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Growth Drivers 2022-2032

Into a new era of innovation, regulation and evolution for animal health

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Animal Health | **Report**

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About the Authors

Joseph Harvey is head of animal health at S&P Global. He collaborated with animal health specialist **Stonehaven Consulting** (www.stonehaven-consulting.com) to author this report. Joseph has been writing insight and analysis articles about the animal health industry for over a decade. In his role, Joseph provides news and business analysis regarding the global animal health market across a range of species and products. He conducts exclusive interviews with the sector's biggest companies and experts, as well as start-ups. He also hosts webinars and gives talks on the industry's major trends. Having gained many years of experience in business journalism, Joseph started analyzing the animal health industry in 2012. He previously built his experience by reporting on the human medical devices and diagnostics sector. Joseph is a well-known figure in the animal health sector through his in-depth articles, interviews, podcasts and webinars. His specialist areas include analysis of business trends, M&A, industry rankings, public markets, company strategy and R&D across the animal health industry. He has previously authored special reports regarding the industry rankings in animal health, in addition to contributing to many other reports regarding innovation and business trends.

This report features a chapter focused on the regulatory landscape that has been prepared by **Ingentium Limited**. Ingentium (www.ingentium.co.uk) is a competitive intelligence and intellectual property consultancy specializing in animal health, agriculture and the broader life sciences space. Joining the Ingentium team as lead author of this chapter is **Gilly Cowan**. Gilly has worked for animal health companies for over 45 years, during which she spent 35 years in regulatory affairs before retiring as director of regulatory affairs for Pfizer Animal Health in 2010. After her retirement, Gilly became a consultant to several animal health companies and organizations, such as GALVmed and HealthforAnimals. For GALVmed, Gilly was instrumental in harmonizing the registration requirements for veterinary vaccines and pharmaceuticals in East Africa and for successfully establishing a mutual recognition procedure for veterinary medicines in the East African community. She has also been involved in initiatives such as the International Development Research Centre's Livestock Vaccine Innovation Fund, providing guidance to academics on the regulatory hurdles involved in bringing their often-novel products to the market.

Executive Summary

Dear Reader,

Each year S&P Global teams up with Stonehaven Consulting to provide a *Growth Drivers* report that touches upon the most important trends in the animal health sector. We aim to select a specific topic as a theme for each year. This year, in light of the new rules in place in Europe and the constant reduction of antimicrobial usage globally, the special topic is regulation.

Naturally, regulation and innovation go hand in hand – you cannot have one without the other. Innovation is on the increase in animal health and favorable regulations will help more next-generation products come to market.

There is a buoyancy in the companion animal health sector – a positivity that was only accelerated by the COVID-19 pandemic – and the livestock segment is also striving for innovation, with sustainability and antimicrobial alternatives in mind.

Many readers will be familiar with these trends already. We will attempt to go beyond these and show the underlining reasons why animal health is currently such a strong segment, while also highlighting barriers to growth. The report features exclusive insight from industry experts, covering key points about the industry.

Regulatory consistency and forward thinking from the national agencies will be crucial to opening the door to more investor interest in the animal health sector. Even though there is a groundswell of new technologies coming from an ever-expanding group of start-ups in this sector, there is still a relatively small amount of investors dedicated to animal health.

The emergence of multiple start-ups in animal health is a key sign of the industry's ongoing diversification. Not only is the type of business in the sector diversifying but so are companies' product portfolios, into adjacent and synergistic market areas such as digital technology, genetics and nutrition. Major companies are crossing sectoral boundaries via acquisitions and innovation, creating new allegiances and rivalries.

The information presented here builds on previous S&P Global reports produced over the past three years. The 2019 version of this report, *The New World of Innovation in Animal Care*, introduced the concept of how the top companies in animal care are benefiting from the convergence of technologies across animal nutrition, diagnostics, vaccines and therapeutics in their ongoing effort to generate dynamic growth for their overall businesses. The previous *Growth Drivers 2020-2030* report focused on how animal care industry leaders are proactively managing their portfolios and driving growth using transformational technologies and synergistic market category opportunities.

Last year's *Growth Drivers 2021-2031* installment outlined why the need for external innovation in the animal care space is growing. It also delved into the ways certain animal care trends that emerged during the early stages of COVID-19 have rapidly become mainstream, with some now appearing to have durability for the future.

