GLOBAL BENCHMARKING SURVEY 2020

Benchmarking the competitiveness of the global animal health industry

OVERVIEW REPORT

AUSTRALIA
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HealthforAnimals is a non-profit, non-governmental organisation representing manufacturers of veterinary pharmaceuticals, vaccines and other animal health products throughout the world, as well as the associations that represent companies at national and regional levels (referred to as Members). The animal health industry provides value to society by protecting animals and as a consequence, humans, from disease. Our products help keep pets and farm animals healthy. The public health benefits we bring include safer and more secure food supplies, more efficient production for increased food security, improved sustainability, and prevention of the transmission of zoonotic diseases.

Introduction

The HealthforAnimals Global Benchmarking Survey is run every 5 years and has now grown to include 11 countries in the 2020 survey (see box). The purpose is to examine the interactions between industry and regulatory systems for veterinary medicinal products, particularly the impact of regulations on the animal health industry's ability to access markets, be innovative, continue to commercialise existing products and be competitive.

- **GBS1996:** Europe, USA
- **GBS 2001:** Europe, USA
- **GBS2006:** Europe, USA, Australia, Canada, Japan
- **GBS2011:** Europe, USA, Australia, Canada, Japan
- **GBS2015:** Europe, USA, Australia, Canada, Japan, China, Brazil
- **GBS2020:** Europe, USA, Australia, Canada, Japan, China, Brazil, India, Mexico, Russia, South Africa

The Global Benchmarking Survey (GBS) focuses on animal health and veterinary products in the following sectors: pharmaceuticals, in-feed medicinals, biologicals (vaccines) and ecto-parasiticide products. It does not consider nutritional products, feed additives that are not regulated as therapeutics, or non-regulated semi- or pseudo-medical products used in animals.

For the 2020 survey, information has been obtained from animal health companies through a questionnaire and via workshops at the regional and national level, at which aggregated data summaries could be discussed and put into context. The questionnaires combined a set of core questions and a set of local questions adapted to each country. The Japan, China, Brazil and Mexico survey questionnaires were translated into the local language.

In total 60 companies took part in the GBS2020 survey, with 10 HealthforAnimals multinational companies (with separate input from their subsidiaries present in most of the 11 markets surveyed) and 50 local companies (members of the national industry trade association, but not corporate members of HealthforAnimals), resulting in a total of 121 completed questionnaires.

Summary of the global outlook

- The perception of companies is that the time needed for new product development has increased by one or two years since the previous survey in 2015.
- The proportion of the R&D budget spent on maintaining existing products on the market (a.k.a. mandatory defensive R&D) continues to be a significant concern for companies.
- The continued rise in the time and cost of product development drives the business case for the need for greater regulatory convergence, as international companies seek to mitigate the risks and spread the costs of significant investments across a global marketplace.
- The rate of positive regulatory change is accelerating at a global level, as transitional countries modernise and up-grade their regulatory systems, and developed countries adapt their systems to new digital tools, new scientific approaches and novel technologies.
- The acceleration of regulatory convergence is facilitated by wider participation in international regulatory harmonisation initiatives (e.g. VICH and PIC/S) and a wider interest in the adoption of international standards.
- Participation in international fora has also helped to build trust and mutual understanding between regulatory agencies and encouraged greater international regulatory cooperation. A future trend may be increased use of parallel or joint / shared assessments.
- These trends support an improved outlook of companies towards local regulatory systems; despite some major local challenges, there is hope for the future from on-going dialogue with stakeholders and continued regulatory convergence.
- Efficient regulatory systems are benefiting from greater stakeholder engagement and the recognition that regulatory procedures need to be adapted to the specific characteristics of the veterinary sector.
- There are calls for the wider application of the "3Rs" principles in all aspects of regulatory science, including product development and routine batch release testing of vaccines.
- International companies are evolving their product portfolios to reflect developments in veterinary medicine. There is a move away from veterinary antibiotics and towards more preventative solutions, such as vaccines. The long-term trend towards more balanced portfolios between livestock products and companion animal products continues.
- Additionally, small companies are increasingly entering the companion animal market through the development of niche products designed to meet unmet market needs.
- Overall, R&D budgets directed at traditional veterinary medicinal products (VMPs) have decreased, except in vaccines and novel therapies. However, new technologies (e.g. digital tools), diagnostics and veterinary services are a growing part of product portfolios, and this investment is not captured in standard analysis of R&D spends on traditional VMPs.
- Regulatory science and frameworks will need to keep pace with the development of novel therapies and new therapeutic approaches.
- Rapid regulatory change in transitional economies reflects a need to modernise, but has created a friction between the low level of local market development and the increasing cost of regulatory compliance.
- Globally, investment is split across the veterinary product categories as follows: approximately 1/3 for companion animal products and 2/3 for food-producing animal products; and approximately 1/3 biologicals and 2/3 pharmaceuticals. Local companies may specialise only in one product category (e.g. pharmaceuticals) while multinational companies will aim for balanced and broad portfolios.

Favorable aspects

Overall regulatory tends: There is a trend towards a more positive perception of the regulatory environment in most countries, although this hope takes various forms. In countries with mature regulatory systems, hope lies in the continued adoption of good regulatory practices that are fast becoming regulatory norms, and in new legislation or systems cementing new approaches into the regulatory framework. In countries with evolving regulatory systems, hope lies in future progress and the knowledge that regulatory change is gaining pace globally, with greater participation in international fora increasing the spread of ideas and international norms.

Progress in good regulatory practice: For established regulatory systems progress is measured in further steps to improve regulatory best practice, the in-house development of high calibre of scientific assessors, improved consistency through science-based assessments, and the further alignment of decisions with a benefit-risk approach. This progress can be seen in reduced registration timelines, supported by a comprehensive library of scientific or technical guidelines creating a transparent and predictable regulatory process, resulting in better quality dossiers and reduced time spent addressing assessors' questions. There is recognition that technical guidelines need to be aligned with international standards, such as those generated by VICH (for technical content) and PIC/S (for GMP). These international bodies are respected by other regulators around the world and under-pin a growing movement towards shared mutual confidence, reliance and recognition of regulatory outcomes.

The positive trend towards efficient regulatory systems is supported by the increased use of digital technologies for all regulatory activities, including online submission portals, tracking systems and pharmacovigilance records and signal analysis.

Good regulations provide certainty and predictability, enabling a stable business environment that creates the confidence to invest.

Adoption of international benchmarks: Many countries are moving towards greater conformity with international benchmarks in their regulatory practices, including moving from a zero-risk approach to a benefit-risk assessment, and acceptance of global standards, such as CODEX agreements and the increased acceptance of data generated overseas. Global approaches facilitate joint and parallel reviews with other regulatory authorities, and this can have a positive impact on innovation.

The move towards more regulatory agencies that are solely dedicated to the regulation of veterinary medicinal products, and away from inefficient and time-consuming national regulatory systems that involve multi-government departments, is helpful.

The global move towards waiving of outdated batch safety tests and potency tests using animals, in accordance with the VICH guidelines, is much appreciated, but is not yet complete. This transition is supported by improved good manufacturing practices and in-process controls.

Australia positives

- Following relocation of the agency, with loss of many staff, the agency has rebuilt and is re-establishing good regulatory performance, with improved communications, timelines, predictability and industry engagement.
- The general business environment in Australia is positive.
- The broader business environment supports investment in innovation (patents, trademarks, protection of technical data and intellectual property protection.
- An environmental assessment is not required where the proposed use pattern does not change the risk to the environment.
- Regulatory quality of the APVMA is regarded as good, with a high calibre of scientific assessors; the APVMA scientific assessments are respected by other regulators around the world.

Brazil positives

- Implementation of SIPEAGRO, an online system used to register companies and products is a first step in decreasing the approval process times.
- Innovative product applications are now prioritized in the regulatory approval process.
- Bureaucracy has been reduced in the process for simple register changes.
- A 'Tacit Approval' process has been implemented whereby approval is normally granted after 720 days.
- Public consultations took place regarding antimicrobials, antiparasitics and the simplified registration for lower risk products.

