Quick-reference veterinary medicines information: what’s available?

To be able to prescribe or supply veterinary medicines effectively and safely, veterinary professionals need access to reliable, up-to-date information. Here we outline the quick-reference sources for prescribing information on licensed and unlicensed drugs available in the UK.
What information must be supplied?

For the medicines and uses that are authorised in the UK, the necessary information can usually be found in the product's summary of product characteristics (SPC) or in formularies containing information derived from SPCs. However, there are many occasions when a medicine is used outside the terms of its licence, under the 'cascade', the provision allowing veterinary surgeons to legally prescribe unauthorised medicines when no authorised product is available.¹ When medicines are prescribed under the cascade, the person supplying the medicine is legally required to supply written information* about the medicine, that includes, at least, the following:²

- name and address of the pharmacy, veterinary surgery or approved premises supplying the veterinary medicinal product;
- name of the veterinary surgeon who has prescribed the product;
- name and address of the animal owner;
- identification (including the species) of the animal or group of animals;
- date of supply;
- expiry date of the product, if applicable;
- name or description of the product, which should include at least the name and quantity of active ingredients;
- dosage and administration instructions;
- any special storage precautions;
- any necessary warnings for the user, target species, administration or disposal of the product;
- the withdrawal period, if relevant; and
- the words “Keep out of reach of children” and “For animal treatment only”.

* The Veterinary Medicines Regulations state that the product must be labelled with this information, but it is reasonable for the supplier to place some of the required information on a separate sheet [personal communication, VMD]. It is not necessary to supply the information if the vet who prescribed the medicine both supplies the product and administers it to the animal in person.

2. The Veterinary Medicines Regulations 2013. (Schedule 3, Part 1, Para. 13)
Summary of product characteristics (SPC)

An SPC is a legal document containing facts about a medicine (animal or human), based on data generated during the development of the product. It forms part of the marketing authorisation of a medicinal product. European Union (EU) law demands that an SPC is available for every licensed medicine (including generics) marketed in a member state. After a medicine has been authorised, the SPC is updated from time to time as more becomes known about the product; all changes must be approved by the regulatory authority. It is an offence to advertise a veterinary medicine if the advertisement is misleading or contains any medicinal claim that is not in the SPC.

What’s in an SPC?

The information in an SPC is presented in standard numbered sections and subsections (including the approved indication(s), dose range, contraindications, special precautions for use, possible adverse effects and drug interactions). The broad contents are determined by EU law but advice on the detailed presentation of the information in SPCs is set out in European Commission (EC) guidance.4,5

The company applying for authorisation to market the medicine drafts the SPC, but the wording must be approved by the regulatory authority (the European Medicines Agency [EMA] for products centrally authorised for the European market, or the Veterinary Medicines Directorate [VMD] in the UK). The SPC sets out what has been agreed about the product as a result of the regulatory authority’s assessment.

The SPC represents a guide to how a medicine should be used and the effects (including adverse effects) it may have on animals (and on humans and the environment). The SPC gives the specific licensed indication(s) for the product, and so can help veterinary professionals to know when a product is being used outside the terms of the licence (so-called off-label use). SPCs will often contain detailed information about a medicine that can be used to make prescribing decisions (e.g. about use in kidney or liver dysfunction; pregnancy; drug interactions; withdrawal periods). SPCs do not state the legal category of the medicine, but this can easily be found on the VMD Product Information Database.


Where to find SPCs

A complete online database of SPCs for veterinary medicines authorised in the UK is available on the VMD website; for products authorised centrally by the EMA, there is a link to the SPC held on the EMA website. SPCs for licensed human medicines may be found in the electronic medicines compendium, which includes most (but not all) SPCs for human medicines authorised in the UK. SPCs for all centrally authorised human medicines are on the EMA’s website. SPCs not in either of these databases can be obtained from the marketing company. There is currently no comprehensive database of SPCs for all human medicines authorised in the UK.

NOAH Data Sheet Compendium

The National Office for Animal Health (NOAH), a membership organisation for UK pharmaceutical companies that produce veterinary medicines, publishes a compendium of data sheets that are contributed by member companies and some non-member companies. The data sheets are prepared by the marketing company as an abbreviated form of the authorised information contained in SPCs. They are presented in a different layout from an SPC, and based on requirements set out in legislation in force before the existence of SPCs. For some products, the Compendium includes an SPC instead of a data sheet. When viewing a document, it is not immediately clear whether it is a data sheet or an SPC.