Growth Drivers 2022-2032 features five interlinking chapters that indicate the direction the animal health industry is headed. **Chapter one** displays the lay of the land by highlighting the fundamentals behind the sector's current status and using market sizing data sourced from Stonehaven Consulting. It indicates the market's leading players – a combination of established names, start-ups and cross-sectoral multinationals from adjacent industries.

Chapter two highlights our predictions for the animal health industry over the next decade. As well as looking at innovation and business trends, we showcase the major changes ahead that will alter the entire value chain across animal health.

Chapter three focuses on innovation and the story behind the race for next-generation products. **Chapter four** is authored by UK-based animal health consultancy Ingentium in collaboration with Gilly Cowan and takes an exclusive look at the regulations impacting the sector. Finally, **Chapter five** provides an overview of the investment trends in animal health. It indicates who is investing across the sector from private equity and venture capital, as well as the spending plans of the industry's leading manufacturers.

Joseph Harvey
S&P Global Commodity Insights
Head of Animal Health

Companion animal services will grow at about 6% over the next decade "driven by volume, price and service intensity".

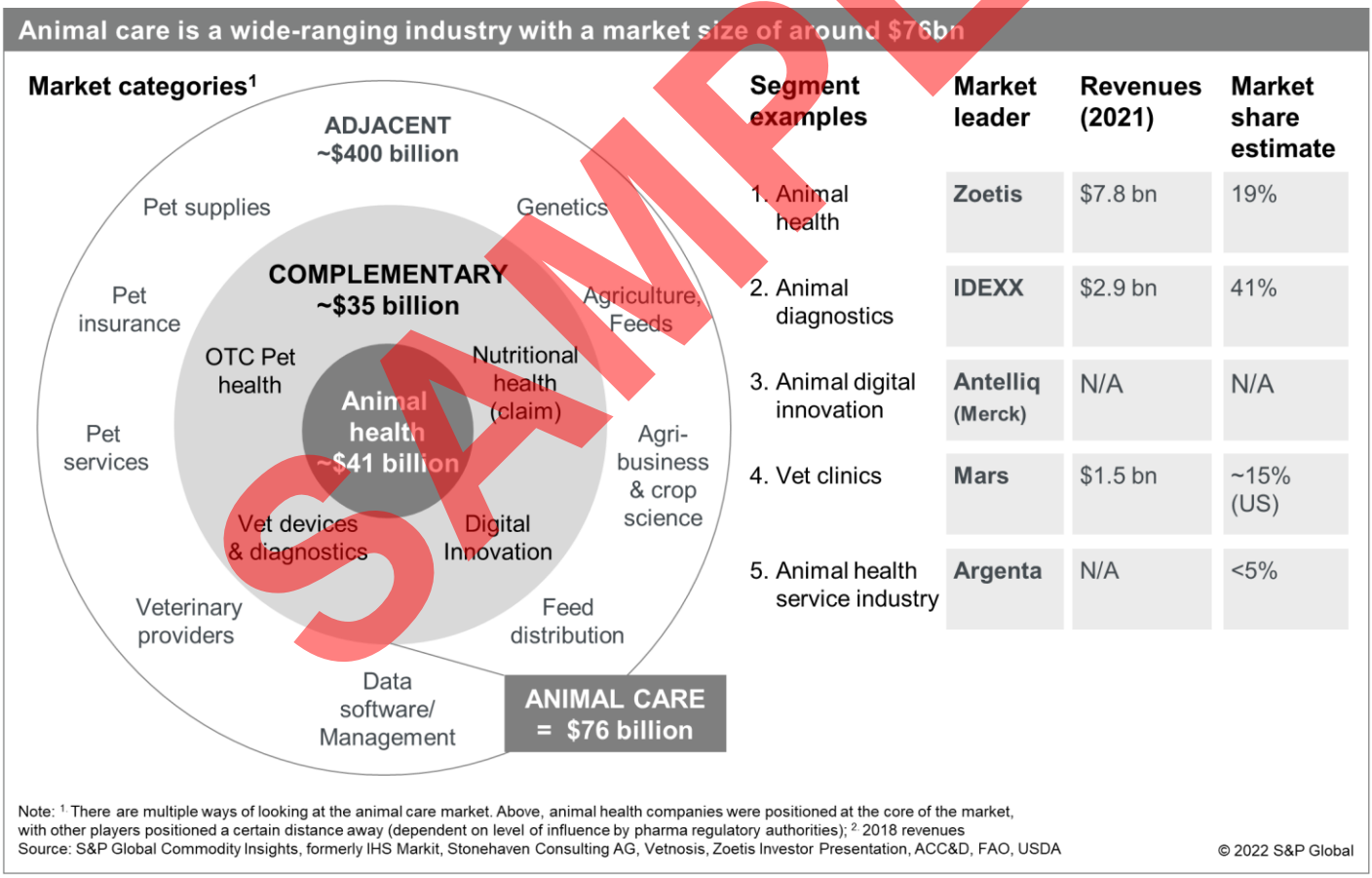
Table 1. **Piper Sandler's 10-year projections for animal health market**

