
Veterinary generics: An enigma among niche markets

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Abstract This paper examines the opportunities and challenges pharmaceutical companies encounter when considering entry into the niche US veterinary generics market. The key points compare the growth of the companion animal market as an attractive lure for potential entrants, to the regulatory hurdles of drug approval, drug distribution and veterinarian relationships and education that could dissuade companies from testing the waters of veterinary generics.

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VETERINARY GENERICS: A DIFFICULT NICHE

At a time when global generic companies seeking growth have expanded from the previous blockbuster strategy into most niche markets, the companion animal pharmaceutical segment may, at first glance, appear attractive because of increasing pet ownership, depth of the human/animal bond and growing expenditures on veterinary

services. On closer examination, however, this sector of the US generics market is a quagmire fraught with inefficiency and regulatory hurdles, compared to the efficient human generics sector.

The fragmented companion animal veterinary practice customer base, the need to develop targeted marketing and communications for veterinarians, and the high margins enjoyed by veterinary distributors have deterred human generic companies from entering the veterinary generics sector.

PRESCRIPTION DRUG MARKET FOR PETS

Pet care is America's second fastest growing retail category after consumer electronics,

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expanding about 6 per cent a year.¹ In 2007, American pet owners spent \$41.2bn on their animals, up 7 per cent from 2006, according to the American Pet Products Manufacturers Association (APPMA). Pet owners were estimated to have spent 52 per cent more on pet medicines in 2007 than they did five years ago.¹

The companion animal market continues to grow, and historically has grown even during recessions (Figure 1). Fifty per cent of pet owners surveyed in December 2007 acknowledged that they would reduce the amount of money they spent on themselves in order to be able to continue to spend money on their pets.² A recent WSL Strategic Retail survey reported that food and pet supplies were the only two categories out of 17 that showed significant spending increases among both women and men in 2008.³ The APPMA estimates that pet spending will grow 6 per cent in 2008, despite the recession, to \$43bn. The largest increase in pet spending is expected to be in veterinary healthcare, which the APPMA predicts will grow 10 per cent, to an estimated \$10.9bn in 2008 from \$10.1bn in 2007.⁴ Expenditures on veterinary care increased 40 per cent between 2002 and 2007.⁵

The US market for prescription drugs for companion animals was estimated to total

\$3.5bn in 2007.⁶ The \$3.5bn total includes flea and tick medications regulated by the Environmental Protection Agency (EPA); biologicals, principally vaccines, regulated by the United States Department of Agriculture (USDA) and prescription drugs regulated by the FDA's Center for Veterinary Medicine (CVM). The total does not include the sale of human approved drugs into the veterinary channel, which is estimated at \$261m at retail level in 2007.⁷ Figure 2 illustrates the breakdown of the US companion animal pharmaceutical market and provides detail for the \$1.4bn US market for regulated products.

According to the APPMA, pet ownership is increasing; 63 per cent of US households have at least one pet, up from an estimated 56 per cent of households with a pet in 1988. A total of 75 million dogs were owned by 45 million households in 2007 with an increase in multiple-dog owning households, which generally have higher veterinary expenses.⁵

Cats and dogs are usually treated as members of the family; living indoors, often sleeping on their owners' beds or on the furniture, and sometimes doted on as if they were furry children. According to the Mechanti Group, two-thirds of American households own a pet, while only one-third have kids. 'The growth of the companion

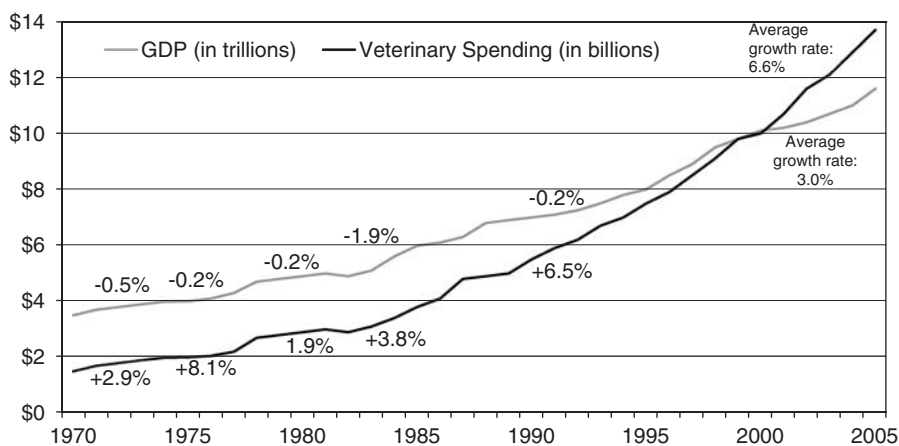


Figure 1: Veterinary spending has grown during years of recession

Source: KPMG, Bureau of Economic Analysis, Packaged Facts, and William Blair & Co., as published in *Veterinary Economics*, April 2008.

