



Vision: All companion animals worldwide receive veterinary care that ensures their optimal health and welfare

Mission: To advance the health and welfare of companion animals worldwide through an educated, committed and collaborative global community of veterinary peers.

Survey on the availability and access to Veterinary Medicinal products: Survey report November 28/16

A key component to achieving the WSAVA Vision and Mission statements is the access and appropriate use of veterinary medicinal products. However, as an international association comprised of over 100 member associations representing close to 200,000 veterinarians in small animal practice globally, it became readily evident that there were distinct regional inequities in this regard and that this hampered the veterinarian's ability to meet their patient care needs. During WSAVA Member Forums, this was repetitively raised as a topic of concern and discussion. In response, the WSAVA has adopted a position statement on this topic (Appendix I) as well as having additional position statements that incorporate access to specific veterinary pharmaceuticals (Minimum Analgesics and Ketamine – see Appendix II & III). In an effort to better quantify the issue and its dynamics, the WSAVA undertook a survey of its members on this topic using an online survey program, with responses tabulated over the fall of 2016. The full report can be accessed at wsava.org.

Summary

Demographics

Response were received from 30 member associations representing all regions of the world: North America 2; Latin America 3; Europe 15; Middle East 2; Africa 3; Asia/Oceania 5.

Key Findings

75% of respondents indicated that access to veterinary medical products hampered their ability to meet the needs of their patients; 20% assessed the impact as a severe restriction in the level of care. The major reasons cited were the regulatory environment and manufacturer related issues (lack of interest due to market size and high product costs). Most respondents indicated the presence of a formal governmental regulatory agency in their country; however, while most allowed for regulatory discretion in the use of other licensed pharmaceuticals in animals in an extra label fashion (prohibited in some regions) and the ability to import medicine from other countries through "emergency drug release", the common theme was that these were very restrictive (e.g., CASCADE in EU) and/or labour intensive to make use of. The manufacturer and/or distributor was the most common way for veterinarians to source veterinary medicinal products. For pet owners, aside from paracitocides and premium diets, the veterinarian remained the most common source for medicine, followed by a human pharmacy. While most products required a prescription, this was not consistent and in some cases troubling (not always applicable to antibiotics or analgesics) as was the fact that in only 60% of the respondents was a valid veterinary-client-patient relationship required to script/dispense. Of interest was the emergence of the Internet as a source for veterinary pharmaceuticals, cited as a simple solution to overcome the lack of product availability as well as to source cheaper products, but also raising concerns over lack of adherence to scripting practices and poor regulatory oversight.

WAVMA responses to survey

Thanks to the assistance of the World Aquatic Veterinary Medical Association (WAVMA), 27 of their members completed the survey with a focus on aquatic ornamental (pet) fish, comprised of finfish and invertebrates. While responses were global in representation, they came predominantly from North America (14) & EU (7), with 2 from Australia and one from Japan, Iran, Egypt, and the Caribbean. As one would expect, the responses mirrored those from the WSAVA national association survey and simply reflect common regulatory oversight. However, there were some unique aspects to the market dynamics and specific product classes worthy of mention, including the fact that many product classes were not applicable to current ornamental fish medicine. Due to the “specialty” aspect of the ornamental fish market, “unregulated sources” and the Internet took on a more prevalent method for owner’s to source product, including antibiotics some of which were over the counter (OTC) in aquarium and pet stores. There was also tremendous support for furthering MUMS (minor use, minor species) caveats to the licensing regulatory environment. There was concern that the well-developed OTC, “hobby market”, and Internet were undermining the veterinarian’s role professional role in ornamental aquatic medicine.

Areas of opportunity

While some of the underlying issues are complex and unlikely to have a simple solution, there is an opportunity in more effective supply chain management – both through education regarding off-label use of various “like medicines” if no licensed product exists but also the potential to import under “emergency drug release” legislation. While the cost to veterinarians of some medicines is comparatively high based on the market dynamics, pricing to the end consumer/pet owner may compound this problem; however, rational pricing models may help address this. Based on the variability in pharmacy practices, there is an opportunity for establishing GCP guidelines. It would be useful to further quantify the Internet pharmacy dynamic.



