

VETERINARY HEALTH MARKETS

***(SAMPLE COPY, NOT FOR
RESALE)***

Trends, Industry Participants, Product Overviews and Market Drivers



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SAMPLE

1. Overview

Veterinary health products, including veterinary pharmaceuticals, biologicals and medicated feed additives (MFAs), have transformed the health and welfare of livestock and companion animals worldwide. The range and complexity of animal health products continues to expand, encompassing anti-infectives, parasite controls, reproductive aids, metabolic drugs, feed additives, antibiotics, vaccines, topical solutions and imaging diagnostics as well as novel treatments for chronic conditions such as osteoarthritis, cardiovascular disease and even cancer. This TriMark Publications report provides a detailed analysis of the global veterinary health market, including common diseases in cattle, pigs, poultry, dogs, cats and horses; veterinary non-steroidal anti-inflammatory drugs (NSAIDs); antibiotics; veterinary antifungal drugs; veterinary anthelmintic (parasiticides); veterinary biologics (vaccines); veterinary diagnostics; and animal feed additives. This report also provides a thorough analysis of the companies known to be marketing, manufacturing or developing veterinary health products as well as detailed tables and figures covering veterinary health markets around the globe. Specifically, this study focuses on advances and changes in:

- Regulatory environment.
- Biological products.
- Pharmaceutical products.
- Animal health diagnostic products.
- Emerging biotechnology products.

The analysis surveys the market dynamics and technological trends to answer several basic, but essential, questions about this market:

- What changes will occur in the regulatory environment (*e.g.*, FDA Guidance for Industry #213 and draft Veterinary Feed Directive (VFD)¹)?
- How will tighter regulation of hormone and antibiotic use in feeds impact livestock markets?
- How are changes in meat consumption influencing the market for livestock health products?
- What new companion animal products are coming on the market?

1.1 Scope of this Report

The global market for veterinary therapeutics and diagnostic products has grown dramatically. This report outlines market size, market growth, forecasts and competitive information. Focusing both on companion (pet) animal markets and agricultural livestock, this report examines the markets for pharmaceuticals, vaccines, diagnostics and feed additives. Specifically the report covers:

- The size of the markets for companion animal products, broken down by type of animal (*e.g.*, cats, dogs and small animals).
- The size of livestock products markets.
- The impact of U.S. Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) regulations on these markets.
- The identity of the top market players, along with its market shares and future prospects.
- The impact of the antibiotic feed additive controversy on the agricultural market.
- The key players in the veterinary pharmaceutical and diagnostic markets.

¹Guidance 213 establishes a three-year timeframe to phase out the use of certain medically important antibiotics as growth promoters and establish veterinary oversight for antibiotics used in feed or water.

Analysis of the key market segments responsible for growth in this industry is reported, and includes accurate and up-to-date research and development (R&D) information from the major veterinary companies; identification of the unmet needs in current veterinary treatment and how far each product goes to meeting these needs; an in-depth comparative analysis of individual products and diagnostic tests; and the future sales potential of veterinary therapeutics and diagnostic testing markets.

1.2 Methodology

The author of this report is a Ph.D. in biochemistry from the University of Minnesota, with many decades of experience in science writing and as a medical industry analyst. He has over 30 years of experience in laboratory testing and instrument and reagent development technology, as well as extensive experience in senior level positions in biotech and medical service companies. Moreover, he has received the American Association of Clinical Chemistry's (AACC) Division of Animal Clinical Chemistry's (DACC) prestigious *Outstanding Contributions to Animal Clinical Chemistry* award for 2013. The editor holds a Ph.D. in Life Sciences with specialization in molecular biology. She has authored several peer-reviewed articles as part of her post-doctoral research.

