A global perspective on the animal health market

By Graeme Peters

Humans are better off when animals are healthy, writes Graeme Peters. Governments can help improve the health of animals by allowing controlled access to modern medicines and vaccines. This requires science-based, sensible regulation which fosters innovation, responsible use, and disease prevention.

Think medicine and the mind conjures images of bathroom cupboards cluttered with pills and potions, but not the one you need.

Self-interest in accessing medicine is understandable given the demand for healing treatments, a $US955 billion market in 2011.

While not front of mind for those wanting a headache cure, animals require medicines too. Indeed, many firms which make human pharmaceuticals also provide veterinary medicines in a market which collectively was worth US$22.5 billion last year.

Despite the David and Goliath scenario there’s a wide range of animal medicines, from abamectin to zolvix.

Animals eat off the ground, sniff backsides, and enjoy dirt and are therefore more likely to be targeted by parasites, inside and out, so the animal health industry has developed useful products such as the two treatments named above for controlling ticks and worms in the gut.

Animal vaccines build immunity to debilitating diseases such as blackleg, which literally turns a cow’s leg black, and scabby mouth, which causes painful sores on a sheep’s lips.

Many animal ailments are similar to those suffered by humans. The most obvious is influenza. But animals pick up conditions such as canine distemper which are endemic to their species.

Antibiotics typically fight bacterial infections by inhibiting their growth or by preventing them from reproducing. Veterinarians performing surgery use a range of different substances.

Pets and pigs

Animal health has two markets – production or farm animals, and companion animals or pets. Globally, about three dollars in five spent on animal health is for farm animals, the rest for pets.

But some countries favour one segment over another. New Zealand, an exporter of protein such as milk and meat, has about 40 million sheep and cattle, compared to an estimated five million companion animals.

The most populous breed of animal worldwide is the chicken, of which there are an estimated 19 billion, or three for every person. China rules the roost with nearly five billion birds.
Keeping Watch

Many governments keep an observant eye on animal diseases and their treatments, for a range of important reasons. The most obvious is that food-producing animals are eaten by people, and no one wants to buy or handle a diseased animal. Governments are also mindful of public expectation that animals will be looked after and have access to treatments which work without distressing side effects.

Governments are taking a growing interest in animal diseases which humans can catch. These zoonotic diseases can pose significant risks to public health and include long-established dangers such as rabies, almost always fatal in humans if left untreated. The H5N1 virus, more commonly known as bird flu, has been described as the world’s largest pandemic threat to people and to financial stability.

Through regulators, governments control access to veterinary medicines to ensure that they work, or that they do not lead to unacceptable residues in meat and milk. Regulators will turn around export shipments of produce that breach maximum residue limits (MRLS) and impose import bans taking months to lift, which means farmers and growers (and taxes) are not paid.

Regulators place controls on when and how a therapy can be used, and what dose. Some treatments are hazardous so governments pass laws to guard safety to humans and the environment. There’s also regulation controlling the group who can prescribe and administer drugs to veterinarians or other trained people.

As expected in a world with 196 countries, governments regulate animal health products in different ways. Globally, the animal health industry is far less disparate.

Ten global companies sell about 80 per cent of the world’s animal health products. Most of them are based in Europe - Merial, Merck, Bohringer-Ingelheim, Lohmann, Bayer, Novartis, Virbac and Vetoquinol. The United States is home to Zoetis (formerly Pfizer Animal Health), and Elanco.

The International Federation of Animal Health is their global association, and has well thought, considered views on adequate regulation that will lead to the best outcomes for animals, people and the world.

Health Animals = Healthy People

Humans do not exist in isolation, but are part of a larger ecosystem, and the activities of each member affects others. This long-understood concept has crystallised under the broad One Health initiative.

Veterinary associations and animal pharmaceutical manufacturers are among the key supporters of One Health.

A report commissioned by the International Federation of Animal Health (IFAH) concluded that animal diseases have economic impacts far beyond the direct costs caused by the diseases themselves.
These costs can be divided into direct costs – the immediate impact on livestock populations and agriculture – and indirect costs, which include mitigation or control effects, losses in trade and other revenues, and impacts on human health.

Recent outbreaks of classical swine fever in pigs, foot and mouth disease in cattle, and highly pathogenic avian influenza in poultry are examples of the broad impact that animal diseases can have.

An increasingly crowded planet – on which man and animals live in ever closer proximity – has enhanced the ability of zoonotic infections to jump between species. And once present in human populations, the unprecedented flow of commodities and people across the world enables pathogens to spread as never before.

