

WSAVA position statement on availability and access to medicinal products for companion animal use

Ready access by healthcare professionals to diagnostics and therapeutic modalities is the foundation for the provision of proper patient care regardless of species involved. However, clear inequities exist between various regions of the world stemming from a variety of factors but commonly involving financial and regulatory decisions.

Regulatory impediments range from antiquated licensing/registration/approval processes that fail to embrace reciprocity, to current processes and oversight that restrict rather than favour product availability and use by appropriate healthcare professionals. Additionally, there is often a lack of consistency in definition and/or inclusion of medicinal products in regulatory frameworks (e.g., medicated feeds).

Financial issues encompass both manufacturer and patient, and may include:

- Low return on investment that precludes therapeutic licensing efforts, or results in the removal of a product from the market
- Product being available but pricing set at a level that excludes a sector of the patient population

Regardless of the cause, where needs exist but restrictions occur, alternate avenues of access often arise (e.g., online, black-market, etc) to source product. As these are unregulated, they raise issues of consumer fraud and patient safety resulting in a "buyer beware" marketplace.

It is clear that this issue is complex and engenders a variety of factors that can best be resolved through collaborative discussion. It is also clear that this issue isn't restricted to any one professional discipline and falls very much under the One Health movement. Templates exist in various parts of the world where these issues have been equitably addressed for the various market sectors involved – manufacturer, regulatory, patient, and/or consumer- allowing healthcare professionals to meet their ethical commitment to provide appropriate patient care.

While many issues contemplated are common between companion and food-producing animals, this position statement concentrates on medicinal products for companion animal use

where medicinal product use is based on individual patient treatment and without food safety implications. Additionally, these guidelines are <u>designed to supplement and help clarify</u> <u>existing legislation</u> with respect to veterinary use of medicinal products in companion animal practice, with a focus on providing the companion animal veterinarian with access to medicinal product use that will enhance his/her ability to meet the health and welfare needs of his/her patients while ensuring proper medicinal stewardship.

This position statement supports the following principles relating to the availability of and access to medicinal products within the companion animal veterinary context:

- The use of a licensed/registered/approved veterinary pharmaceutical should remain the decision of a licensed veterinarian under a valid veterinarian---client-patient relationship (VCPR).
- Dispensing/sourcing a specific veterinary licensed/registered/approved pharmaceutical should only occur by or on the order of a licensed veterinarian, unless the pharmaceutical is licensed/registered/approved for over-the-counter use.
- Where potential product abuse issues exists (e.g., narcotics), appropriate safeguards (with regulatory oversight) should be employed. Prohibition of use is not ethically justifiable.
- Where human but no veterinary licensed/registered/approved pharmaceutical exists, regulatory flexibility should encompass veterinary patient need, so long as information as to proper product use exists and the prior bullet points have been satisfied. Accessing pharmaceutical products outside of the traditional distribution network (e.g., veterinary distribution centres, veterinary clinics, and/or veterinary pharmacies) should satisfy all of the previous bullet points and should be subject to licensing, registration or regulatory oversight. Such non-traditional access points may include human, compounding, and internet pharmacies.
- Open, transparent, and ongoing discussion on drug availability should be a common goal
 of the companion animal veterinary healthcare industry and community (encompassing
 users, manufacturers, and regulators), to protect the health and welfare of the
 veterinary patients. This should occur at both a regional and international level.
- Proper use, access, and ordering/dispensing are common concerns for all stakeholders to ensure appropriate availability and use of medicinal products, and should be the focus of collaborative continuing education for the professionals involved.

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