Company-specific information is obtained mainly from industry trade publications, academic journals, news and research articles, press releases and corporate websites, as well as annual reports for publicly-held firms. Additionally, sources of information include the Animal Health Institute (AHI), the American Pet Product Manufacturers Association (APPA), International Federation for Animal Health (IFAH), Kleinpeter Equine Veterinary Services, LLC, American Society for Microbiology, European Union (E.U.) Feed Additives & Premixtures Association, United Soybean Board (USB), U.S. Soybean Export Council (USSEC), Illinois Soybean Association, HighQuest Partners, LLC, Soyatech, LLC, Agriculture & Food (Denmark), World Society for the Protection of Animals (WSPA), Australian Companion Animal Council, American Horse Publications (AHP), Strategic Equine, Inc., Swedish University of Agricultural Sciences, Agriculture and Agri-Food Canada's Market Indicator Report, SeQuent Scientific Limited Annual Report, American Veterinary Medical Association (AVMA), New Zealand Trade & Enterprise, U.S. Commercial Service, U.S. Department of Commerce, IFAH Europe, National Office of Animal Health (NOAH), International Starch Institute and several other veterinary industry groups, as well as U.S. and international governmental departments of agriculture and livestock. Where possible and practicable, the most recent data available have been used.

Some of the statistical information was taken from Biotechnology Associates' databases and from TriMark's private data stores. The information in this study was obtained from sources that we believe to be reliable, but we do not guarantee the accuracy, adequacy or completeness of any information or omission or for the results obtained by the use of such information. Key information from the business literature was used as a basis to conduct dialogue with and obtain expert opinion from market professionals regarding commercial potential and market sizes. Senior managers from major company players were interviewed for part of the information in this report.

Primary Sources

TriMark collects information from hundreds of Database Tables and many comprehensive multi-client research projects, as well as Sector Snapshots that it publishes annually. TriMark extracts relevant data and analytics from its research as part of this data collection.

Secondary Sources

TriMark uses research publications, journals, magazines, newspapers, newsletters, industry reports, investment research reports, trade and industry association reports, government-affiliated trade releases and other published information as part of its secondary research materials. The information is then analyzed and translated by the Industry Research Group into a TriMark study. The Editorial Group reviews the complete package with product and market forecasts, critical industry trends, threats and opportunities, competitive strategies and market share determinations.

TriMark Publications Report, Research and Data Acquisition Structure

The general sequence of research and analysis activity prior to the publication of every report in TriMark Publications includes the following items:

- Completing an extensive secondary research effort on an important market sector, including gathering all relevant information from corporate reporting, publicly-available data and proprietary databases.
- Formulating a study outline with the assigned writer, including important items, as follows:
 - Market and product segment grouping, and evaluating their relative significance.
 - Key competitors' evaluations, including their relative positions in the business and other relevant facts to prioritize diligence levels and assist in designing a primary research strategy.
 - End-user research to evaluate analytical significance in market estimation.
 - Supply chain research and analysis to identify any factors affecting the market.
 - New technology platforms and cutting-edge applications.
- Identifying the key technology and market trends that drive or affect these markets.
- Assessing the regional significance for each product and market segment for proper emphasis of further regional/national primary and secondary research.
- Completing a confirmatory primary research assessment of the report's findings with the assistance of expert panel partners from the industry being analyzed.

1.3 Executive Summary

Modern medicines, biosecurity measures, healthier housing systems and food additives have significantly improved the health and productivity of livestock. The sustained growth of the animal health industry has enabled livestock producers to achieve production levels required to meet future food demands. Most pharmaceutical companies are focused on two production stages: new product development and manufacturing and distribution. The animal health industry is diversified in terms of the number of species it covers, and faces constant challenge from emerging or established pathogens. The threats include diseases that affect animals exclusively like foot and mouth disease (FMD), as well as agents that affect both animals and humans, such as bovine tuberculosis and paratuberculosis, avian influenza, anthrax, bovine spongiform encephalopathy (BSE) and West Nile virus. The OIE estimates that diseases in food producing animals cause a % loss in productivity worldwide. This represents a loss of approximately [REDACTED] tons of meat and [REDACTED] tons of milk, equivalent to a loss in revenue of \$ [REDACTED] per year.