Canada positives

- There is a more positive outlook towards the regulatory environment in Canada.
- The predictability and quality of the Canadian regulatory procedures are regarded positively.
- The time required for the product registration step has decreased slightly.
- Moves towards the implementation of shared and joint reviews, electronic submissions, and pharmacovigilance are welcomed.
- Moves from a zero-risk approach to a benefit-risk assessment, and acceptance of JECFA agreements are also welcomed.
- Joint and parallel reviews with other regulatory authorities have had a positive impact on innovation in Canada.

China positives

- More multinational companies have set up their R&D and or manufacturing facilities in China due to changing policies.
- The number of animals included in biological clinical trials has been reduced.
- A General Priority Review guideline was initiated for some specific product types based on the Chinese market needs.
- Registration fees and confirmatory quality testing fees are exempted.
- Public consultations on draft regulations have become standard practice.
- China is moving towards greater conformity with international benchmarks in its regulatory practices.
- Product registration pathways are much improved recently, including in the quality of the technical reviews and support.

European Union positives

- Regulatory predictability and regulatory quality in the centralised procedure are highly valued.
- There is high satisfaction with the work-sharing and grouping for variations and the efforts made by the coordinating committee for the mutual recognition/decentralised procedure.
- The new Veterinary Medicines Regulation is cautiously welcomed, but with concerns about how it will be implemented.
- The rate of increase of product development time and cost over recent decades is slowing down.
- The average time for the marketing authorisation (registration) process has reduced by one or two months.

India positives

- The regulatory environment has changed positively with the formation of a dedicated Veterinary Cell at the CDSCO and exclusive guidelines for animal healthcare products are being framed.
- Recent regulatory reforms have mandated the requirement of Zone IVb stability studies, however the same may lead to increased time and cost to market.
- The government is supportive of innovation and is providing incentives (e.g. patents) to support development of new ideas.
- The regulatory processes are generally predictable. The online registration portal brings improved transparency, ease and predictability into the system.
- Improved pharmacovigilance systems and globalization of post-marketing surveillance outcomes are welcomed.

Japan positives

- There have been several changes in regulatory approach since the previous survey and the large majority are appreciated.
- The improved acceptance of data generated abroad for new product applications and national subsidies are welcomed.
- The data protection provisions for new products are generally seen as an incentive (but the 2 years data protection for the subsequent addition of indications is not an incentive).
- Intellectual property protection is helpful towards the ability to commercialize existing products, as are the 'good practice' standards of GLP, GMP and GCP.
- The regulatory system in Japan is seen as good quality and based on the best available science. The scientific expertise of evaluators of new product applications is highly appreciated.
- The regulatory systems are generally regarded as efficient, timely, transparent and predicable (but not always prompt).
- The waiving of batch safety tests and potency tests in accordance with the VICH guidelines is welcomed.
- The increased acceptance of overseas data is valued.

Russia positives

- Joint reviews and parallel assessments are two new forms of official cooperation that have been implemented.
- A new EAEU Regulation (including EAEU GMP issues) is under development, and may bring some efficiencies.
- Introduction of 180 days transition period for renewals, maintenance of MA number (unchanged after a variation is approved) and removal of Russian GMP requirement for APIs sites (amendments to the Law on medicines circulation, 2019).
- Certifications regulations cancellation for veterinary medicines (amendment to the Law on technical regulations, 2019)
- Bracketing approach acceptance for process validation during GMP inspections.
- More public consultation in draft regulatory processes.
- Moves from a zero-risk approach to a benefit: risk assessment.
- Increasing globalisation of post-marketing surveillance process.
- Russia has participated in the VICH Outreach Forum.

South Africa positives

- There is hope that the new SAHPRA will bring positive changes to veterinary product registration and strengthen the process.
- There is hope that Regional regulatory harmonisation in sub-Saharan Africa will bring increased efficiencies to the region.
- Act 101/1965 is considered to strongly enforce product quality, certainty, predictability and safety.
- The Minor Use / Minor Species (MUMS) guideline was positively received; there is hope this will decrease defensive R&D expenditure for these particular products.
- Recent measures by SAHPRA to implement electronic dossier submission and reliance for companion animal products are positively received.
- Work has started to review and implement the VICH guidelines.

USA positives

- Regulations for pharmaceuticals provide a stable business environment and create the confidence to invest (certainty and predictability).
- The EPA's movement from conditional registrations via enhanced reporting is progressing, which could lead to a decrease in mandatory defensive R&D costs.
- EPA's 10-year data protection period is a strong incentive to bring new pesticide-based products to market.
- The implementation of a new digital tools has improved the process of pharmacovigilance reporting.
- The CVM provides a high level of regulatory predictability about when a regulatory response is expected.
- Increased use of electronic submissions has improved efficiency of the submission process.
- Within CVM there is a move towards mutual recognition of regulatory processes and the use of common technical documents (e.g. VICH guidelines).
- The exclusion of vaccines with well-established vectors and approved risk analysis can bypass environmental assessments through the categorical exclusion process. This is helpful for this class of preventative medicines.
- The Regulatory Cooperation Council (RCC) between USA and Canada has a positive effect.
- The adoption of policies to spur innovation, such as expanded conditional approval, were positive actions.

The challenges going forward

A long-standing challenge in the veterinary medicines sector is the cost of meeting regulatory requirements that can be disproportionately high in relation to the size of the market. Suitable periods of **intellectual property protection**, essential to support investment, are not always present.

Predictability: Product development requires a long-term investment, and depends on the ability to secure a return on investment over a reasonable period of time. The longer the product development and registration timeline, the higher the risk towards obtaining a return on investment. Predictability of the regulatory processes is critical and is sometimes lacking. Improvements are often needed in: (a) transparency and clarity around the requirements that must be fulfilled to obtain marketing authorisation, (b) consistency in the scientific assessment and (c) predictability in timelines.

Cost and time of product development: The trend towards increasing cost and time required for product development has been persistent for decades. This creates a need to spread the cost and risk across global markets and raises the importance of global regulatory convergence, particularly for smaller national markets.

Regulatory best practices: Several countries, outside of the VICH regions, have not yet implemented regulatory best practices with respect to the points above. Companies face unannounced or changing requirements, poor lines of communication to regulatory agencies, and long and unpredictable timelines. This situation is often caused by insufficient resources allocated to the regulatory agencies, resulting in under-staffing, lack of sufficient training and lack of investment in regulatory infrastructure, including digital tools. Improved efficiencies, such as adoption of risk-benefit approaches may be hindered by national legislation that is in need of review.

Several countries are in the process of **upgrading their regulatory systems**. While this is welcomed, particularly if reforms embrace international norms and standards of good regulatory practice, it also creates a period of painful adjustment for local businesses. This can be a challenge if these national markets are under-developed and do not yet support the increased costs, and if the transition creates a period of uncertainty. The viability of long-established products is potentially threatened when new data requirements are applied retrospectively.

Occasionally, during the upgrading of regulatory systems, requirements implemented for the human medicines sector may also be automatically applied to veterinary medicines. This can create problems if these regulatory measures are disproportionate in cost to the much smaller sector, and inappropriate to the difference in risk-profile from that of human medicines. An example is the use of individual pack serialisation to combat counterfeit trade in medicines.

Meeting societal standards: As regulatory systems evolve, increases in safety are mirrored by increases in societies' levels of expectation. When societal standards rise, data requirements expand, and product development costs increase. New data requirements mean high costs persist in mandatory defensive R&D needed to maintain licences for existing products. Other post-authorisation costs are also increasing with the implementation of Good Manufacturing Practice requirements and improved pharmacovigilance systems. Some countries still have not removed the outdated target animal batch safety testing of vaccines. Both illegal compounding and illegal use of cheaper human medicines by the veterinary sector act as disincentives to investment in new products in animal health.

Australia challenges

- The cost of meeting the regulatory requirements is disproportionately high in relation to the size of the market.
- Efficacy requirements set out in VICH guidelines differ for some product types.
- The requirements for anything 'new' can be unpredictable, particularly in relation to Australia's strict biosecurity and import regulations.
- The GMP inspection intervals in Australia are different to those of other regulators.