The Compendium is not a comprehensive source of such data sheets/SPCs for authorised products. It contains data sheets for products (such as febendazole [Lapizole] for use in small animals), which are not required to have a marketing authorisation but are marketed under the Exemptions for Small Pet Animals Scheme. There is a list of included exempt products in the introduction to the Compendium. The Compendium is available online free of charge, and as a book (price £44 in the UK).
The British National Formulary (BNF)

The British National Formulary (BNF), published jointly by the British Medical Association and the Royal Pharmaceutical Society, contains prescribing information and guidance on human medicines. The information in the Formulary is drawn from SPCs, medical and pharmaceutical literature, UK health departments, regulatory authorities, and professional bodies. Advice is constructed from clinical literature and reflects, as far as possible, an evaluation of the evidence from diverse sources. It is available as a book (published twice a year, in March and September), at a cost of £40. Access to the online version is available through annual subscription costing £146. The BNF is updated monthly online.

BSAVA Small Animal Formulary

The BSAVA Small Animal Formulary, published by the British Small Animal Veterinary Association, contains monographs on drugs arranged in alphabetical order of generic name. Each includes information on formulations, action, uses, safety and handling, contraindications, adverse reactions, drug interactions and dosages. Unauthorised drugs are marked with an asterix, but monographs do not indicate whether an authorised product is licensed for all of the species and indications listed, and the Formulary’s editors advise checking the individual product SPCs. The doses included are those recommended in SPCs, or are based on published articles or textbooks or on clinical experience. Monographs include some trade names of available products, but not a comprehensive list of these. The Formulary is compiled by an editorial panel using published and unpublished evidence. References to supporting evidence are not included. The printed version of the Formulary is updated every 3 years (the latest edition [number 8] was published in 2014) and there is an online version, which is revised more often. The printed Formulary costs £45 (for members) and £60 for non-members; online versions of the Formulary are free to BSAVA members.
VetFormulary

VetFormulary is an online formulary that contains prescribing information on authorised and unauthorised drugs for a wide range of species (amphibians, invertebrates, birds, cattle, dogs, foxes, goats, deer, marine animals, donkeys, horses, hedgehogs, wild and domestic cats, fish, rabbits, hares, marsupials, mustelids, sheep, monkeys, reptiles, rodents, pigs, bears and pandas). The Formulary can be searched by drug name, with the option of going straight to the dosage recommendation for a particular species. Drug monographs contain sections on products (including the brand names of those available in the UK and links to their SPCs), indications (with separate sections on authorised and unauthorised uses), dosage, pharmacology, patient safety (including adverse effects, contraindications, reproduction, monitoring and administration) interactions, toxicology, and human safety. There are links to supporting references. The site also provides client information sheets that include the information required by the VMD when supplying a medicine under cascade, together with consent forms (not a legal requirement, but a requirement of the RCVS Code of Professional Conduct for Veterinary Surgeons) for use when prescribing an unauthorised medicine. The forms can be edited to include the practice name and address and can be integrated into some practice management systems for ease of use when prescribing. Access to the formulary costs £50 per year.
Vetstream Ltd provides Canis, Felis, Lapis and Equis which are online databases of point-of-care veterinary information and images related to the care of dogs, cats, rabbits and horses. The database includes a formulary section (entitled “pharmacology and therapeutics”). Each drug monograph includes sections on uses, administration (including dosage), pharmacokinetics, precautions and adverse effects, and a list of references to supporting evidence (with online links to some); each is linked to peer-reviewed content on relevant diseases, diagnostic tests and pathogens. The information has an international focus; it does not include trade names of products available in the UK, and it states when certain drugs are not authorised for use in certain species in the USA. Most of the drug monographs are written by named clinicians. Access to each species section costs £285 per year (or £75 per quarter).

Conclusion
Prescribing information on authorised veterinary medicines is easily accessible online in the form of summaries of product characteristics (SPCs), which are available free via the Veterinary Medicines Directorate website. The authorised prescribing information contained in SPCs can also be found in formularies either in book form (BSAVA Formulary) or online (BSAVA Formulary, VetFormulary).

For unauthorised uses of medicines, for which there is a legal requirement for veterinary professionals to provide certain written information to clients when supplying under cascade, the availability of information is less well defined. VetFormulary is the most comprehensive source of quick-reference prescribing information on unauthorised uses. The British Small Animal Veterinary Association and VetFormulary provide downloadable client information sheets that contain information required when prescribing under the cascade. This is a development that will help veterinary professionals comply with law on cascade prescribing. Occasionally, it may be helpful to refer to information on human medicines, which can be found in the electronic medicines compendium (containing most SPCs) and the British National Formulary.
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