

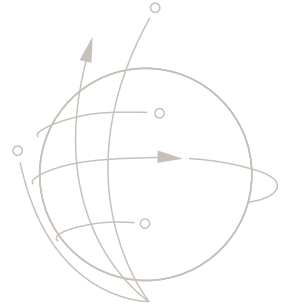


PROMOTING A POSITIVE ENVIRONMENT FOR VETERINARY MEDICINES

The case for separate regulation for the animal medicine sector



Improving the quality of life for animals and people



About IFAH

The International Federation for Animal Health (IFAH) is an organisation representing manufacturers of veterinary medicines, vaccines and other animal health products in both developed and developing countries across five continents.

IFAH's mission is to foster a greater understanding of animal health related matters and promote a predictable, science-based regulatory environment that facilitates the supply of innovative and quality animal medicines, vaccines and other animal health products into a competitive market place. These products contribute to a healthy and safe food supply as well as a high standard of health and welfare for animals and people.

To fulfill that mission, IFAH will:

- Act as the voice of the industry in dialogue with the major international bodies that have an impact on the animal health industry (OIE, FAO, WHO, Codex, WTO and others);
- Encourage and assist the development of predictable, science-based regulatory procedures and standards;
- Represent the industry with a unified, global voice in dealings with governments, food-industry partners and consumers; and
- Facilitate the international harmonisation of regulatory guidelines governing animal health products.

The case for separate regulation for the animal medicine sector



Peter and Trixie's story

Peter Schmidt would be the first to admit that neither he nor his Labrador Trixie are in the first flush of youth. Both enjoy full and rewarding lives, however, thanks to medicines that help keep them fit and healthy.

A single tablet taken daily before the two enjoy their morning stroll helps Peter keep his cholesterol levels under control.

Once a month he also makes sure Trixie receives a dose of medicine that keeps her free from infestation with parasites such as fleas, ticks and lice.

Both products are from classes that did not exist little more than a decade ago. Along with a growing number of other, increasingly sophisticated medicines, they have transformed the length and quality of lives enjoyed by millions of human and veterinary patients.

Veterinary medicines

Veterinary medicines play a vital role, not only in the preservation of animal health and welfare standards across the globe, but also to the supply of safe, nutritious food and the protection of public health. IFAH is immensely proud of the huge advances its members have helped to achieve in these fields, and is excited by the potential that their current research efforts promise to unlock. But the federation is increasingly concerned at approaches to the regulation of animal health products, which threaten to smother innovation under a blanket of unnecessary or inappropriate requirements.

At the heart of the problem is a growing tendency to impose rules developed for human pharmaceuticals on veterinary medicines, without proper consideration of either:

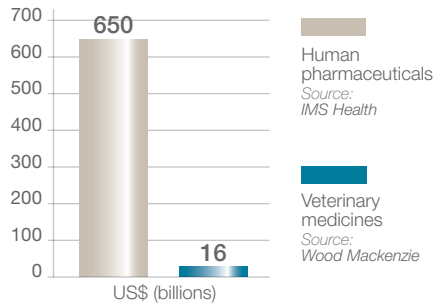
- The very different requirements of human and animal medicines and the conditions under which they are used;
- The contrast between the resources available to the two industries and the financial implications of regulatory requirements on individual sectors.

The trend is at its most extreme where products for food animals are concerned. Tests on these medicines must not only confirm their safety, quality and efficacy, but must also rule out the possibility that their use will have a negative impact on the environment or pose problems in terms of residues of the drug and or its metabolites to the consumer of foods derived from the treated animals.

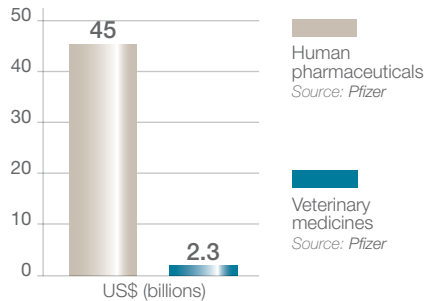
IFAH supports fully the rigorous application of science-based scrutiny in all of these areas. But as the cost of developing innovative new products and maintaining existing ones continues to rise, it is vital that the regulatory framework governing them is proportionate.