Brazil challenges

- As a result of a major re-organization of the regulatory bodies, the number of assessors has been greatly reduced causing a major backlog in the approval process (upwards of 4 years).
- Assessors are not adequately trained causing delays, misinterpretations and inconsistencies in approvals.
- Innovation is hindered due to a lack of regulatory framework and little Intellectual Property protection.
- New regulations or alignment of more restrictive requests by MAPA causes a large increase in defensive R&D costs, which siphons funding away from new innovations.
- The lack of legislation on specific types of products is a hurdle to simplify the registration process considering a risk analysis.
- Biological products are not included in SIPEAGRO (electronic system for pharmaceutical product registration).

Canada challenges

- There is a need for modernisation of the existing regulatory framework and improved transparency.
- New regulatory requirements have caused a significant increase in mandatory defensive research and development costs.
- Costs have increased for licence renewals, due to increased requirements for AMR data and environmental safety data.
- Regulatory changes outpace updates to related guidelines and there is insufficient harmonization with the US and the EU.
- Significant issues persist with registration of EU-approved biologics, medicated feed additives and products for minor uses and minor species.
- Fees are disproportionate to the small size of the Canadian market.
- Additional service fee increases already planned will further raise the costs of maintaining products on the market, and may not be sustainable for some products.
- Procedures related to medicated feed additives are seen as unpredictable and of poor quality (and there is a big backlog).

China challenges

- The regulatory requirements are not very detailed.
- There is an import ban on MLV vaccines against class A diseases and/or vaccines from class A pathogens.
- Domestic generics are allowed earlier market access than the imported original product or pharmaceutical equivalents if the data are from themselves.
- The timing of applications of original pharmaceuticals are restricted during monitoring periods of domestic generics.
- China has different regulatory data requirements from other countries. Data requirements, or their explanations on the same regulation, are becoming stricter.
- There is an increase in time and cost for product registration especially for live vaccines and new technologies.
- Individual pack serialisation coding has increased costs.
- There are no joint review or parallel assessment between China and other countries.

European Union challenges

- The regulatory framework is ill-adapted to biologicals, particularly the data requirements and the variations regulations.
- The biggest hurdle to innovation is environmental safety legislation, the resource intensive manufacturing inspections and the EMA policy on public access to documents.
- The growing cost of pharmacovigilance systems has become a significant challenge.
- There is great concern that efforts by the European Commission to reduce administrative burden through the Regulation 2019/6 will be steadily eroded when implemented by the EU member states.
- Some companies are still spending up to 40% of their R&D budget on mandatory defensive R&D.

India challenges

- The market is large, but the value is low, hindering investment.
- The availability of skilled manpower for R&D especially biotechnology remains a challenge.
- Bringing new products to market has become more costly.
- The involvement of 3 regulatory authorities presents challenges; the increase in regulatory process time is mostly due to this multi-stage and multi-department authorization process.
- Regulatory fees for animal healthcare products are at par with human medicines and are disproportionate considering the small market size in India; there has been a ten-fold increase in registration and renewal fees.
- Imported products have higher registration fees considering they have renewal fees every three years.
- The registration and import certificate validity is only 3 years and should be 5 years (the same as local manufactured products).
- Pre-registration testing is mandatory for both Therapeutics and Biologicals and is negatively impacting launch timelines.

Japan challenges

- The small size of market segments is the biggest factor having a negative impact on innovation. Other significant factors include the Japanese regulatory framework (particularly post-approval defensive R&D costs), and lack of availability of financial resources.
- The most notable change in the 2020 survey is the increased importance of the lack of skilled staff (possibly due to the retirement of experienced staff).
- Increases in development time and costs (associated with AMR and GCP) as well as a perception of uncertainty (e.g. around GMP rules) and unpredictability are all a concern.
- Post-authorisation costs have also increased (e.g. for renewals and especially for post-marketing surveillance).
- Other unhelpful areas are variations, import regulations, and packaging/labelling change rules.
- The use of human drugs for companion animals and off-label use are disincentives to further development of existing products.
- The increasing requirements for data on environmental safety and antimicrobial resistance are problematic for existing products.

Russia challenges

- Regulatory problems and GMP inspection have become the major barrier for market development, indeed, even simply to access the market.
- Generally there is a strong trend towards increasing regulation.
- Strict national regulations, insufficient harmonization with international standards and lack of adequate infrastructure, do not provide incentives for R&D in Russia.
- The regulations restrict bringing innovative veterinary medicines to the Russian market. Innovative product launches have almost completely ceased.
- Despite some local beneficial changes in the regulatory framework, overall the regulatory problems have become the major barrier for marker development.
- National GMP, implemented in 2017, in the veterinary sector is restrictive and unpredictable with ever increasing demands; it has worsened business conditions through translation issues and different law enforcement practices; major changes are needed.
- New rules for GMO medicines make it virtually impossible to launch vector vaccines.
- The time and cost for market authorisation has significantly increased.
- The target animal batch safety test is still required for vaccines.
- National quality control of registration samples require supply of all testing reagents' require logistics in time and supply of reagents even those that are commercially available

South Africa challenges

- Long delays to bring an innovator product to market have a large negative impact on the investment in new product developments.
- The regulatory framework, small market size, weak intellectual property protection, a scarcity of skilled staff available to companies and the regulatory authorities, and lack of available financial resources are all barriers to innovation.
- Product development time and costs have increased for all product groups.
- For Stock Remedies a multi-agency approach to clinical trial permit approval drives trial costs up while substantially delaying approval.
- Illegal compounding negatively impacts innovative veterinary products, and affects the sales of registered products.
- Maximum Residue Limits are not aligned to international changes in a timely manner.
- Regulatory timelines are not predictable, and established timeframes are not adhered to.
- There is an urgent need for an effective pharmacovigilance system.

USA challenges

- Inefficient practices, such as FDA's need for copies of raw data, burdens the review process.
- Compounding from bulk drug substances disincentivises investment in animal health and the FDA regulatory process.
- Inconsistencies between review teams perceived as changing regulatory requirements.
- The time and cost of product development continues to increase.
- FDA's data protection incentives for New chemical entity approvals and subsequent approval are weak.
- USDA review of all export labels and USDA release of every batch are burdensome.
- Uncertainty surrounding regulations on labelling is unhelpful as this leads to variability between reviewer expectations.
- Illegal compounding causes significant loss of sales for affected pharmaceuticals.
- Unannounced changes in the regulator's current thinking and policies create unpredictable issues.
- Packaging and labelling rules for single-tier labelling adds cost and reduces predictability of approval if claims are reassessed.
- There is no regulatory framework in place for new technologies.
- There is a decrease in public confidence in EPA regulatory process; the government needs to take measures to improve the situation.

Markets and investment

The combined worldwide revenue of the 60 animal healthcare companies participating in the GBS2020 survey was $23.08 billion in 2018, of which 96% ($22.74 billion) is generated by the 10 HealthforAnimals member companies.

The 11 markets included in this survey account for 71% of the combined global revenue of HealthforAnimals companies, with the US and EU holding half of this global share (Figure 1).

The average annual growth rate across HealthforAnimals companies for the period considered (2014–2018) is 5.4% and the stepwise growth of global sales revenue indicates this is mainly the result of merger and acquisition activities of the larger companies (Figure 2). The fastest growing regions are in Asia and South Asia.