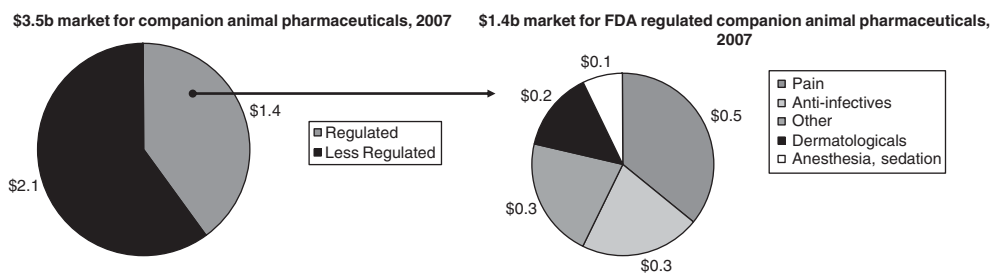


Figure 2: US companion animal pharmaceutical market, 2007

Source: Fountain Agriconsult, LLC and Putney estimates, April 2008.

animal health market is driven by the growing human–animal bond, leading to more aggressive and expensive medical intervention, and therefore longer life spans for pets’,⁸ according to William Blair’s Veterinary Industry Report. Pain drug usage is increasing in pets, as veterinary pain protocols become the standard of care and pet owners are reluctant to see their pet family members suffer.

Pet owners increasingly demand the same level of care for their pets that they expect for themselves and want complex issues addressed by a specialist. Specialisation is increasing among veterinarians, with 20 specialties recognised by the American Veterinary Medical Association. A recent study indicates that 73 per cent of veterinarians said their clients see more referrals to veterinary specialists today than they did five years ago.⁹ Specialty veterinarians prescribe more drugs and perform more testing and procedures than generalists.

The strong human–animal bond supports increasing expenditures on veterinary care for the pets, including sophisticated, specialised veterinary care such as orthopaedic surgeries and cancer treatments, and the use of chronic medications for conditions such as arthritis, parasites and allergic skin conditions. Behavioural issues are being treated medically, including the launch of Eli Lilly’s Reconcile brand of fluoxetine for dogs with separation anxiety, the same ingredient found in human Prozac and its widely used generic, fluoxetine. About 77 per cent of dogs and 52 per cent

of cats have been medicated in the past year, an increase of about 20 percentage points from 1996.⁵

Sales of FDA approved prescription drugs for companion animals grew at a compound annual growth rate (CAGR) of 8 per cent from 2000 to 2007 and are projected to grow at a CAGR of 6 per cent from 2008 to 2012, including the expected price declines resulting from generics.¹⁰

While dogs represent the largest pet medicine market, cats present a market that is both significantly underserved and price sensitive. A total of 88 million cats were owned by 38 million households in 2007. Cat owners spend less on their cats and visit their veterinarian less frequently. According to a report by the American Veterinary Medicine Association titled ‘Perceptions and Attitudes of Pet Owners’, about 33 per cent of cats in household with both dogs and cats do not see a veterinarian annually, whereas only 15 per cent of the dogs do not visit a veterinarian.¹¹ Few generics are approved for cats, and no oral solids have been demonstrated to be bioequivalent in cats.

VETERINARY GENERICS: THE ROAD LESS TRAVELLED

Today’s animal health market resembles the human pharmaceutical market of the early 1980s, prior to the development of the human generic drug industry that now sells 65 per cent of all US prescriptions.¹² The market for prescription veterinary drugs for companion animals; generally defined as dogs,

cats and horses but sometimes also including pocket pets and exotics, differs from the large animal pharmaceutical market where medical treatment and prescription medication decisions are based entirely on economics. There are also no third-party payers to drive generic substitution, as the pet insurance market is in its infancy.

Trends in pet healthcare mirror those in human medicine. Pets are living longer and experiencing health issues associated with old age, including arthritis, metabolic disorders, and cancer, as well as dermatological conditions and infections — many of which require frequent or chronic drug use. The American Veterinary Medical Association estimates 44 per cent of the country's dogs are more than six years old, compared with 32 per cent in 1987. The Association for Pet Obesity reports that 45 per cent of US pets are overweight or obese.

Treatment plans for pets can be as complicated as they are for humans. As more is understood about pain in animals, pain protocols are being revised and use of analgesic drugs is increasing.