Industry	Food animal market	Companion animal market
Market size	$25-30bn	~$25bn
10-year growth rate	3-5%	5-8%
Drivers	Human population growth, rising middle class demand for protein and pricing increases	Patient volume in vet clinics, pricing, alternative sales channels, and improvement in pet owner engagement
Risks	Shifts in consumer preferences, synthetic meat, and regulations	Consolidation and price concessions, as well as labor constraints at vet clinics

Source: Piper Sandler

With the market already a sizeable and growing industry with adjacent categories like pet insurance, pet supplies, genetics, feed, and feed distribution, S&P Global and Stonehaven Consulting believe the traditional animal health arena is transforming into a broader 'animal care' sector that could potentially be valued at $400 billion – a sizeable market with many attractive opportunities for growth.

Figure 2. Animal care is a wide-ranging industry with a market size of around $76bn



Note: [1] There are multiple ways of looking at the animal care market. Above, animal health companies were positioned at the core of the market, with other players positioned a certain distance away (dependent on level of influence by pharma regulatory authorities); [2] 2018 revenues
Source: S&P Global Commodity Insights, formerly IHS Markit, Stonehaven Consulting AG, Vetnosis, Zoetis Investor Presentation, ACC&D, FAO, USDA

The core animal health sector was historically dominated by the farm animal industry but there has been a great shift towards pet health in recent years. The **opportunity for growth** in the companion animal space is clear, as the sector begins to look more like the human biopharma world – driven by consumerism, e-commerce and innovation. This has led to the increasing importance and prevalence of biologics and therapeutics in the animal health industry. Although the farm animal sector remains the largest portion of the animal health industry, the

Figure 5. Increasing pet ownership, spending and innovation are key growth drivers