The spread of infections such as avian influenza has highlighted both the crucial role played by veterinary medicines and the need for continued development of new and improved products. And yet, as this document explains, the availability of these vital tools is sometimes being compromised by current regulatory approaches. Failure to address this issue risks undermining the ability of our industry to provide solutions to problems that threaten both human and animal health.

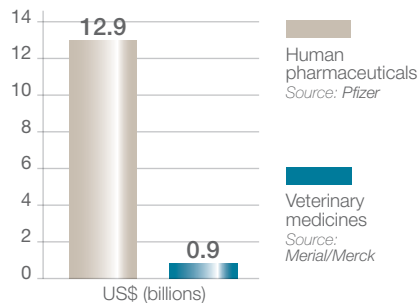
Global market value



Global sales of leading company



Global sales of leading brand



Contrasting resources

The products prescribed to Peter Schmidt and his canine companion are the best-selling brands in their respective sectors. But while global sales of Peter's cholesterol reducer total almost US\$13 billion a year, annual revenues generated by Trixie's parasite control are equivalent to less than one-tenth of that figure. No matter how we measure the two sectors, comparisons between the human and veterinary pharmaceutical industries illustrate disparities on a huge scale:

- The global market for human pharmaceuticals is worth 40-times more than its veterinary equivalent;
- Sales generated by the world's leading human pharmaceutical company are 20-times higher than those of the biggest veterinary products business;
- There is a 30-fold difference between the research spending capacity of the market leaders in the two sectors;
- The top-ranked human pharmaceutical company employs more research scientists than the world's 20 leading animal health businesses put together.



A complex market

The market for veterinary medicines is not just many times smaller than its human counterpart – it is also more complex and fragmented.

- Many veterinary medicines are used in a variety of species. Target animal tests must be conducted for each species, while products must often be developed in a range of dosages and formulations to cater for the needs of individual species segments and the conditions under which medicines are administered.
- Where products for use in food-producing animals are concerned, comprehensive residue testing must be undertaken to ensure that food from treated animals is safe for human consumption.
- Manufacturers must also conduct thorough tests to ensure that veterinary medicines do not have a detrimental impact on the environment.
- Antibiotics developed for veterinary use must undergo additional testing to ensure that they will not affect the development of microbial resistance to human drugs.

On top of this – and despite a ten-year programme designed to harmonise regional regulatory frameworks – requirements imposed on veterinary medicines still vary widely between individual markets. This further complicates the development of new products, and can delay significantly their availability in some countries.



Similar regulatory burdens

The tendency in recent years has been for regulators to develop and implement requirements for ‘pharmaceuticals’ – a catch-all definition that includes both human drugs and veterinary medicines. This simplistic approach not only fails to take account of the huge gulf in resources available to the two industries, but also neglects the substantial differences that exist in terms of both product requirements and the conditions under which they are used.

The failure to differentiate properly between the resources and requirements of the two sectors has

led to the imposition of superfluous and often illogical regulatory demands on veterinary medicines. As a result, the animal health industry is being forced to cope with a growing – and in many cases unnecessary – regulatory burden.

There are plenty of examples, and the list of problem areas continues to grow – from safety and efficacy testing, through administrative requirements to product labelling and even, in some cases, the distribution and sale of veterinary products. Here are just a few examples:

Product testing

- Many ectoparasiticides are defined as agricultural products in the United States, where they fall outside the remit of the Food and Drug Administration. By contrast, these products are defined as pharmaceuticals by regulators in Europe, where they are subject to full compliance with good manufacturing practice (GMP) standards applied to human drugs.
- Regulators in the EU have imposed similarly onerous requirements on medicated pre-mixes where microbiological purity is concerned. This means identical standards are being demanded of products administered to children via intravenous injection and those consumed by pigs from a feeding trough.
- Despite the fact that finished products are already subject to strict quality controls, veterinary active ingredients are now subject to GMP standards in Europe. This threatens the availability of many low-volume products, sales of which are not sufficient to justify the level of investment required to generate such data.
- The availability of packaging materials used widely in the veterinary sector is also at risk following the introduction of new standards being applied equally to both human and veterinary medicines. Because no monograph exists to benchmark the quality of PET-based plastic containers for parenteral medicines, regulators are now demanding the submission of exhaustive data – including proprietary information unlikely to be released by plastics manufacturers – to support the registration of such products.
- In Japan, no distinction is made between toxicology and pharmacology data requirements for veterinary medicines and human drugs. So, despite the provision of thorough target-animal-safety testing data, animal health companies must undertake a raft of additional studies normally conducted in laboratory species.

Product labelling

- Local representative contact details must be included on human pharmaceutical labelling in Europe for the benefit of patients travelling abroad who may have queries regarding their medication. This serves no practical purpose where animal medicines are concerned, but manufacturers must nevertheless update redundant information – at considerable expense – each time a contact name or telephone number changes.
- Space must also be provided on product labels for written recommended dosing regimes. We are all familiar with these where human drugs are concerned, but since veterinary surgeons include such information on written prescriptions this too serves no purpose for animal medicines.
- In the US, labelling requirements for veterinary medicines now actually exceed those for human drugs in some respects. Minor label changes for human drugs can be updated through an annual report filing system. However, there is no provision for veterinary medicine minor label changes to be filed in the annual report.
- Regulators in the US are also pushing for the application of Structured Product Labelling (SPL) – a system developed for the exchange of medical information between healthcare providers – to veterinary medicines. This has potentially significant financial implications for regulators and manufacturers alike but, asked to cite a single advantage for either party, the Center for Veterinary Medicines has been unable to do so.





From the unnecessary to the inappropriate

The rationale behind decisions to impose some regulations to both human and veterinary medicines is particularly difficult to understand, given the entirely unconnected nature of the economics that drive the two sectors. Bizarrely, this has seen animal health products subjected in some cases to regulations that are designed to limit government drug spending. Since the concept of public sector reimbursement for veterinary medicines does not exist, this is particularly hard to understand.

Regulators in Japan decreed recently that products for the treatment of chronic conditions in companion animals should no longer be prescribed for longer than 14 days at a time. This is essentially a direct transposition of a measure designed to check the cost of reimbursing human drugs by tackling perceived over-prescribing among physicians.

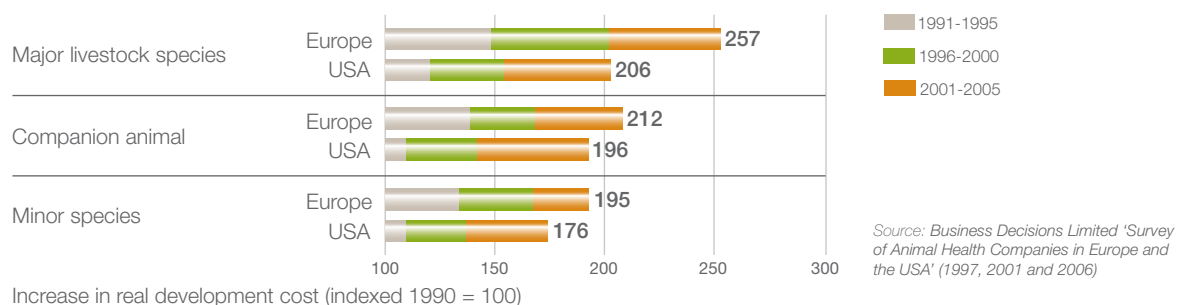
Of potentially greater significance are moves in Europe and the United States to waive bioequivalence requirements for generic drugs. Again, these are measures designed to curb government spending on the reimbursement of human pharmaceuticals. By smoothing the passage to market for generics, they aim to make cheap alternatives to original brands available as early as possible. But again, like prescribing limits imposed in Japan, they serve no purpose in the animal health sector, where their sole impact will be to erode further the returns available to research-based companies on sizeable, high-risk investments.