Pet owners pay out of pocket for veterinary visits and prescriptions for their pets and many have trouble paying for prescriptions. Often, an inability to pay compromises compliance as pet owners will skip or halve doses to extend the life of a prescription — resulting in the animal not getting the treatment prescribed by the veterinarian.

On the practitioner side the business landscape is also changing. The veterinarian customer base is consolidating as small, independent veterinary practices are acquired by corporate chains. Internet buying by pet owners threatens existing supply chain relationships as well as veterinary pharmacy income — which represents 28–33 per cent of the revenues at an average veterinary practice — while providing the pet owners with convenience and service. To help keep prescriptions in the clinics, home delivery of pet prescriptions is available in partnership

with veterinary practices, which is likely to increase drug usage by providing convenience for prescription drug refills and cost savings to pet owners. Human generics used 'extra-label' are a staple of veterinarian prescribing, because there are fewer molecules approved for pets than for humans. For instance, cancer is being treated in both dogs and cats, while as yet no oncology drugs have ever been approved by the FDA for pets. Human generics are also used on an extra label basis by companion animal veterinarians to offer lower cost options to pet owners.

These trends support increased drug usage as well as future higher rates of penetration for generics, in contrast to the historically low rates of generic penetration for the limited number of generics approved for pets to date. Veterinary generics for leading chronic and frequently used pet medicines in the future will offer alternatives to branded medicines often costing more than \$3 per pill or \$90 a month for a pet.

GENERIC PENETRATION TO DATE

The US companion animal health segment is roughly one twentieth the size of the human market and to date there haven't been any animal generic companies focused on development of true generics with the experience and skill set to successfully achieve bioequivalence and overcome barriers to entry for key veterinary products.

As of 2006, according to the CVM's 'Green Book', of the products listed for dogs and cats, 86 per cent have no generics approved and another 7 per cent have only one generic approved. Ninety seven per cent of the CVM approved drugs for dogs and cats have fewer than three generics.¹³ The small number of products where cost competitive generics are available contrasts with the human pharmaceutical market, where the vast majority of products in the Orange Book whose patents have expired have three or more approved generics, the usual standard in the human market for heavy competition.¹⁴

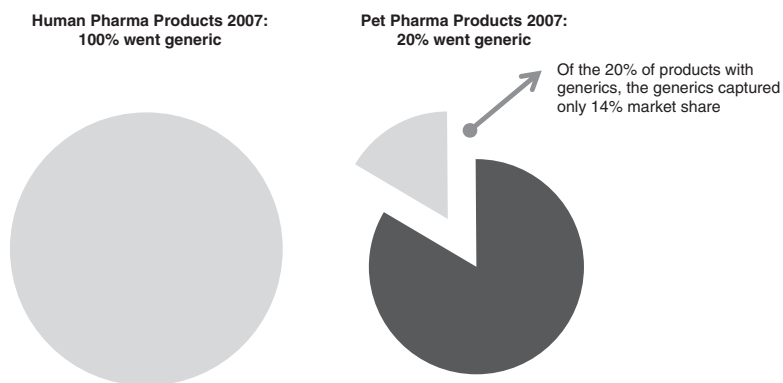


Figure 3: Comparison between human and veterinary products after patent expiry
 Sources: Wolters Kluwer Health Phast Leading Human Products 2005, 2007; Market Dynamics, Inc. Leading Companion Animal Products 2005, 2007; FDA Orange Book; FDA Green Book.

Between 2005 and 2007, 80 per cent of the top 20 selling companion animal veterinary products (16 products) had expired product patents. Equivalent generics were approved for only 19 per cent (three) of these products¹⁵ (Figure 3). All of the human pharmaceutical products in the top 20 (by sales) that lost patent protection between 2005 and 2007 (five products) had generics approved and launched (Figure 3). On average the human generic drugs captured 87 per cent share of the market within 12 months of entry.¹⁶

Brakke Consulting estimates generic sales of drugs for companion animals totalled a mere \$140m in 2007, representing an estimated 4 per cent of the sales in dollars of the companion animal market.¹⁷ Unlike the human pharmaceutical market, where generics usually erode 80–90 per cent of brand market share within six months of launch, the veterinary pharmaceutical market has historically had a low rate of generic penetration and most products with expired patents have no generics. Large pharmaceutical branded animal health subsidiaries generate 85 per cent of vet pharmaceutical revenues and have retained 50–85 per cent market share even where generics have been approved. The combination of a market dominated by

branded animal health subsidiaries and very weak generic companies, plus a historically fragmented customer base comprised of small, geographically dispersed vet practices, explains the small generic market to date.