Figure 1: Revenue distribution of HealthforAnimals companies across 11 markets in 2018

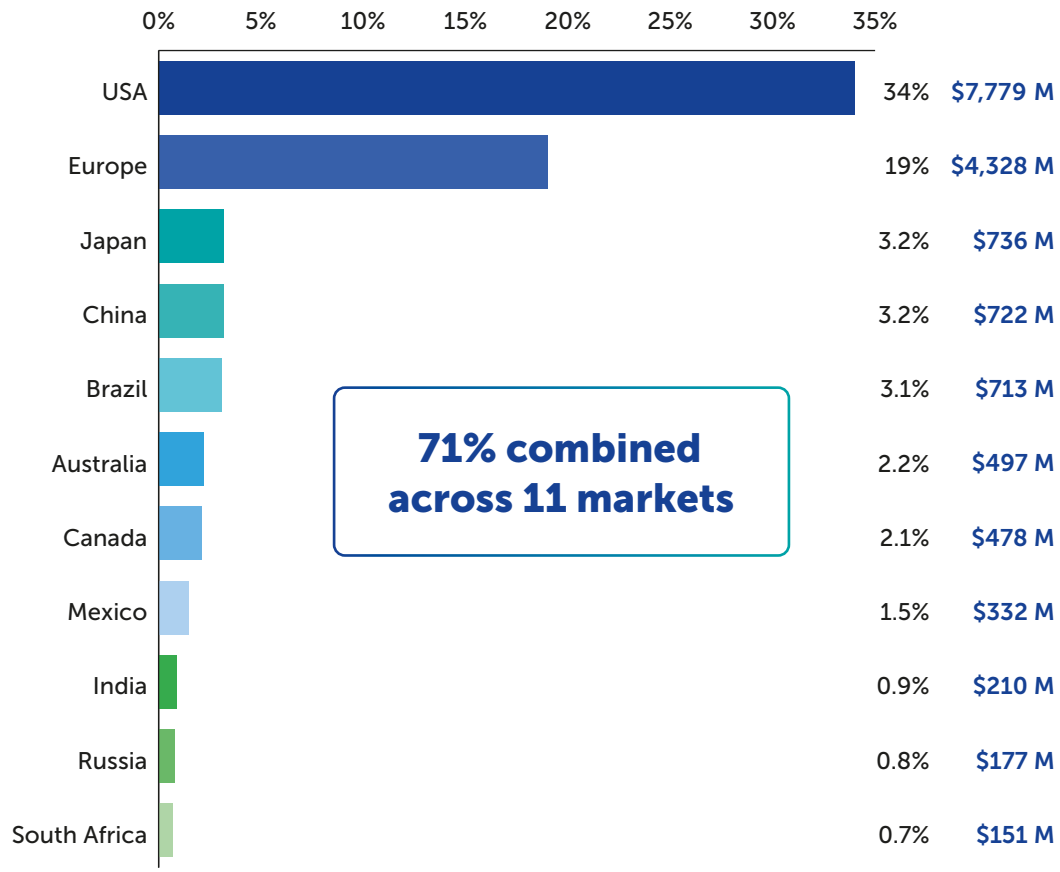
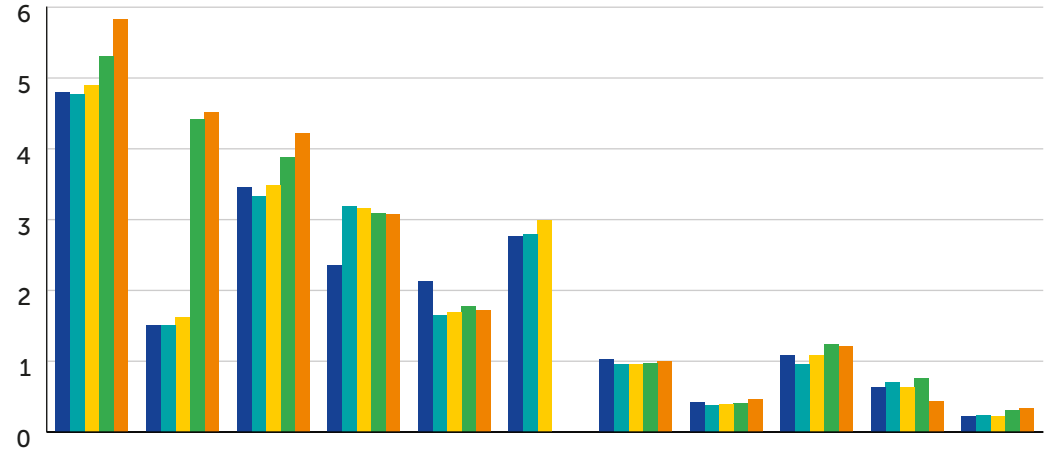


Figure 2: HealthforAnimals 2018 member companies: evolution of global sales revenue (in $ billion)*



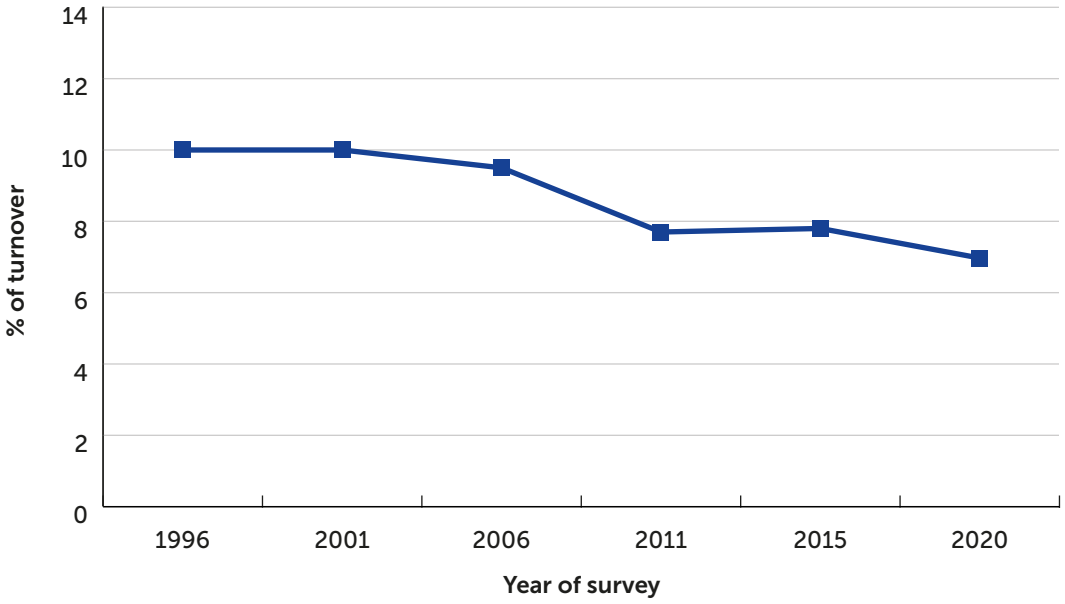
	Zoetis	Boehringer Ingelheim	MSD AH	Elanco	Bayer AH	Merial	Virbac	Vetoquinol	Ceva	Phibro AH	Zenoaq
2014	4.79	1.50	3.45	2.35	2.12	2.76	1.03	0.42	1.08	0.63	0.22
2015	4.77	1.51	3.32	3.18	1.65	2.79	0.95	0.38	0.95	0.70	0.23
2016	4.89	1.62	3.48	3.16	1.69	2.99	0.96	0.39	1.08	0.63	0.22
2017	5.31	4.41	3.88	3.09	1.77		0.97	0.40	1.24	0.76	0.31
2018	5.83	4.51	4.21	3.07	1.71		0.99	0.46	1.21	0.43	0.33

**Merial was acquired by Boehringer-Ingelheim in 2017, turning it into the second-largest global animal health company*

Product category share of investments: For the 10 HealthforAnimals member companies, R&D investment in traditional veterinary medicines (pharmaceuticals and biologicals) ranged from 2% to 9.4% of turnover in 2018, with an average of 7% (versus 7.8% in GBS2015). The top 5 companies continue to invest more than 8% of their turnover in R&D.

For the period 1996 to 2006, the benchmarking survey consistently reported a level of R&D investment of approximately 10% of turnover (Figure 3). The decrease to 7 or 8% over the last decade is linked to several factors, including: (a) a change in the HealthforAnimals membership, (b) a shift towards more companion animal products; (c) a shift away from veterinary antibiotics and towards vaccines and (d) an evolution of company portfolios towards a broader range of animal health products and extending more into ancillary products and services; this means an analysis focussed only on investment in traditional veterinary medicinal products no longer captures the full investment picture for companies.

