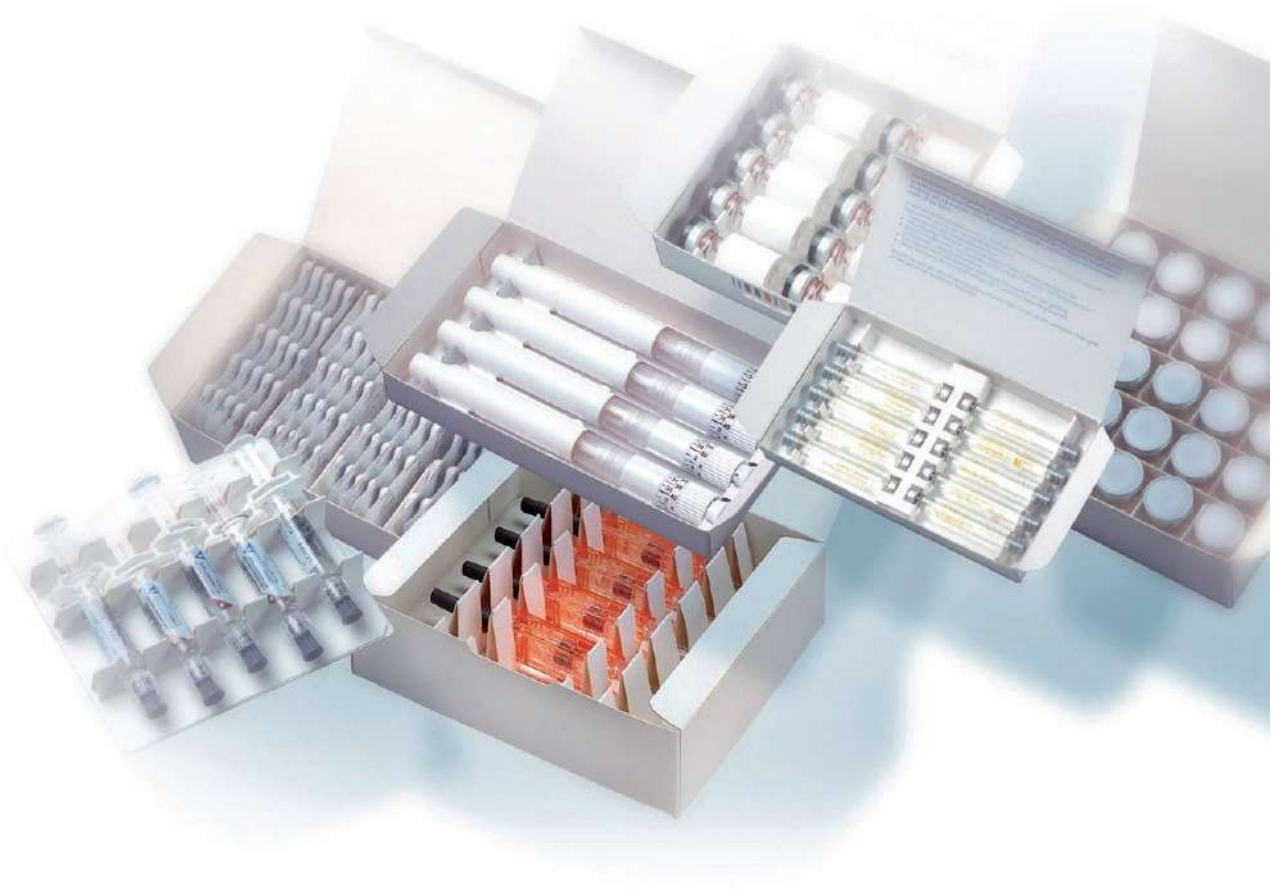
The veterinary medicine must be shown to be safe when used in accordance with the label instructions by not causing unacceptable side-effects or harm to:

- the animal being treated
- the person administering the medicine
- the consumer of milk, meat, eggs or honey (if administered to a food-producing animal)
- the environment.
- Where necessary, specific warnings are added to the labels or package leaflet to minimise any risks.

As with any human medicine, a veterinary medicine must be shown to be effective when the instructions on the label are followed. Detailed instructions for the correct use of authorised veterinary medicines can be found in the summary of product characteristics (SPC) for the product. SPCs for UK authorised veterinary medicines are available through the VMD's product information database on the VMD website

Exemptions[1]
There are, as might be expected, exemptions from the above marketing authorisation requirements as it is accepted that certain small pet animals will be kept exclusively as pets and will never be used to provide food for human consumption. The exempt species are:

- aquarium animals (including only fish kept in closed water systems)
- cage birds (e.g. birds kept in cages or aviaries)
- homing pigeons (pigeons kept for racing or exhibition)
- terrarium animals (reptiles, amphibians and arthropods kept in tanks and cages – including animals free-living in



domestic gardens)
- small rodents (domestic mammals of the order Rodentia)
- ferrets
- rabbits.