The small sales of veterinary approved generics, however, are in contrast to the US \$271m in human pharmaceuticals, mostly generics, sold to pet owners by vets or purchased by pet owners from human pharmacies.⁷

Brand price erosion on the few FDA approved veterinary products for which generics do exist has reached only 50 per cent even years after generic launch. The price erosion is even less significant for products with one generic entrant.

THE VETERINARY GENERIC MARKET: IS IT POISED FOR GROWTH?

The companion animal pharmaceutical market is expected to grow at a CAGR of 6–7 per cent in the next few years. Market trends and drivers supporting that growth are also predicted to contribute to the entry and acceptance of veterinary generics.

Large veterinary practices will play a significant role in the expansion of the veterinary pharma market. These practices, which are run as businesses, will look to

veterinary generic drugs as a means by which they can increase margins and keep prescriptions in the animal hospital rather than losing prescriptions to human pharmacies such as WalMart. The availability of lower cost generic prescribing options allows veterinarians to make treatment decisions based on medicine rather than on the clients' ability to pay — allowing their customers to afford to treat pets with chronic and frequent needs for drugs.

Veterinary practices both prescribe and dispense drugs, so they are in competition with online retailers offering vet drugs direct to pet owners. To date, veterinarians have turned to human generic drugs to help find cost-effective solutions for their clients. The human generics that have been substituted for economic reasons, however, often offer less convenient dosing or are less efficacious in pets than veterinary approved drugs. Veterinary approved bioequivalent generics will help to solve veterinarians' need for high quality, low cost prescribing options.

Many veterinary hospitals are starting to work with online service organisations to offer home delivery of pet prescriptions to further combat the loss of prescription sales to internet pharmacies such as www.1800petmeds.com that do not work with veterinarians. The convenience to the pet owner is likely to increase refills and consequently drug usage.

The veterinary market will benefit and grow from the improved customer service and secure supply chains offered by generic companies built on the human model, in contrast to the poor service and frequent stock outs common to veterinary companies. Any generic company seeking to grow market share in the veterinary sector will, however, need to create brand recognition and trust to enable veterinarians to have confidence in the products. Human generic companies pursuing generic veterinary drug approvals to date have largely abandoned their applications after failing to achieve significant sales without a dedicated sales team and veterinary-focused

marketing and branding effort. For instance, one human generic company that received the first generic approval for a US \$60m chronic drug use has achieved only low single digit market share several years after launch. Market share has been limited both by lack of understanding of and inability to communicate to veterinarians and the big pharma veterinary brand company's anti-generic tactics and market limiting contracts with veterinary distributors that have successfully blocked the generic from every national distributor serving the veterinary sector.

Finally, patent challenges have not been a strategy for US veterinary market entrants. Experienced generic manufacturers, however, could employ this tactic in the future — particularly to gain entry for the large selling, well-known flea and tick products, several of which have more than US \$100m in annual sales. But, the leading parasiticides are combination products with ingredients regulated by the EPA, rather than the FDA, and therefore require regulatory and legal expertise outside of the human realm in order to overcome barriers to entry and achieve regulatory approval.

CHALLENGES

Prior to commercialisation, the veterinary regulatory process poses significant hurdles for companies looking to enter the vet pharma market. Although the CVM (regulating veterinary drugs) and Center for Drug Evaluation and Research (CDER; regulating human drugs) are both FDA agencies, they are different centres with different reviewers and different regulations, guidance, standards, applications and formats. Today, CVM has a significant backlog resulting in lengthy approval times for generics — a barrier to entry that will take time to correct. On the human side, the FDA's Office of Generic Drugs (OGD) averages 16.3 months to review and approve an Abbreviated New Drug Application (ANDA).¹⁸ In sharp contrast, CVM approval times for Abbreviated New

Animal Drug Applications (ANADAs) can be two to three times as long, resulting in applications that often take four to five years for approval, particularly for drugs required to demonstrate bioequivalence.¹⁹

To address the backlog and lengthy review times, the veterinary generic trade association, the Generic Animal Drug Alliance (GADA) recently negotiated user fees with CVM. In May 2008 the first generic user fee program, the Animal Generic Drug User Fee Act (AGDUFA), was sent to Congress alongside the reauthorisation of the Animal Drug User Fee Act (ADUFA). ADUFA authorises CVM to collect fees for New Animal Drug Applications (NADAs) to achieve shorter, more predictable review times by adding reviewers at CVM. AGDUFA creates a provision by which drug manufacturers would, if the Act is authorised by Congress, pay fees to supplement the Agency's appropriations to speed review of generic animal drug applications. Funding will be tied to specific and measurable performance goals.