The financial impact of over-regulation

The failure in the past by regulators to acknowledge the major differences between human and veterinary medicines has driven up both the costs involved in the development of new animal health products and the time it takes to bring them to market.

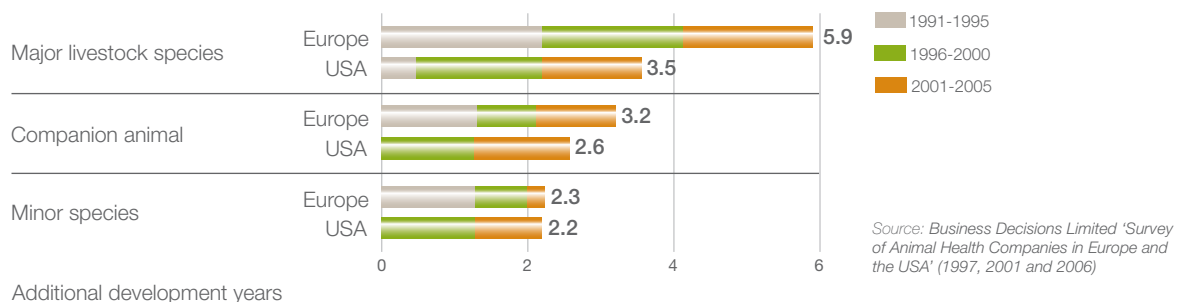
Impact of regulatory factors on the average cost of developing a new product in Europe and the USA

Changes in real terms over the last fifteen years: 1991-2005



Impact of regulatory factors on the average length of time taken to develop a new product in Europe and the USA

Changes over the last fifteen years: 1991-2005



The existing regulatory climate clearly acts as a disincentive for investment and innovation by the animal health industry. It also imposes a heavy workload on regulatory agencies, however, compromising their ability to meet performance targets and inflating unnecessarily the costs involved in monitoring the development, registration and use of veterinary medicines.



Seeking solutions

A shift in the attitude of regulators is essential if existing problems are to be tackled successfully. Adapting legislation drawn up for human pharmaceuticals to obtain a 'best fit' for the veterinary sector is clearly not an option. Instead, those charged with drafting new regulations must consider from the very start exactly how and why measures for the control of veterinary products should differ from those designed to govern human drugs.