It’s generally accepted that of the nearly 1,500 infectious diseases that affect people, almost two thirds can pass between animals and people. Three-quarters of emerging human infections are believed to have originated in animals.

IFAH commissioned global analysis and advisory firm Oxford Analytica, which was supported by experts in animal health, to compare social and economic impacts of three well-documented animal health diseases: the animal-only foot-and-mouth disease; salmonella, a disease in animals and people transmitted through food; and a zoonosis, rabies.

Insights were gained by focusing on recent outbreaks in various regions.

- Salmonella costs the United States as much as $US3 billion ($NZ3.6 billion) annually and, disturbingly, there has been no discernible drop in the incidence of salmonella in humans over the past 15 years.
- The economic and social impact of rabies stems from its ignominious title as the worst killer zoonotic disease, claiming 55,000 lives annually in developing countries and one million cattle in Central and South America each year.
- Tourism was the worst affected sector in Britain following a foot and mouth outbreak, with one study estimating the loss of tourism revenue at $US12 billion in 2001.
- A foot and mouth outbreak in California could cost as much as $US69 billion.

Veterinarians and animal health products are clearly key parts of the solution. Parvovirus, once a common cause of canine deaths, is now prevented routinely – alongside a growing range of other potentially fatal infections – by safe, effective vaccines. Cats, horses and other companion animals have benefited from similarly dramatic developments in veterinary immunology, while revolutionary new products have enabled the effective control of parasites such as fleas and ticks to which companion animals are exposed.

IFAH commissioned the report to spark discussion with international stakeholders on what future efforts are needed for effective disease control and prevention.

To achieve progress in the control of animal diseases and in the reduction of their socio-economic impacts, further investments and continued efforts are needed in capacity building, infrastructure development, governance of food safety, good veterinary legislation including appropriate regulation of animal health products, and consistent application of guidelines relevant to animal health and trade.
The global animal health industry is a strong supporter of One Health, and wants to work with regulators in a partnership that will bring about recognition that healthy animals equals healthy people.

**Converting ideas into invoices**

One of the most important ways to improve health outcomes for animals is through the introduction of new medicines.

The inventors of new medicines need to know that their medicines can be commercialised; brought to the market and protected from copies made by competitors who do not face the overheads of supporting a research department.

Innovation is a business and without the ability to make a fair return, inventors switch their talents to other spheres.

Manufacturers protect their inventions through a patent which lasts 20 years. This might seem plenty but nearly half of the patent life can lapse before a product is launched on the market. The delay stems from the time to fully develop and test the product, including tests on live animals, and obtaining regulatory approval. Marketing cannot begin until that happens.

Globally, the industry accepts a 20 year patent term but it should be accompanied with two important aids to ensure that two decades means two decades.

For example, some jurisdictions allow for ‘spring boarding’ – meaning that generics companies can seek regulatory approvals for their copy products before the patent has expired. This allows the me-too product to be launched on the day the patent expires.

Another important area is patent protection extension – which allows a manufacturer to apply for an extension to 20 years if they can prove that regulatory approval took an unreasonably long time.

While some jurisdictions either prohibit springboarding or allow patent term extension, some continue to discourage innovators through a zealous belief that generic competition must be favoured.

**And protect the data too**

While patents protect the invention, the dossier of research which supports the invention cannot be patented. This data includes all things that regulators want to know about the product, including its efficacy, toxicology, residues, and safety to humans and the environment.

Data packages are intellectual property in their own right and assume great importance when a product’s patent has expired. In some countries, the data is protected from unfair commercial gain for 10 years, but this rare. Five years is typical in many western countries, but in others there is no protection.

A lack of data protection is a barrier to the launch of medicines which are off patent, denying farmers and pet owners access to a medicine for an emerging disease. Data protection is even more important for encouraging the extension of label claims – meaning, say, that a medicine registered for cows can also be used for other animals.
IFAH is asking governments to support innovation and to reflect this importance in national legislation. Specifically IFAH is requesting the extension of data protection to 10 years for new medicines and to 5 years for additional information required to extend labels for new benefits of the medicine or maintaining current market approvals.

There is a clear link between the rate of development of economies and their innovative abilities, which is driven by companies willing to take risks to make major investments in new product developments.

Including data protection into national law will give much-needed certainty to innovators so they continue to invest in the development of new technologies and medicines, which will ultimately benefit animals, owners and individual economy.

**Clear pathway to market**

Access to medicines can also be blocked by excessive time delays or over-regulation.

A key area of work for the global animal health industry is pathway to market. That is, allowing companies a fair go at obtaining approval for a product to be used.