Figure 3: Long-term trend in investment in R&D in traditional veterinary medicines as a % of global total sales (all benchmarking surveys)



R&D spend

The companies participating in this section of the survey included 10 HealthforAnimals companies and 12 local companies. In 2018, these 22 companies split their R&D budgets across the main product categories as follows:

- 34% on companion animal products and 66% on major food animal products
  - N.B. In western markets, such as USA and EU, this split is closer to 50:50
  - Six (50%) of the local companies focussed entirely on food animal medicinal products
- 69% on pharmaceutical products (including ectoparasiticides) and 31% on biological products (primarily vaccines).

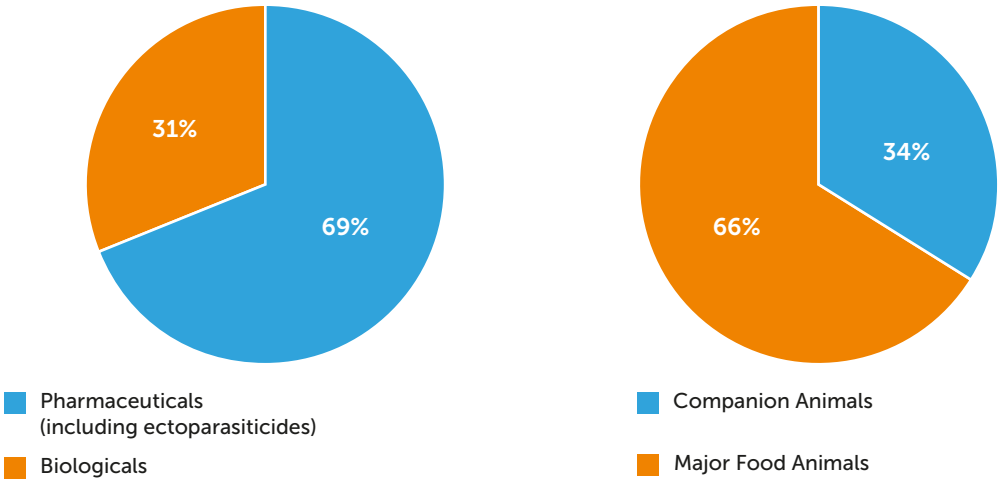
The HealthforAnimals companies tended to have portfolios balanced between companion animal products and food-animal products, with an average split of 49% and 51% respectively. Their R&D portfolios were more weighted towards pharmaceuticals than vaccines, with an average split of 73% versus 27% of R&D spend. But the long terms trends appear to be a reduced spend on livestock products and on pharmaceuticals, and an increased spend on companion animal products and on vaccines. However, these trends must be seen also in the context of the following considerations:

- biologicals require less R&D investment, therefore the split in share of projects will be different than the split in share of R&D budget;
- the cost of developing pharmaceutical products for livestock has significantly increased due to increased data requirements for environmental safety, and on potential development of resistance (both for antibiotics and for antiparasitics).

Table 1: Distribution of R&D by product category in 2014 and in 2018

Product category	HealthforAnimals companies	HealthforAnimals companies (10)	12 'Local' companies	All 22 companies
	2014	2018	2018	2018
Pharmaceuticals (including ectoparasiticides)	77%	73%	64%	69%
Biologicals	23%	27%	36%	31%
Companion Animals	39%	49%	21%	34%
Major Food Animals	61%	51%	79%	66%

Figure 4: Distribution of R&D for all surveyed companies by product category



N.B.: These pie charts do not reflect the number of product development projects in the pipe-line between these categories of products. The cost to bring a food animal product to market is considerably higher than for companion animal. Likewise, the cost to develop a pharmaceutical is higher than for a vaccine.

Key trends

- The sector continues to grow, with several different drivers, including both technological, geographical and societal.
- The sector continues to make significant investments in R&D, although the nature of those investments is shifting, such as towards companion animals, vaccines and other non-medicinal areas of animal health (diagnostics and disease detection using sensor technologies and big data).
- There is a shift away from livestock products towards companion animal products
- Mandatory defensive R&D is declining in large mature markets.

Key regulatory findings

Company profiles

The GBS2020 survey participants included 10 HealthforAnimals member companies and their national subsidiaries, as well as 50 local, regional and internationally active companies that are members of the national industry associations. A total of 121 completed questionnaires were received (59% from HealthforAnimals members companies and their national subsidiaries and 41% from 'local' companies), and 8 workshops were organised at the country level (Table 2).

Table 2: Total respondents per country

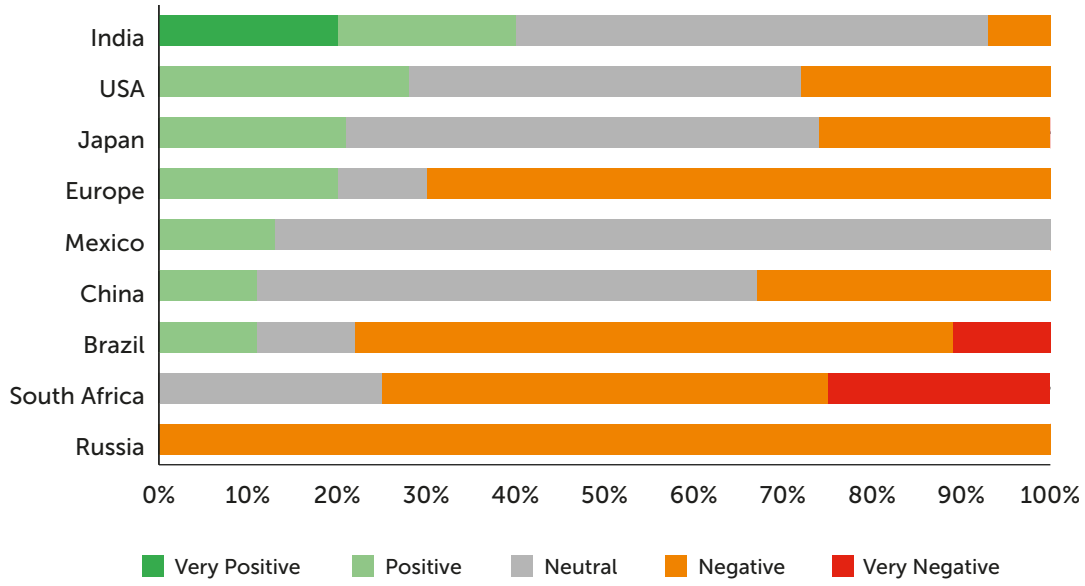
Country	Respondents	Workshop
Australia	9	Yes
Brazil	8	No
Canada	14	Yes
China	9	Yes
Europe	12	Yes
India	15	Yes
Japan	19	No
Mexico	9	Yes
Russia	4	No
South Africa	12	Yes
USA	10	Yes
TOTALS:	**121**	**8**

Regulations and innovation

Companies' perceptions of the impacts of national regulations on their ability to innovate is illustrated in Figure 5. In the majority of countries there was a mixed response, highlighting the dual role of regulations in both restricting and facilitating innovative activities. For 2 countries, Brazil and Russia, no positive views were expressed, indicating the strong challenges present in their local regulatory environment. It is hoped that future surveys in these countries will map progress towards overcoming these challenges.

Companies appreciate a well-regulated market, but are negatively impacted by excessive or, in their view, certain unnecessary aspects to regulations. Negative views may also reflect regulations that are unclear, complex or enforced in a disharmonised or unpredictable manner.

Figure 5: Perceptions of Impacts of Regulations on Ability to Innovate



N.B.: In Canada the consensus opinion was generally positive and the perception of the individual companies was not recorded. Australia is not included in this topic.

There may be some cultural differences introducing a local bias in response to questions related to national authorities.

The survey participants in Canada and Russia each reached an overall opinion by consensus. Input from the USA reflects opinion across all three regulatory agencies (FDA, USDA and EPA).

Mandatory Defensive R&D

Mandatory defensive R&D is defined as the cost of additional studies demanded by the regulatory authority to maintain a product on the market, either at licence renewal, or during other regulatory activity (such as product periodic reviews or referrals). It does not include additional post-authorisation studies conducted voluntarily by the marketing authorisation holder.