Large animal veterinary medicine is becoming an important facet of public health, worldwide. Public health and food supply, everywhere, are at constant risk from animal diseases that can place a heavy burden by destroying animal stock or causing zoonotic outbreaks in humans. The toll of animal diseases can be measured in terms of losses in production, resources needed to monitor and control outbreaks, restrictions on trade and its negative impact on human health and welfare. As the demand for livestock production continues to grow, the need for superior animal health control systems emerges, driving the costs of animal disease management. For example, greater spending on disease surveillance and control leads to smaller losses in animal production and lower impacts on human health when outbreaks occur. The main cost of animal diseases in these situations is fueled by the need to monitor and control disease. A serious outbreak can precipitate damage within the industry and impact local and regional economies by affecting potential production, incurring costs of treatment, losing attractive export markets and resulting in death or disability when the disease passes to humans. As newer challenges emerge and evolve, the veterinary medicine industry needs new products to prevent and treat new, as well as established, pathologies. Emerging diseases, such as the recent outbreak of H7N9 Avian Influenza virus, demand research and development of new, safe and effective vaccines.

Growth in the companion animal medicines and vaccines sector is driven by stabilizing economies and related increases in disposable income, increasing pet ownership, longer life expectancies for companion animals, increasing medical treatment of companion animals and advances in animal health medicines and vaccines. Industry sources indicate that companion animals improve the physical and emotional well-being of pet owners. Pet ownership and spending per pet are increasing globally, and industry sources report that pet owners indicate a

preference for reducing spending on other aspects of their lifestyle, including entertainment, clothing and household goods, before reducing spending on pet care.

Within the companion animal segment of the industry, there has been significant growth in the prevalence of age-related pathologies in companion animals, creating market pressure for re-formulation of current products and the discovery of new drugs. Current veterinary product development necessitates expertise in the emerging landscape within the companion animal sector, supplemented by an understanding of both global and local regulatory requirements. In order to maintain a competitive edge, access to sources of new active ingredients and the ability to deliver within existing timeframes are critical to the veterinary drug-discovery process for participants in the animal health industry.

Global sales of human drugs are more than █ times higher than those of veterinary medicines; the value of the world animal health market represents less than █% of the world human health market. Current veterinary medicine identifies potential new drugs from its internal industry research laboratories, while also leveraging R&D from the human health and the agrochemical sectors. Important active ingredients such as Fipronil (discovered and developed by Rhône-Poulenc for use against a wide range of field and horticultural crop and soil pests) became a blockbuster in the animal health market as Frontline[®], the spot-on against fleas and ticks from Merial, earning revenues of just over \$█ in █. (Sanofi, the parent company of Merial, reported the sales of Frontline products at \$█ for █). From human health, a number of modern therapies that induce autoimmunity have found their way into the veterinary sector, leading to the development of products such as Pfizer's Improvac[®], an anti-GnRH vaccine to control boar taint.²

According to the Pharmaceutical Research and Manufacturers of America (PhRMA), the average cost to develop a new human drug is about \$█, partly due to the █- to █-year development pipeline, but also because of the high rate of failure. For example, PhRMA also reports that for every █ to █ promising compounds tested, just five medicines will make it to clinical trials involving patients and, of those, only one will eventually receive FDA approval. IFAH estimates that it takes █ to █ years to bring a new product to the animal health market, at an average cost of about \$█ (€█). The ten largest animal health companies invest an average of █% of their sales into research and innovation activities, a total amount of about \$█ every year. While the figures are much lower for animal health products, the processes are similar, creating similar high costs to develop and release new drugs. According to AHI, R&D expenditures on animal health products in the U.S. crossed \$█ in █.