However, there are several classes of medicines which are not included in this exemption:

- antibiotics
- narcotic or psychotropic substances
- medicines intended to be injected or infused into the body (e.g. intravenously) or ophthalmic use, or for insertion into the ear canal.

If the veterinary surgeon diagnoses a condition in a small animal pet for which treatment by one of the above classes of medicine is deemed to be appropriate, then a prescription for a product with an MA will be necessary.

Regulations Governing Other Animal Medicinal Products
There are, as might be expected, regulations governing the manufacture and supply of products such as pesticides which are designed to improve or maintain the quality of both food animals and pets. Examples are as follows:

1. **Feeding Materials Designed for a Particular Purpose**
   There are feeding regulations specific to each of the different countries in the UK and these are enforced by local trading standard officers

2. **Nutraceuticals**
   A nutraceutical is defined as a food or naturally occurring food supplement which is marketed to improve animal health. The manufacturers are required to obtain an MA if a medicinal claim is made or the formulation includes something which will exert a pharmacological effect on the animal

3. **Biocides, Insecticides and Repellants**[3]
   There are two classes of the above: those which require an MA and those which do not. An MA is necessary:

   a). If the veterinary product contains ingredients that will kill insects, such as pyrethrins or pyrethroids, which defines their function as medicinal
   b). If the veterinary product is designed to control internal parasites
   c). If the veterinary product claims to treat or prevent a disease caused by a bacterial, fungal or bacterial organism.

   An MA is not required if:
   a) The product contains an insect repellent and claims to simply repel insects
   b) Is a product to be applied only to housing or bedding or
   c) Is a topical disinfectant applied to intact skin and does not claim to treat or prevent disease.
   The marketing of these products is controlled by legislation related to biocides[4].

4. **Shampoos**
   A shampoo for animals will be considered medicinal and require an MAI if it contains an insecticide or an ingredient which has a pharmacological effect or is presented as an insecticidal shampoo.

5. **Teat and Udder Products**
   A product designed for the treatment of teats and udders and applied internally to same for the prevention of mastitis will be considered to be medicinal and therefore the manufacturer will need an MA.

A product applied topically to disinfect teats and udders and for which no medicinal claims are made does not require an MA, as these are regarded as biocidal products and regulated by the Health and Safety Executive.

6. **Herbal Products**
   Herbal products require an MA if they are medicinal by presentation or function. For example, a product containing an alkaloid, such as digoxin from Digitalis sp., would function medicinally.

7. **Homeopathic Remedies**
   A new homeopathic veterinary remedy to be placed on the market must either be registered under the VMD's Homeopathic Registration Scheme, or have a full MA. A homeopathic product on the market prior to 1 January 1994 may remain on the market provided no medicinal claims are made.

Summary and Conclusion

From the above information, it can be seen that the manufacture, licensing and supply of veterinary medicines is far from straightforward, and involves many more steps than are anticipated or appreciated by veterinary surgeons, farmers and pet owners alike. The procedures and regulations are essential if the quality of our food and the health of our pet animals is to be guaranteed. Also, ensuring that animal medicines are properly and safely administered, particularly those designed to eliminate ecto- and endo-parasites, contributes actively to a reduction in zoonotic diseases.

The following is a brief summary of the criteria related to the legal supply of veterinary medicines[4]:

1. A qualified veterinary surgeon is licensed to administer or supply any veterinary medicine
2. There are four classes of veterinary medicines, two of which are prescription only
3. Generally, the veterinary medicine authorised to treat the diagnosed condition for a particular animal species should be prescribed but, if there is none, then the cascade system allows the veterinary surgeon to prescribe and administer medicines – including human medicines – for a species and/or condition for which they are not authorised
4. There are specific criteria for the registration and training of SQPs and the premises from which they may legally supply veterinary medicines
5. Pharmacists and veterinary surgeons must supply veterinary medicines from appropriately registered premises.

It is still unclear as to what changes in legislation will be necessary to ensure that veterinary medicine licensing continues to be effectively implemented once Britain leaves the European Union but we shall, without doubt, be informed appropriately in due course.

REFERENCES

1. https:www.gov.uk/government/organisations/veterinary-medicines-directorate
   Relevant pages:
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3. https:www.hse.gov.uk/biocides/eu-bpr.
4. Dale and Appelbe's Pharmacy and Medicines Law, eleventh edition, Wingfield J and Pitchford K eds, 2017, Pharmaceutical Press, ISBN 978 0 85711 202 6:249-271.

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