It is clear from the data gathered that companies have very different strategies regarding allocation of R&D funding to support products already on the market. A small number of companies focus their funds almost entirely on developing new products and have taken a decision to no-longer re-invest in repeatedly 're-developing' existing products. For multinational companies, the defensive R&D investment is evident in the countries where their research is based; in other countries where no research is done on new products then 100% of the R&D budget is allocated to local defensive R&D work.

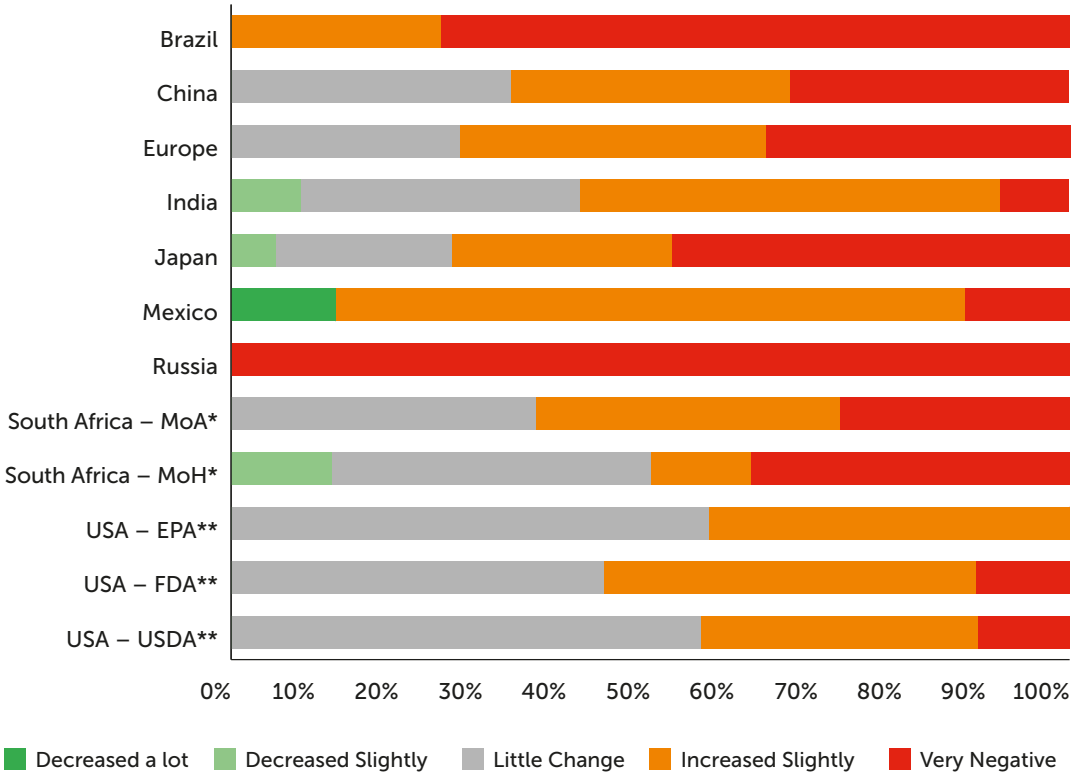
Consequently, the amount of the R&D budget invested in mandatory defensive R&D ranged from <1% to 100%. The lowest proportion of the R&D budget spent on defensive R&D was in USA (range <1% to 40%) and Europe (range <1% to 40%).

In Canada, India, Japan, Russia and South Africa some companies were utilising 90 to 100% of their local R&D budget on maintaining existing products on the market.

Due to the inherent variance in the data, average values are misleading and are not reported.

Company perceptions of changes in the level of mandatory defensive R&D over recent years reveal some differences between the 11 markets. In USA there appears to be little change. Brazil, Russia and Canada believe that levels have increased. All other countries show a mixed response; 3 countries ranging from neutral to increased-a-lot (China, Europe, South Africa-MoA) and only 4 countries reporting any level of decrease in defensive R&D costs (India, Japan, Mexico and South Africa-MoH).

Figure 6: Company experience on whether Mandatory Defensive R&D has increased or decreased



** South Africa: Ministry of Health (Act 101 products) and Ministry of Agriculture (Act 36 products)*

***USA: Environmental Protection Agency, Food and Drug Administration and US Department of Agriculture*

N.B. Canada and Russia show a single coloured bar depicting a local group consensus opinion.

Times-to-approval for new products: submission of data to licence issue

One measure of the efficiency of a regulatory system is the length of time the registration step takes. This is the time from submission of a dossier to the granting of a marketing authorisation.

In Figure 7, the longest and shortest registration times reported by the survey participants are shown, and the average times per country are shown in Table 3. No data is presented for Australia, Japan and Canada (insufficient sample sizes) or USA (which uses a phased submissions system that cannot be directly compared).

Table 3: Average length of the product registration step

Country	Average (years)
Europe	1.3
Russia	1.8
Mexico	2.0
India	2.4
Brazil	3.1
South Africa – MoA	5.0
China	6.1
South Africa – MoH	6.4

The data illustrates a marked difference between countries, ranging from an average of 1.3 years to 6.4 years.

Within these averages may lie marked differences between registration times for different product categories. In most countries, there is no significant difference in registration times between companion animals and food-producing animals (Figure 8). But there often is a significant difference between biologicals and pharmaceuticals, with biologicals taking significantly longer, particularly in China (Figures 9 and 10). The exception is USA, where the registration of biologicals takes considerably less time than pharmaceuticals.

An emerging trend is for some countries to offer a faster registration process for products that are already registered in another country with a regulatory authority working to international standards, such as the VICH countries (e.g. biologicals can be approved in 6 months in Canada if previously approved in the United States).

In South Africa, there is dual registration system for Veterinary Medicines, which are the responsibility of the Ministry of Health (MoH), and Stock Remedies, which are the responsibility of the Ministry of Agriculture (MoA). The registration time for stock remedies is currently shorter than for veterinary medicines, although both are significantly longer than other countries, except for China.

The United States utilizes a phased review process allowing the regulator to evaluate specific sections as data become available. The review process begins with opening an investigational new animal drug (INAD) application and culminates with a new animal drug application (NADA) approval. Target deadlines for review of critical sections of the application, also known as performance goals, are specified in legislation. The performance goals range from 50 days for review of study protocols to 180 days for review of

study data. An internal survey of US companies estimated that over the past five years the time from INAD to NADA approval was around 7 years for companion animal pharmaceuticals and over 9 years for food animal pharmaceuticals.

In the EU legislation the target deadlines for the scientific review of an application for marketing authorisation is set at 210 days. Additional months are added to allow time for the applicant to respond to questions, for translating the approved product packaging and information, and for the marketing authorisation to be officially issued.