In the highly competitive landscape of the animal health industry, innovation is indispensable in developing a pipeline of new products to keep animals healthy. One strategy that these companies have employed successfully in the past has been to compete by jumpstarting their research pipelines through the acquisition of start-ups which may emerge from government or university laboratories. Another way to capture new product lines and new markets is through mergers and acquisitions (M&As). There have been a series of high-profile M&As in the recent past, leading to a higher degree of consolidation within the industry. In April █, Eli Lilly and Company purchased Novartis Animal Health, in an all-cash transaction worth \$█ that will strengthen Lilly's animal health business, Elanco. The transaction is expected to close by the end of the first quarter of █. Through this acquisition, Elanco will be the second-largest animal health company in terms of global revenue, and will solidify its number two ranking in the U.S. In █, the top five players in the industry garnered ~█% of the total market share: Zoetis (█%), MSD Animal Health (█%), Merial (█%), Elanco (█%) and Bayer Animal Health (█%).

²Guérin, M. C., Ramon, G., & Salmon, D: "Expanding New Developments and enlarging business into animal health," *International Pharmaceutical Industry*, Volume 3, Issue 3.

Investments in animal health segments are an attractive option for the pharmaceutical industry as it seeks to diversify its offerings; animal health segments provide a steady revenue source. Animal health is also considered an attractive business for pharmaceutical manufacturers as there are fewer pressures over patent expiries and regulatory interventions, and less competition from generics. According to Generic Animal Drug Alliance (GADA), among the top █ human drugs that lost patent protection between █ and █, █% went generic; and of the top █ veterinary companion animal drugs during the same time frame, only █% went generic. The companion animal health market is small compared to the human health market, but it is lucrative because pet owners consider cats and dogs part of their families and will pay dearly to care for them. Performance of animal health divisions varies by company; within major pharmaceutical companies, companion health products add between █% and █% to company earnings. In pure-play companies the contribution can be much higher—for example, animal health products for companion animals made up █% of annual sales for Zoetis in █. While there has been increasing interest in operation of animal health segments by the top pharmaceutical companies, the animal health business within the global health market is also in a state of flux with a select few pharmaceutical giants opting out of the veterinary business due to lower sales and more regulatory restrictions. So far in █, the animal health industry has seen several deals and mergers, most notably Eli Lilly's acquisition of Novartis Animal Health. In April █, Merck entered talks with Bayer over swapping assets of its OTC unit for Bayer's Animal Health business. While Bayer agreed to buy Merck & Co.'s consumer unit for \$█, it chose to stay on in the animal health business, reaffirming its commitment to its animal health unit.

Several factors influence the trend for investment in the animal health sector by the pharmaceuticals industry: for one, the time and capital taken to bring a new veterinary health product to market is significantly lower than in human pharmaceuticals. The animal drug discovery and approval process encounters fewer hurdles and the firms are able to leverage their human health R&D. For example, in █, Sanofi spent only █% of animal health revenue on R&D, versus █% for the firm's pharmaceuticals sector. Generic entrants make market segments increasingly crowded and, although price tends not to fall as dramatically as it does in human medicine, the pricing structure within a segment is generally altered. Some reference brands have still been able to maintain a competitive edge by adding additional claims, changing formulation (*e.g.*, from traditional tablets to flavored chewable tablets) or by adding additional active agents.

In the companion animal sector, companies encounter much less pricing pressure. Companion animal products, such as flea and tick products for dogs are bought by individuals with little bargaining power. The decentralized buyer pool also minimizes the gravity of sales drop offs when a product loses patent exclusivity. In the human health market, the large payers make patients aware of generic options and pressure patients to use them, but since companion products are purchased by individuals, the companies are often able to maintain market share with off-patent products. Since there are fewer generic competitors, individuals are usually unaware of generic alternatives, or they are usually willing to pay a premium for a brand they trust, similar to the market for over-the-counter consumer products. Given the costs incurred and time required (around █ to █ years) to develop new animal health products, it is likely that intellectual property, not only in and around new chemical entities but also on formulations and manufacturing processes, will remain an important and highly competitive, and potentially litigious, area.

