



## WVA Position Statement on Availability of Veterinary Pharmaceuticals

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### Background

Veterinary pharmaceuticals are crucial for animal health and welfare. In turn, animal health and welfare impact human health and welfare, because humans rely on animals for food, fibre, work, entertainment, and companionship. In a wider context, animal health is critical for ensuring food safety, public health, food security and adequate nutrition for people and helps to alleviate poverty. Proper use of and access to high quality pharmaceuticals, and appropriate oversight of ordering, prescribing and dispensing these pharmaceuticals are common concerns for all animal health stakeholders and should be the focus of continuing professional development for veterinary professionals and paraprofessionals.

Animal health depends on access to safe and effective veterinary pharmaceuticals. However, in many regions of the world, safe and effective veterinary pharmaceuticals are not readily available. Inequities in availability are most often related to financial reasons and regulatory shortfalls. For example, the high costs associated with manufacturing, testing and distributing or importing certain veterinary pharmaceuticals may encourage production of counterfeit medications. Additionally, regulatory processes may be ineffective or insufficient to ensure that available pharmaceuticals are of high quality (i.e. safe and efficacious) [1]. High costs coupled with insufficient regulatory processes may, in turn, lead to the availability of only black-market or counterfeit pharmaceuticals of questionable safety and efficacy. A strong national or regional regulatory infrastructure is needed to oversee all aspects critical to the ongoing availability of high-quality veterinary pharmaceuticals.

Transparent and ongoing discussion at the national, regional and international levels to promote equitable availability of high quality veterinary pharmaceuticals in all regions of the world should be a common goal of the veterinary healthcare and food animal production industries and the regulatory community with the aim of protecting animal and human health and welfare and the environment.

### WVA Position Statement

Veterinary pharmaceuticals must be manufactured under strict guidelines and be licensed or registered and approved for use only after undergoing a rigorous quality assurance assessment that is regulated and evaluated by national or regional authorities. Additionally, legislation to authorize such regulation should be based on scientific evidence obtained through studies conducted by qualified

veterinarians and scientists. Such regulatory measures will help ensure that veterinary pharmaceuticals, when used in accordance with the approved product label, will have minimal harmful or unintended effects on animals, people or the environment.

The dispensing and sourcing of licensed or registered and approved veterinary pharmaceuticals through traditional distribution channels or non-traditional access points, such as human, compounding, and internet pharmacies, should only be done by or on prescription of a licensed veterinarian within the context of a veterinarian-client-patient relationship (VCPR) [2], unless the pharmaceutical is licensed or registered and approved for over-the-counter sale, (i.e., drugs labeled with information necessary for safe use and available without need of a veterinary prescription).

Given the wide range of animal species needing treatment, veterinarians should also be authorized to use or prescribe approved therapeutic agents in an extra-label (or off-label) manner (i.e., in a manner that is not in accordance with the product label/specific product characteristic). Extra-label drug use by prescription of a licensed veterinarian within a VCPR must also be regulated and reserved for exceptional circumstances to ensure the following:

- There are no approved animal drugs labelled for such use in that species, or that contain the same active ingredient(s) as the extra-label drug in the required dosage form and concentration;
- If an approved animal drug exists but the veterinarian finds that it is clinically ineffective, extra-label use of an alternative medication is permissible;
- The identity of the animal(s) treated in an extra-label manner must be maintained;
- An extended withdrawal period supported by appropriate scientific information must be enforced for any drug used in an extra-label manner prior to marketing any edible products (e.g. meat, milk, eggs) from the treated animals;
- Drugs labelled for use in humans can be administered, but only to non-food animals, even if an animal-label drug for that species and medical condition exists; and
- Prescribing veterinarians should always carefully consider the use of an antimicrobial, with special attention given to the risk of development of resistance to these products as part of the benefit/risk assessment.

Regardless of whether a drug is prescribed for use in a label or extra-label manner, veterinarians should engage with their clients to promote the responsible use of veterinary pharmaceuticals in all animals.

1. [Code of Federal Regulations, Part 211, Current Good Manufacturing Practice for Finished Pharmaceuticals](#), (see specifically Subpart D, paragraph 211.84, subparagraph 6e): “Any lot of components, drug product containers, or closures that meets the appropriate written specifications of identity, strength, quality, and purity....”
2. [www.avma.org/KB/Resources/Reference/Pages/VCPR.aspxhttps://www.ecfr.gov/cgi-bin/text-idx?SID=16eeac0919d71785492812eeb6a67918&mc=true&node=pt21.4.211&rgn=div5-se21.4.211\\_180](http://www.avma.org/KB/Resources/Reference/Pages/VCPR.aspxhttps://www.ecfr.gov/cgi-bin/text-idx?SID=16eeac0919d71785492812eeb6a67918&mc=true&node=pt21.4.211&rgn=div5-se21.4.211_180)