Figure 7: Average shortest and longest times from submission to approval

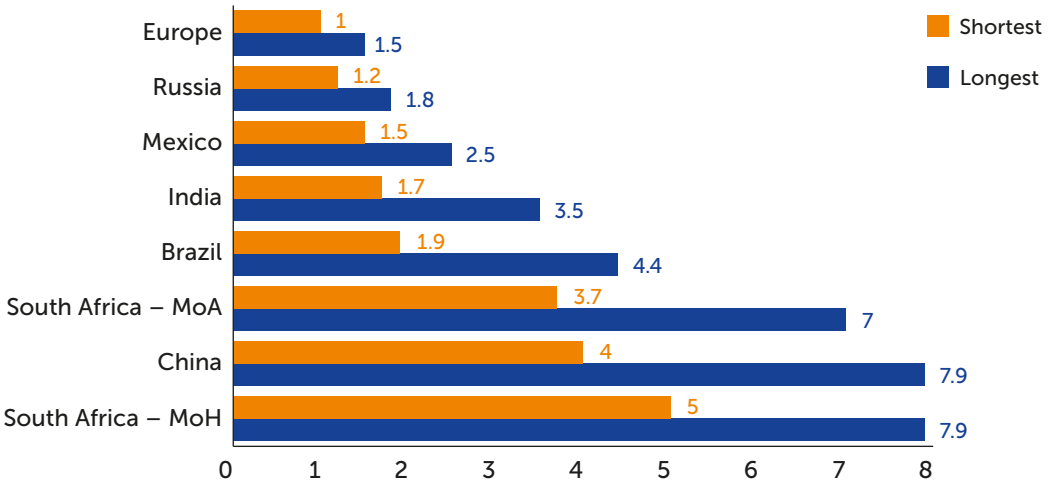


Figure 8: Average times to approval for new products from submission

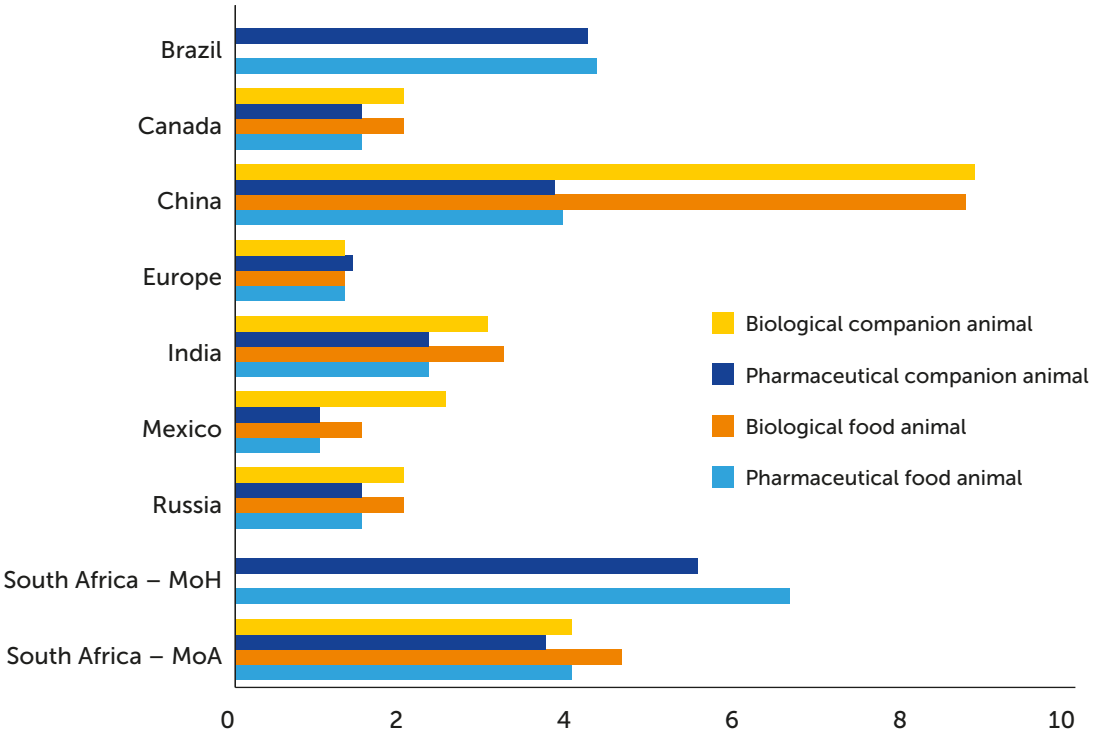


Figure 9: Average times-to-approval for new product for Major Food Animals

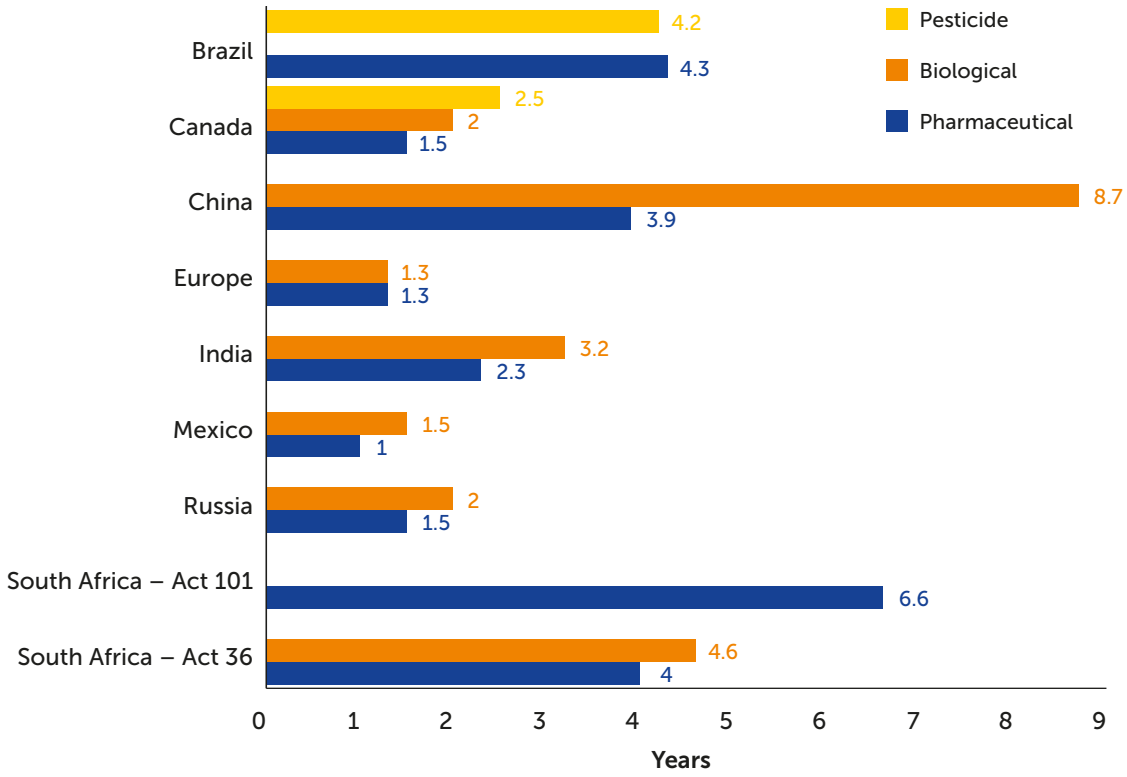
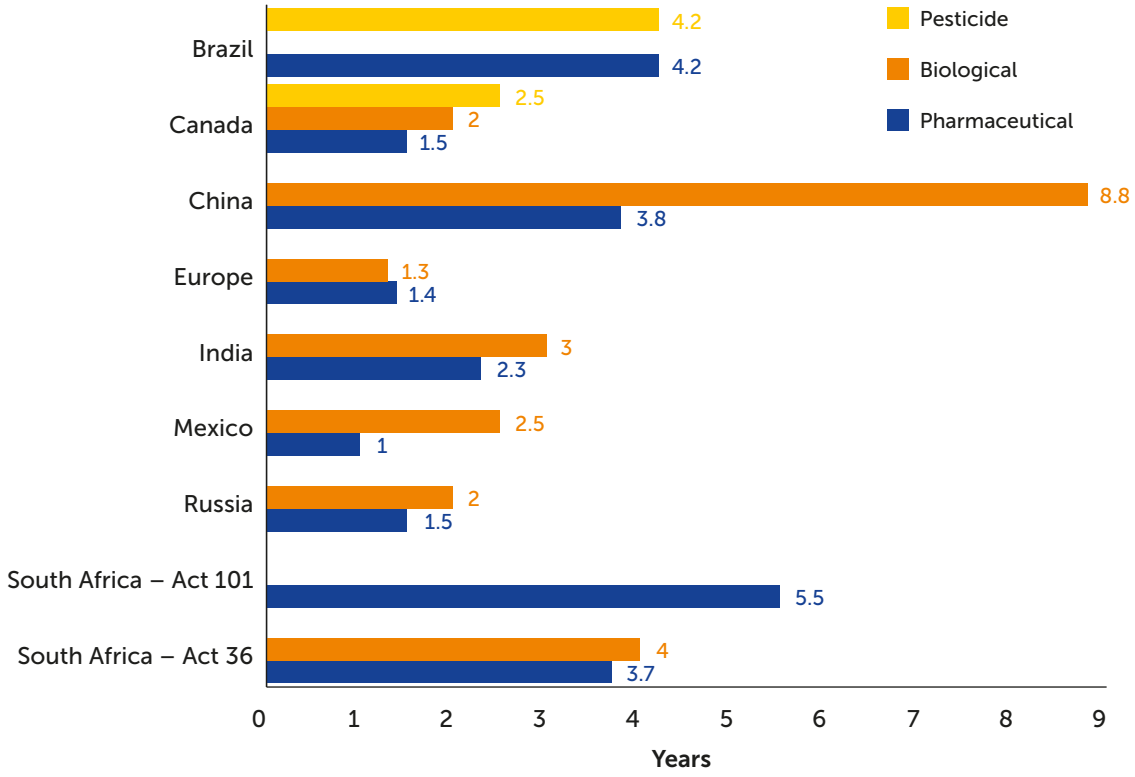