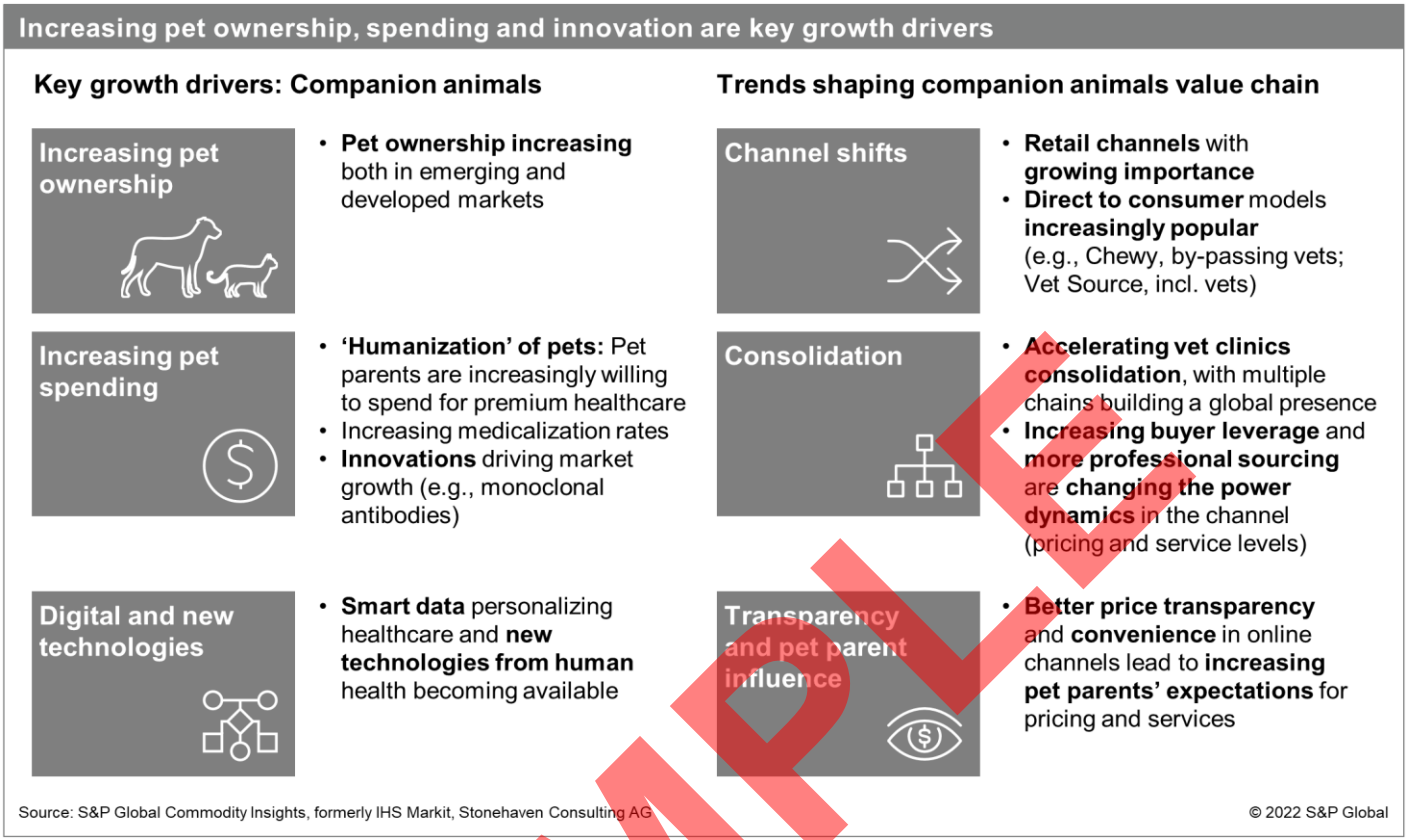
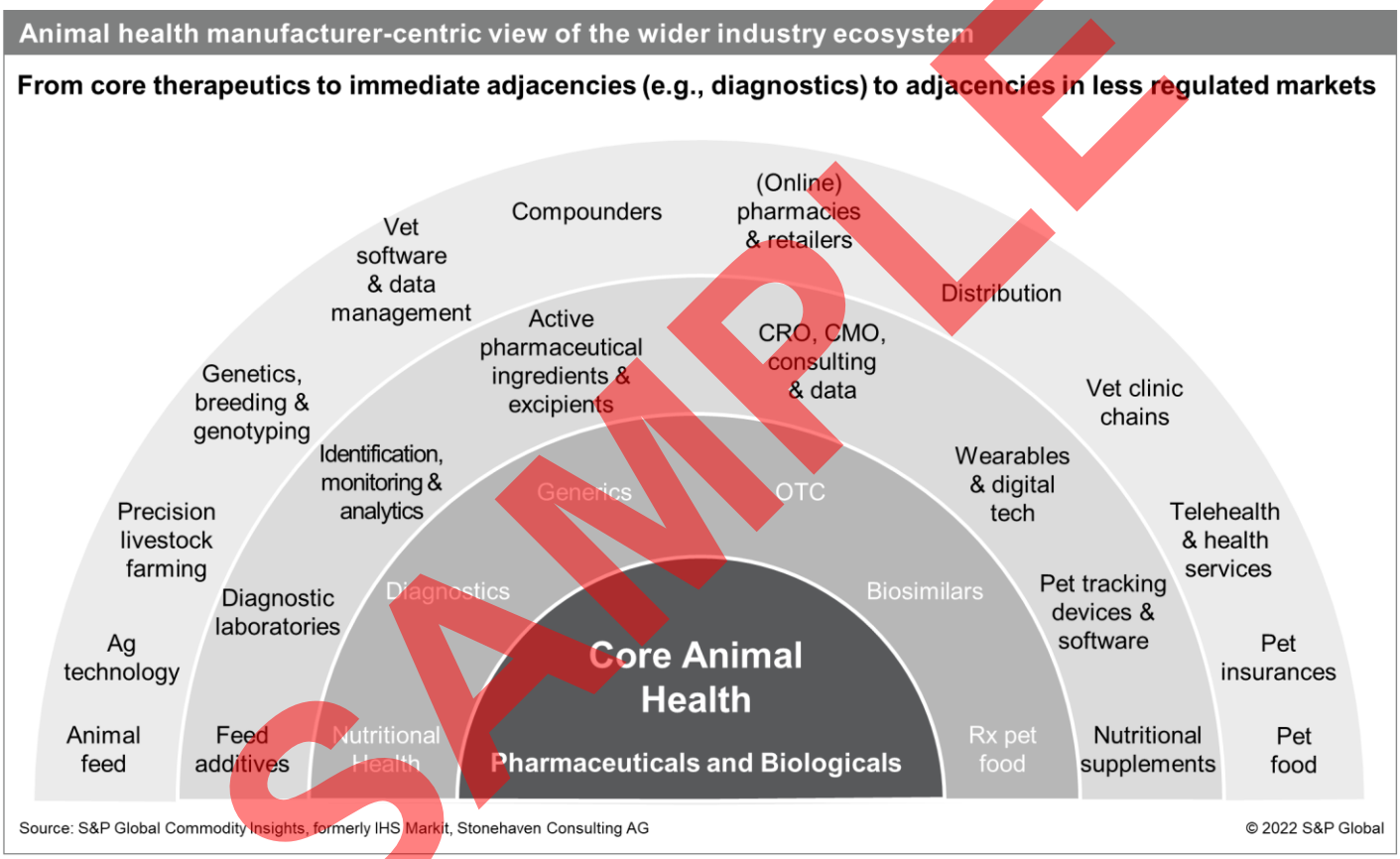