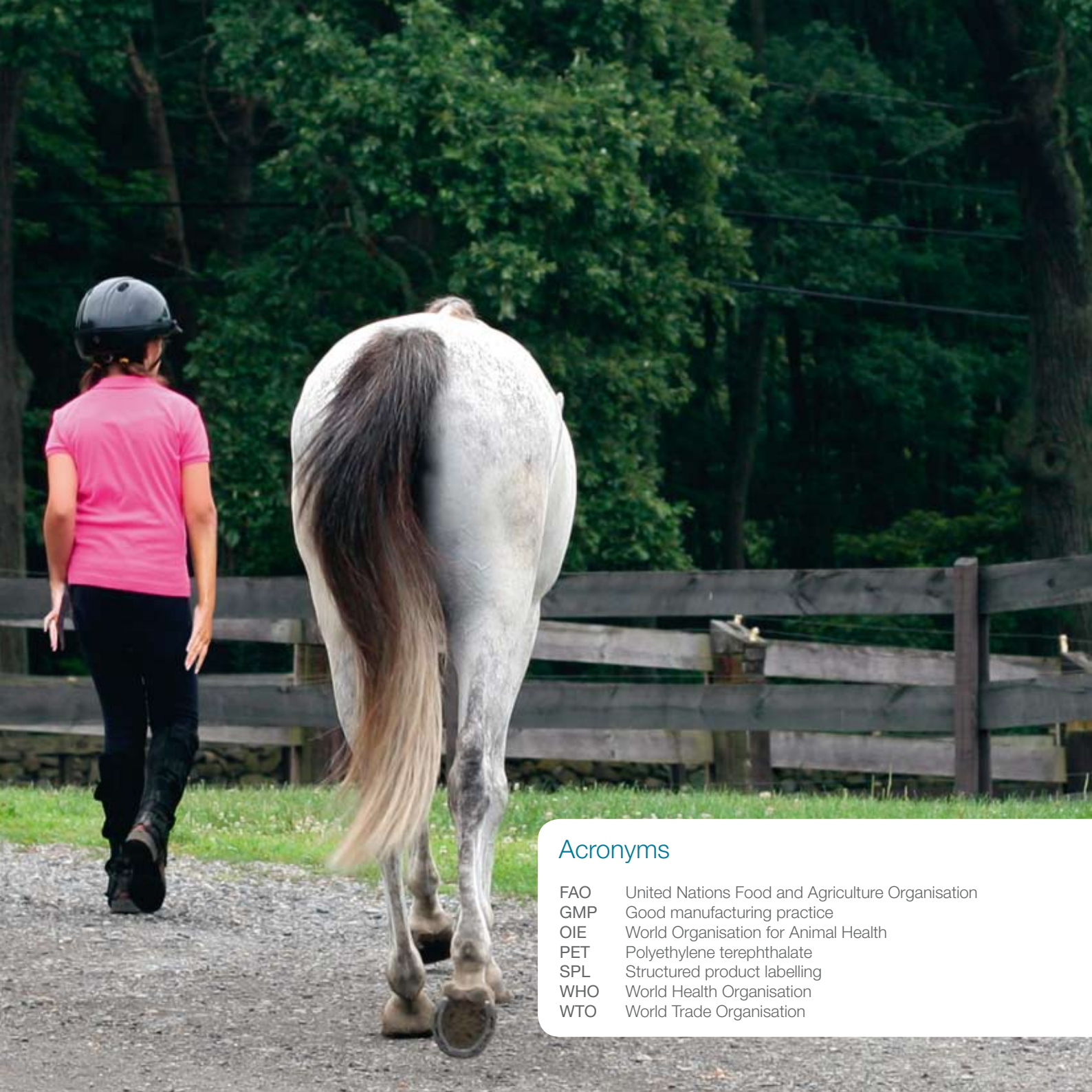
In doing so, they must take account not only of the resources available to the animal health industry, but also of the needs of animals, their owners and the veterinary profession. Scientifically sound, risk-based safety assessments should provide the platform on which regulatory requirements are based.

As a first step, IFAH urges regulatory agencies to disband 'joint' regulatory committees and replace them with sector-specific working groups capable of drafting legislation that is both pertinent and proportionate to the industry it is designed to regulate. Agencies must also revisit existing regulations governing veterinary medicines, amending or abolishing requirements that are clearly either excessive or irrelevant. Efforts to harmonise regulatory frameworks in individual market regions should also be stepped up.

Early targets for change should include:

- **Product labelling:** Abolish requirements that are of no benefit to users or animal owners, relax demands regarding the disclosure of excipients, switch to annual filing of minor label changes in the US.
- **Quality standards:** Harmonise regional GMP standards; remove GMP requirements for active ingredients; relax site documentation requirements; develop more proportionate purity, quality and stability thresholds that take account of individual product requirements, routes of administration and dosing regimes; shelve plans to apply GMP standards to excipients; limit packaging test requirements for existing materials where monographs have yet to be developed.
- **Pharmacology and toxicology:** Shelve additional requirements where full target animal safety data has already been generated, abolish detailed test requirements for products that have already been used safely for long periods in human medicine .
- **Financially-driven regulations:** Exclude veterinary medicines from regulations designed to limit public sector spending on pharmaceutical reimbursement, which does not exist in the animal health sector.

IFAH is determined to engage constructively with regulators in a bid to improve the regulatory framework governing veterinary medicines. By doing so, it aims to secure the future of investment and innovation in a sector that plays such a vital role in safeguarding animal health and welfare, protecting the health of consumers and conserving the environment.



Acronyms

FAO	United Nations Food and Agriculture Organisation
GMP	Good manufacturing practice
OIE	World Organisation for Animal Health
PET	Polyethylene terephthalate
SPL	Structured product labelling
WHO	World Health Organisation
WTO	World Trade Organisation

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