There are still some unknowns associated with AGDUFA. The bill has yet to be passed by the United States Congress. Once passed, CVM will then need to implement the plan that will position the agency to achieve the agreed upon goals. Even with AGDUFA, review times for generic veterinary drugs are unlikely to change dramatically for some time. In the first year, the first review cycle is planned to be reduced to 23 months, and by 2013 to nine months — timing that will still lag behind the target of six months at OGD for human generics and behind reviews of NADAs.

Not only are review times significantly longer on the veterinary side, but there are also certain regulatory and legal practices that, while common in human medicine, have not yet played out at CVM. Patent challenges, as an example, are uncharted territory for CVM and the agency will need to develop standards as they handle their first cases — initially increasing, rather than decreasing, regulatory timelines.

Commercial challenges in the veterinary pharmaceutical channel exist as well. The customer base is fragmented and difficult to reach. There are approximately 27,000 private veterinary practices in the US, of which roughly 21,000 are companion animal focused.²⁰ The majority of companion animal practices are one to two veterinarian practices scattered around the US and too dispersed for product manufacturers to reach efficiently. Distributors that serve veterinarians exclusively have broad and deep product lines and experienced sales reps with long relationships with their veterinarian and vet practice manager customers. Vet distributors are not motivated to take on one or two products from a new manufacturer, and have too many products to give attention to one or two small ones. The veterinary distributor reps have, over time, become valued resources of product information for the busy veterinarian, often exceeding brand pharma detail reps in their knowledge and depth of relationship and service to the vets. In fact, 89 per cent of veterinarians who participated in a recent William Blair survey indicated that they are satisfied or very satisfied with the leading distributors.²¹

Veterinarians turn to academics and thought leaders, continuing education programmes, as well as brand pharmaceutical and distributor sales representatives for product information. As true veterinary generics — CVM approved, bioequivalent generics marketed as generics rather than branded generics — have not been available, there are limited resources from which vets can learn about, and better understand, the safety, efficacy and benefits of generic drugs. Consequently there are many misconceptions about generics that must be addressed before a generic manufacturer can successfully launch products and gain market share. Veterinarians' limited understanding of the value of generic drugs, when coupled with the lack of third party payors, suggests that generic substitution is far from guaranteed and will require a process of education.

In addition to understanding the valuable role generic drugs can play in a veterinary practice, veterinarians need to know the generic company will support them as the brand pharma companies do today. Brand companies have veterinarians and veterinary technicians on staff to respond to product questions, including information about dosing, delivery and potential adverse events. Generics companies will need to provide technical support in order to become established as a trusted source of veterinary drugs.

The companion animal veterinary community is tightly connected through industry organisations and online user groups. Veterinarians are quick to share information and challenges in public forums. Manufacturer entrants that do not understand how the customer wants to be served will quickly have their shortcomings shared widely among veterinarians through message boards such as the Veterinary Information Network (VIN) and at frequently held national and regional conferences.

WHO WILL SUCCEED?

First and foremost, success in the companion animal veterinary generic market will be determined by a company's willingness to listen to, and learn from, the customer — companion animal veterinarians. Not only are they the decision makers and prescribers of treatment plans, but also dispensers of prescriptions to the end users — pet owners.

Generic veterinarian pharmaceutical companies must have a willingness to develop a broad basket of products, in multiple therapeutic categories and multiple dose forms, including oral solids, soft and hard chews, liquids and injectables as well as ophthalmics and otics. Generic vet companies will need to mimic brand pharma companies investments in education about their products and to increase awareness of the safety, efficacy and value of generic drugs as well as committing resources to support the industry

and veterinary practices with technical information about products and resources that will support pet owner compliance.

Even before launch, the company that is successful will have strong relationships with the regulatory officials at CVM. Complete, detailed applications supported by high-quality manufacturing will potentially limit reviews to one cycle — speeding time to market. Companies looking to employ strategies not yet documented by CVM, however, will need to work with the reviewers to pave the way and be patient as CVM develops procedures and guidance to manage the process.

Once in the market, manufacturers will need to be able to control costs in order to compete while allowing for the industry average 25–35 per cent mark-up taken by distributors — the price to reach the fragmented customer base.

Ultimately market entrants will need to put aside the human generics 'hat' and build a uniquely veterinary brand that stands for quality and service to vets who treat pets — building marketing and education functions that are not core competencies of the traditional US generic business model. In spite of the challenges of developing and filing submissions for a broad basket of products, creating a brand, communicating with a fragmented customer base and working with the FDA's CVM to achieve regulatory approvals, companies will tackle the companion animal generics market. Generics will change the future of pet healthcare as generics have changed human healthcare. The question is not if, but when.

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