Figure 6. Increased protein demand, sustainability and improved productivity are key drivers

One trend that straddles the companion animal segment and the livestock area is the **greater adoption of non-traditional products**. We see top players increasingly **venturing into adjacencies** beyond their traditional competencies, such as technology, genetics and diagnostics. The companies are attempting to become holistic providers of all types of products and technologies that benefit veterinary clinics and farms. This shift will further spread the boundaries of what is included in the remit of the traditional 'animal health' industry.

This evolution is blurring the lines between what were previously considered separate industries. This is perhaps most apparent in the ongoing **crossover between the animal health and animal nutrition sectors**. With the increasing barriers to using antibiotics, businesses are looking towards nutritional solutions to ensure healthier animals. This has led to the emergence of R&D in the animal microbiome segment.

Figure 7. Animal health manufacturer-centric view of the wider industry ecosystem



For new products and innovation to come to market, animal health needs to cultivate its industry ecosystem. Innovation will come from big multinationals and start-ups alike. The larger businesses need the early-stage companies to help fuel their pipelines and maintain their high growth levels. In order to help the start-ups thrive, **more capital needs to flow into the animal health industry**. There is something of a vicious cycle for the start-ups, as more investment will only arrive when successful exits occur. However, with the industry's second wave of companion animal therapeutic start-ups now progressing their products, more exits could be on the horizon. Companies such as PetMedix, Invetx and Rejuvenate Bio have sourced funding and snared partnerships with top players – indicating the next acquisition of a therapeutics start-up by a top 10 player may not be far away.

Investors from the wider agribusiness sector, as well as funds focused on sustainability and human health, will continue to grow their interest in the animal health industry. However, what the industry needs is **more dedicated funds** that have money set aside for specific animal health deals – usually in the form of venture firms that know the industry well and have domain expertise. This is also the case on the **private equity side** of investment. The

3.
Innovation is the big differentiator

No company ever achieved anything by standing still. Innovation is currently key for growth in animal health. Consolidation among the biggest businesses in the sector means there are not many major acquisition possibilities left available that can completely revolutionize a company's portfolio. The animal health sector has recently seen an increase in its rate of innovation, as it becomes cheaper to work with technologies that have prospered in the human health world over recent decades.

What remains is the option to tap into the pipelines of budding start-ups or fuel internal innovation. Both of these routes are being trod by the major players in animal health. The big four – Zoetis, Merck, Boehringer Ingelheim and Elanco – currently play in very similar areas with only nuanced variations in their portfolios. The broad themes among the species categories are an effort to develop new ways to keep animals healthy using less antibiotics or anti-infectives, and a 'humanization' of companion animal innovation in order to address unmet needs.

Zoetis recently became the first animal health company to spend in excess of $500 million on R&D in a single year. This milestone for Zoetis, combined with healthy increases in spending on innovation from all of the top six pharmaceutical manufacturers in animal health, means the **leading players spent an estimated $2.089 billion on their R&D** programs in 2021. This is the first time over $2 billion has been spent on R&D by the majors.

In recent years, there seems to have been a widening split in animal health between the pet sector and the food animal world. The levels of growth from the companion animal segment have been much higher than that of the livestock sector, especially during the onset of the COVID-19 pandemic.