The world market for animal health products (a sector spanning veterinary pharmaceuticals, biologicals and medicated feed additives (MFAs), but not nutritional supplements or pet food), was worth \$█ in █. The market is expected to grow and reach \$█ in █. The veterinary market for Europe accounted for about \$█ in █ at approximately █% of the total global market. The veterinary market for North America accounted for about █% of the total market share, and was worth \$█ billion in █. Growth in livestock production has been very strong in Latin America and Asia. In these regions, improvements in animal health, new productivity gains and increased purchasing power should result in further increases in production. The veterinary market for Latin America accounted for about █% of the total market share, and was worth \$█ in █. The Asian market was worth about \$█ which accounted for █% of the total global market. Within the \$█ animal health market, █% was accounted for by pharmaceuticals (\$█), █% by biologicals such as vaccines (\$█) and █% by medicinal feed additives (\$█).

Of the global \$█ animal health market in █, healthcare for food animals accounted for about \$█ and the companion animals segment was worth \$█. Brazil is spending more on animal health and, in █, the country spent about \$█ on veterinary health products. According to the national union of

industry of products for Animal Health products (SINDAN), Brazil is one of the world's largest markets; it grows an average of █% per year. This growth involves every category of products except for swine and every animal category shows consistent growth. Animal vaccines had a global market of \$█ in █, and this market is likely to reach the value of \$█ in █. Although most countries in the world depend on food animals for protein, the developed countries consume nearly █% of animal vaccines and the developing and poorly developed countries consume only about █% of vaccines. The U.S. veterinary vaccine market was worth about \$█ in █ and this figure is predicted to grow to \$█ in █.

Europe is the second largest market for animal health products and according to IFAH Europe, the veterinary health market in Europe was worth about \$█. NOAH represents the companies that research, develop, manufacture and market animal medicines in the U.K. In █, NOAH's members accounted for £█ of sales (through September █), representing around █% of the U.K. animal health market. Veterinary products for companion animals in the U.K had a market share of █%, while products for food animals had a share of █%.

The global market for animal feed additives in █ was worth about \$█, and is anticipated to reach \$█ billion by █. The global feed additive market is shared by a number of regional and international players including Adisseo, Ajinomoto, Alparma, Alltech, Archer Daniels Midland, BASF, Cargill, CJ Corporation, Danisco A/S, Degussa Feed Additives, DSM Nutritional Products, Eli Lilly's Elanco Animal Health, Evialis, Kemira Industries, Kyowa Hakko Kogyo Co., Lallemand, Lesaffre Yeast, Novozymes, Novus, Nutreco, Phibro, Provimi Holding and Tessenlerlo. The value of the animal feed additive market within the North American region was about \$█ and this value is expected to reach \$█ by █. The U.S. accounts for approximately █% of market share within this segment. The feed additive market in Europe was worth about \$█ in █ and is expected to steadily rise to \$█ by █. The estimated market for the Asian region was about \$█ in █ and it will be about \$█ in █.

There is significant growth potential for enzymes in regions such as North and South America as well as in China. Enzymes used in animal feed represent about █% of the global enzyme market, with human food, starch processing, and industrial applications representing █% of the market. The global market for antibiotics to be used in animal feeds was worth about \$█ in █, and this figure is likely to grow slowly and reach \$█ in █. The global market for feed additive grade enzymes was about \$█ in █, and it will grow at not less than █% CAGR to \$█ by █. The global sales of amino acids used in animal feeds were worth about \$█ and this market is likely to expand to \$█ in █. Poultry's share of world meat demand is expected to rise from █% in █ to █% by █, reaching volumes of █ tons in █, and █ tons in █. The demand for methionine is proportionate to the demand for protein, poultry in particular. As a result, the methionine market will grow at a rate of █% or slightly higher over the next decade. The total methionine market is projected to increase from the current size of █ KMT to █ KMT by █.