One of the most common issues is the amount of time taken by regulators to consider and approve a product registration – eating in to the 20 year patent. One of the reasons for delays is regulatory capacity; that is, the ability of the regulator to carry out its workload.

Regulators may not have the resources they need to do their job effectively, leading to difficulties in recruiting and retaining employees who require a high level of technical knowledge. As the work comes in, delays lengthen. The industry is supportive of efforts to build capacity of regulators, especially in Asia and Africa where need is greatest.

On the other side of the coin there is excess regulation which unnecessarily increases the time and cost to market.

The findings of an IFAH benchmarking report highlighted the need for a realistic risk-benefit analysis during the evaluation process to provide the assurances needed on product safety without placing unnecessary hurdles in the way of essential new treatments.

One of the areas that industry can help is by provide expertise on emerging diseases and fulfil its role as part of the solution to control these diseases in animals.

IFAH fully supports the application of rigorous, predictable, proportionate, science-based regulatory standards to all veterinary medicines. Legislation must be balanced and be applied consistently to support a sustainable, innovative industry capable of delivering new products and technologies that address the needs of animals and their owners.

Existing problems stem partly from the tendency to apply common regulations to both human and veterinary medicines, ignoring major differences in terms of product requirements, the conditions under which they are used and – crucially – the gulf in resources that exists between the two industries.

This trend has imposed a growing, often unnecessary burden on the animal health industry. IFAH pursues a constructive approach towards tabling proposed solutions to current problems and works alongside regulators to improve procedures and standards.
Harmonisation

The animal health industry is a strong support of two institutions – VICH and Codex - which are seeking to harmonise regulation.

VICH, an animal offshoot of an International Conference on Harmonisation (ICH) of human medicines, promotes common testing requirements to help speed availability of new products.

VICH brings together the regulatory authorities of the European Union, Japan and the United States and experts from industry to explore scientific and technical aspects of new product registration.

Regulatory authorities and industry experts from Australia, Canada, South Africa and New Zealand participate as observers.

IFAH is also a strong supporter of the Codex Alimentarius Commission (CAC). CAC has a vital role in setting global standards to ensure that food is safe for consumers.

Animal health companies work closely with CAC to write science-based standards so that animal-sourced food is safe.

Codex’s decisions are the cornerstones of its success and these should remain at its core in the years to come. CAC has adopted numerous global standards relating to animal health products that safeguard human health. These range from Maximum Residue Limits (MRLs) for veterinary medicines to guidelines on risk analysis for food.

Only through the establishment and adoption of science-based, global standards and guidelines will it be possible to ensure a safe food supply while enabling fair trade.

Responsible Use

Antibiotics are an essential part of any veterinarian’s toolkit; they’re invaluable in treating infectious diseases in livestock and pets, ensuring that animals are healthy and live longer, better lives.

Diseases controlled by veterinary medicines, including antibiotics and other antimicrobial agents, also help deliver safe and wholesome food and protect consumers from harmful diseases.

Globally, there has been growing concern about the implications of anti-microbial resistance to the health of humans and animals. The emergence of so-called ‘superbugs’ in humans which are multi-drug resistant has correctly been identified as a serious public health concern.

It’s important that each country has good management of resistance. An effective regulatory system that can recognise its emergence is a critical factor, along with veterinary services which promote the responsible and prudent use of antimicrobial agents in animals.

Resistance is not a new phenomenon, but global organisations appear to be increasing their activity.
Manufacturers of veterinary medicines have established a global working group dedicated to the topic, mainly to deal with increased stakeholder interest and to coordinate a response, promote sensible use and discourage restrictions which prevent the supply of products.

Some parties call for a reduction in the use of antibiotics in veterinary medicine. This is not appropriate and in the long term will be damaging to the health and welfare of animals, with potentially a significant impact on people (e.g. when zoonoses go untreated, or when people who rely on animals). The responsible use of antibiotics, including the principle as much as necessary, as little as possible needs, to be further encouraged.

IFAH has called for the continued availability of antibiotics for both human and veterinary medicines, encouraging a stronger dialogue and co-operation between the two medical sectors to ensure continued access for humans and animals.

In summary, the animal health industry is acknowledges that its products need to be regulated by governments. But this regulation must facilitate access to medicines, not put unnecessary or bureaucratic roadblocks in the way.

To help achieve positive outcomes for animals and humans, regulators need to:

1. Recognise that healthy animals bring economic and health benefits to humans
2. Strive for science-based, practical regulation specifically for animal health.
3. Harmonise regulation and standards with other jurisdictions, and support international fora which encourage cooperation.
4. Support competition through innovation
5. Regulate for responsible use that ensures continued access to medicines

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