Piper Sandler recently noted: "We think investors should target end markets in companion animal over food animal, as pet owners are willing to pay for innovation versus livestock producers who are only willing to pay for economic benefits of the products. We peg companion animal at a 10-year CAGR of 6%, versus 4-5% with production animal."

Over the past decade, businesses have been evolving their pipelines to feature more than just treatments. Integrated offerings are now targeting tools that can treat, predict, prevent and detect health issues in animals – opening animal health players to new product categories and adjoining industries. While firms previously leant heavily on product lifecycle innovation strategies and M&A activity to drive their top-line sales, they are now leveraging internal R&D capabilities and partnerships with external innovators to create an increasingly competitive quest for growth at the top of the animal health industry. The big businesses are not only complementing their existing core strengths but also delving into new sectors to find new 'blue ocean' opportunities.

Mergers and acquisitions remain a key strategy in animal health. However, the majors have increasingly been turning to purchases of smaller companies among animal health's growing pool of biotechnology firms and start-ups. There are many start-ups translating innovation from the human health field into animal care – innovation that is being harnessed by the likes of Zoetis, Merck Animal Health, Boehringer Ingelheim and Elanco via acquisitions, partnerships and licences. While this theme has largely emerged in the companion animal sector, it is also apparent in the livestock segment.

Broadly, S&P Global and Stonehaven Consulting believe the areas expected to fuel sales growth among the leaders in the animal health industry over the next decade include:

4.
Animal health regulations: Now and in the future

4.1. Regulations for bringing a product to market

4.1.1. Pharmaceuticals, biologics, and pesticides

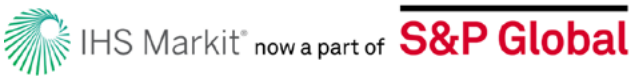
The introduction of legislation requiring veterinary medicinal products to be licensed before they can be placed on the market occurred at different times in different parts of the world. Before discussing specific regulations, it is important to look at definitions that apply to veterinary medicines. A veterinary pharmaceutical product is one in which the mode of action of the active ingredient is pharmacological, whereas the mode of action of a veterinary vaccine is immunological. Another term to be clarified is the claim, or indication, of a product. A licensed veterinary medicine will have a medicinal claim. If it has not been awarded a license (a term often used in the US) or marketing authorization (MA), it cannot have a label claim that makes a specific medicinal claim/indication. Only licensed medicines may have label claims such as 'Treatment of gastro-intestinal nematodes in chickens infected with *Ascaridia galli* (L5 and adult stages)' or 'For the active immunization of pigs to reduce viraemia caused by PCV2 infection'.

In the US, pharmaceuticals – also referred to as drugs – are regulated by the Food and Drug Administration (FDA), while veterinary vaccines tend to be regulated through the US Department of Agriculture (USDA). More specifically, vaccines are governed by the USDA Animal and Plant Health Inspection Service's (APHIS) Centre for Veterinary Biologics (CVB).

Within Europe, registration of veterinary medicines became a legal requirement at different time points in different countries. The data requirements and dossier structure differed in each country and several countries only had one set of requirements, which applied to both pharmaceuticals and vaccines. This led to some challenging requests from regulators, such as one Benelux authority demanding the weight of the freeze-dried pellet be stated on the label of a vaccine vial. Registration of medicines in the UK became a legal requirement in 1968. This was through the Medicines Act, which was enacted following the thalidomide disaster. The government introduced measures to ensure that in future, only medicines that met the required standards of quality, safety and efficacy would be licensed for sale. Formal harmonization of standards for registration of veterinary medicines in the EU became mandatory through EU Directives 81/851 and 81/852. These only covered veterinary pharmaceuticals at the time but the scope of 81/851 was later extended to immunologicals by Directive 90/677.

With advances in technology, it was necessary to regularly update legislation, the latest version being EU Regulation 2019/6 (*Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC*), which covers many aspects of the legal requirements for the testing, registration and sale of veterinary medicines. There are four different routes available to register veterinary medicines in the EU and the UK. These are the national, centralized, decentralized and mutual recognition procedure (MRP) pathways.

In addition to Acts, Codes, Regulations and Directives, most regions endorse official guidelines, such as the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) guidelines, while the World Organization for Animal Health (WOAH) guidelines are mainly applicable to products to treat diseases occurring in low- and middle-income countries. Pharmacopoeia is also available to consult where relevant. Figure 10 provides a high-level overview of how these various legal and non-legal instruments interface with one another.



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