WSAVA
Global Veterinary Community

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 **designed to supplement and help clarify existing legislation** 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 exist (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.

Adopted by WSAVA Executive Board February 10, 2016



WSAVA
Global Veterinary Community

Analgesic drug availability – Recommendations on minimum pharmacological need

World Small Animal Veterinary Association and Global Pain Council Position Statement

Pain is a common clinical occurrence in all species, including small domesticated animals. Whether part of an underlying illness, the result of an injury, or as a consequence of needed surgery/diagnostic test, its occurrence negatively impacts the health and welfare of animals it afflicts, causing needless suffering, and therefore its identification and resolution is a key feature of the Hippocratic and Veterinary Oath (<http://www.wsava.org/sites/default/files/WSAVA%20Veterinary%20Oath.pdf>). Fortunately, a variety of highly effective pharmaceutical agents have been developed; unfortunately, these are not always available for veterinary use – primarily due to licensing and regulatory issues. Where possible, every effort should be made to overcome these impediments to use to achieve the common goal of ethically meeting our responsibility as veterinary practitioners.

With respect to pain management, the following minimum requirements, would define the therapeutic options necessary to properly manage pain in small animals.

1. As opioids are critical for acute and moderate to severe pain management, veterinarians should have access to this class of analgesics. Ideally, this would include veterinary licensed opioids. However, where this is not possible, veterinarians should have regulatory discretion to use human licensed opioids in an extra-label fashion, ensuring all regulatory requirements regarding their use are met. Due to its common use in human medicine, as a minimum this should include morphine as it can be used for moderate to severe pain in both dogs and cats.
2. Nonsteroidal antiinflammatory drugs (NSAIDs) are effective for varying types and degrees of pain and combine the synergistic effects of both analgesia and antiinflammatory activities. They are the foundation of treatment for many inflammatory conditions commonly afflicting aging dogs and cats (e.g., osteoarthritis). Many veterinary licensed NSAIDs exist and since their safety and efficacy profile is known, every effort should be made to ensure veterinarians have access to at least one in their region of practice. A list of veterinary licensed NSAIDs is provided as Appendix I.
3. Local anesthetics are highly cost-effective analgesics with a high therapeutic safety margin when used correctly and commonly available in most countries, although not always labelled for veterinary use.

Where veterinary licensed products do not exist, veterinarians should have regulatory discretion to use human licensed local anesthetics in an extra-label fashion. Due to its common use in human medicine, as a minimum this should include lidocaine as has well-defined therapeutic protocols and administration techniques for dogs and cats.

4. There are a number of adjunctive analgesic products (e.g., ketamine, etc) and modalities that go beyond a “minimum required” list but can be extremely beneficial for the treatment of pain in a multi-modal clinical approach. One of the minimum requirements, already cited in the previous text, would be the regulatory discretion to use human-labelled product when no veterinary licensed product exists, information exists as to safe and effective product use, and all regulatory requirements over their storage and use are met.

Appendix I: NSAIDs licensed for veterinary use in various regions of the globe

- Carprofen
- Cimicoxib
- Deracoxib
- Etodalac
- Firocoxib
- Flunixin meglumine
- Ketoprofen
- Mavacoxib
- Meloxicam
- Pheylbutazone
- Robenacoxib
- Tepoxalin
- Tolfenamic acid

Adopted WSAVA Executive Board February 2015

Appendix III

Global Pain Council Position Statement Ketamine:

Access to anesthetic and analgesic drugs is imperative for the mitigation of animal suffering and the WSAVA's Global Pain Council was created to address inequalities in both education and access to analgesic/anesthetic modalities in differing regions of the world. In some regions, ketamine is the only analgesic/anesthetic agent available to the veterinary profession and is essential to enable veterinarians to perform their day-to-day activities in an ethical and humane manner. Restrictions on its use would have a significant and negative impact on animal welfare on a global scale. As such, the WSAVA and its Global Pain Council lend their support to the Ketamine Fact Sheet and efforts to halt any initiatives that seek to have it rescheduled.