Figure 10: Average times-to-approval for new product for Companion Animals



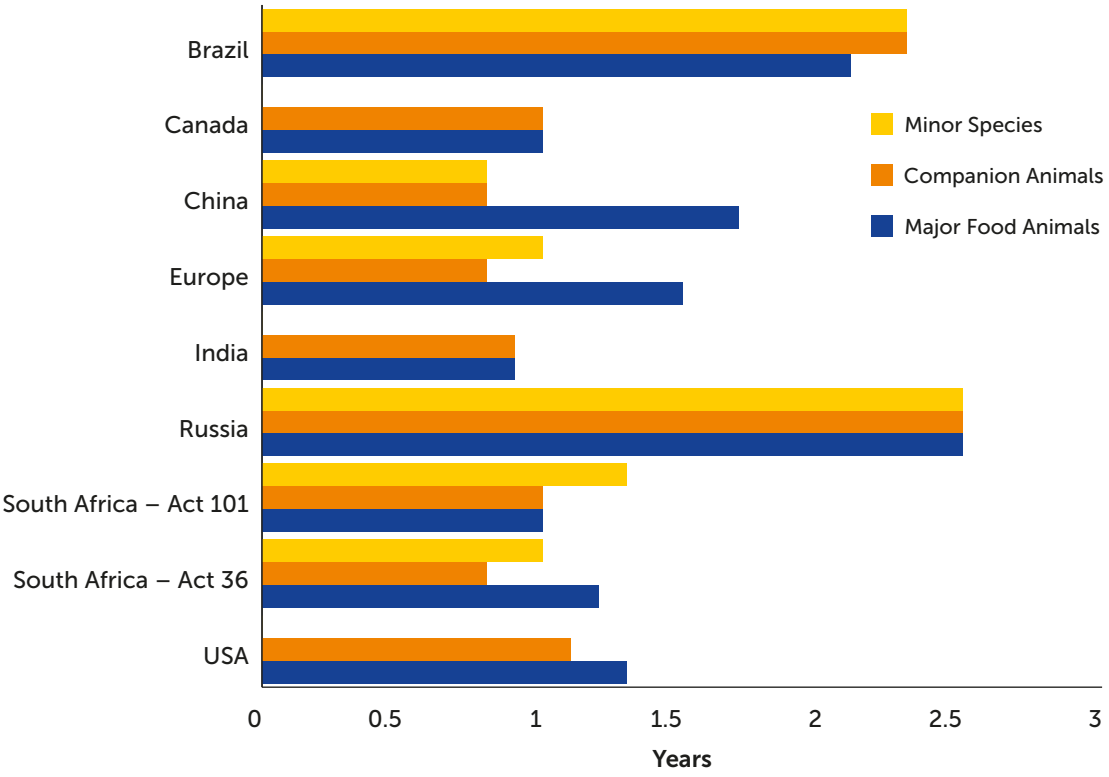
N.B.: Pesticide: this refers to ectoparasiticides that are registered through a process similar to pesticides in some countries

Trends in time for New Product Development

The time for new product development (the research phase) does not include the time for the registration step (the phase from submission of data to the authorities to licence issue).

The perception of companies is that the time needed for new product development has increased by one or two years since the previous survey in 2015 (Figure 11 for pharmaceuticals; insufficient data was obtained for biologicals). This is a long-term trend that has continued for several decades, probably since the inception of the first regulatory systems. The increase in R&D time is believed to be across all countries, but is particularly noticeable in Brazil and Russia.

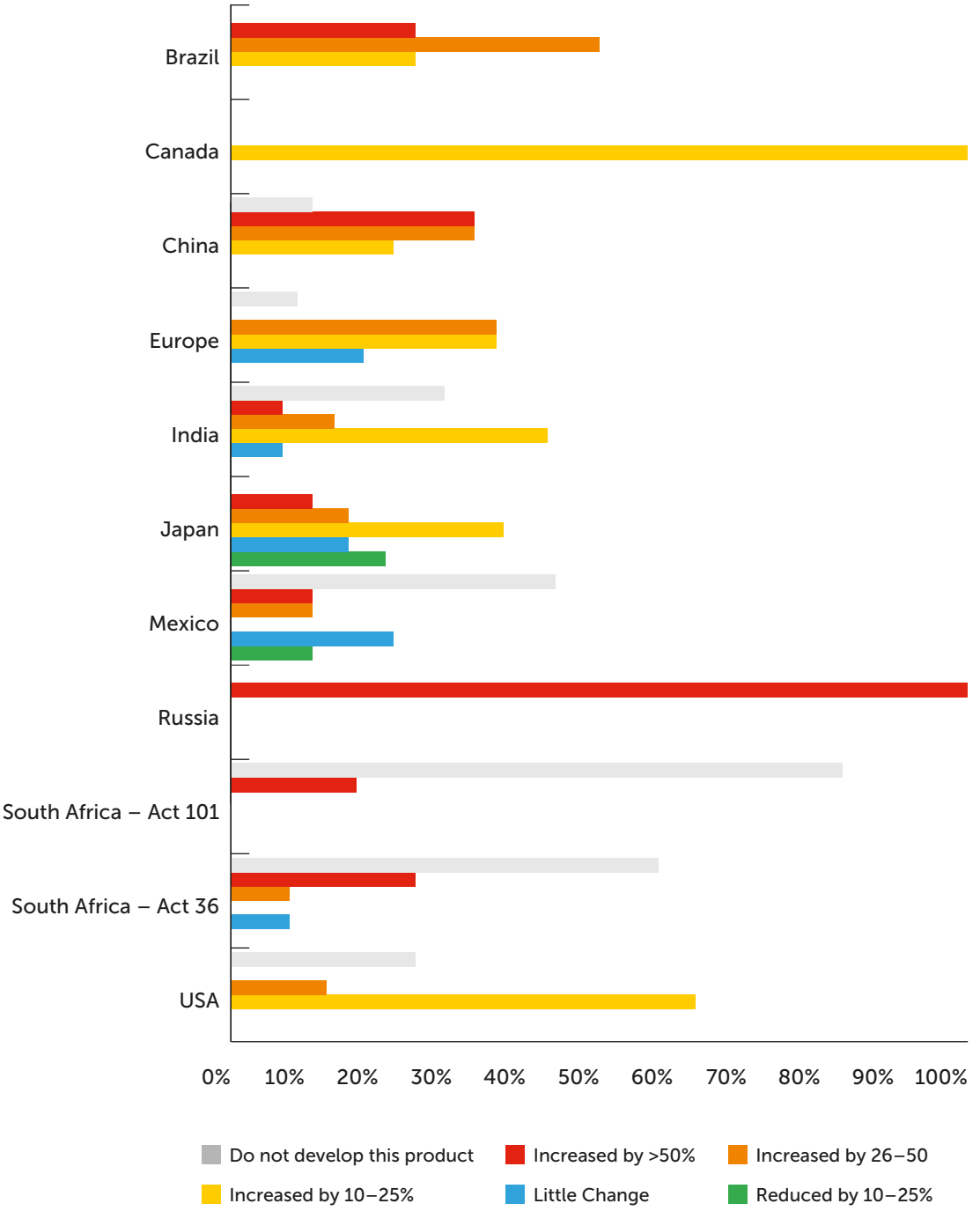
Figure 11: Increase in PHARMACEUTICAL NPD time since 2015 by species product category



Costs of new product development

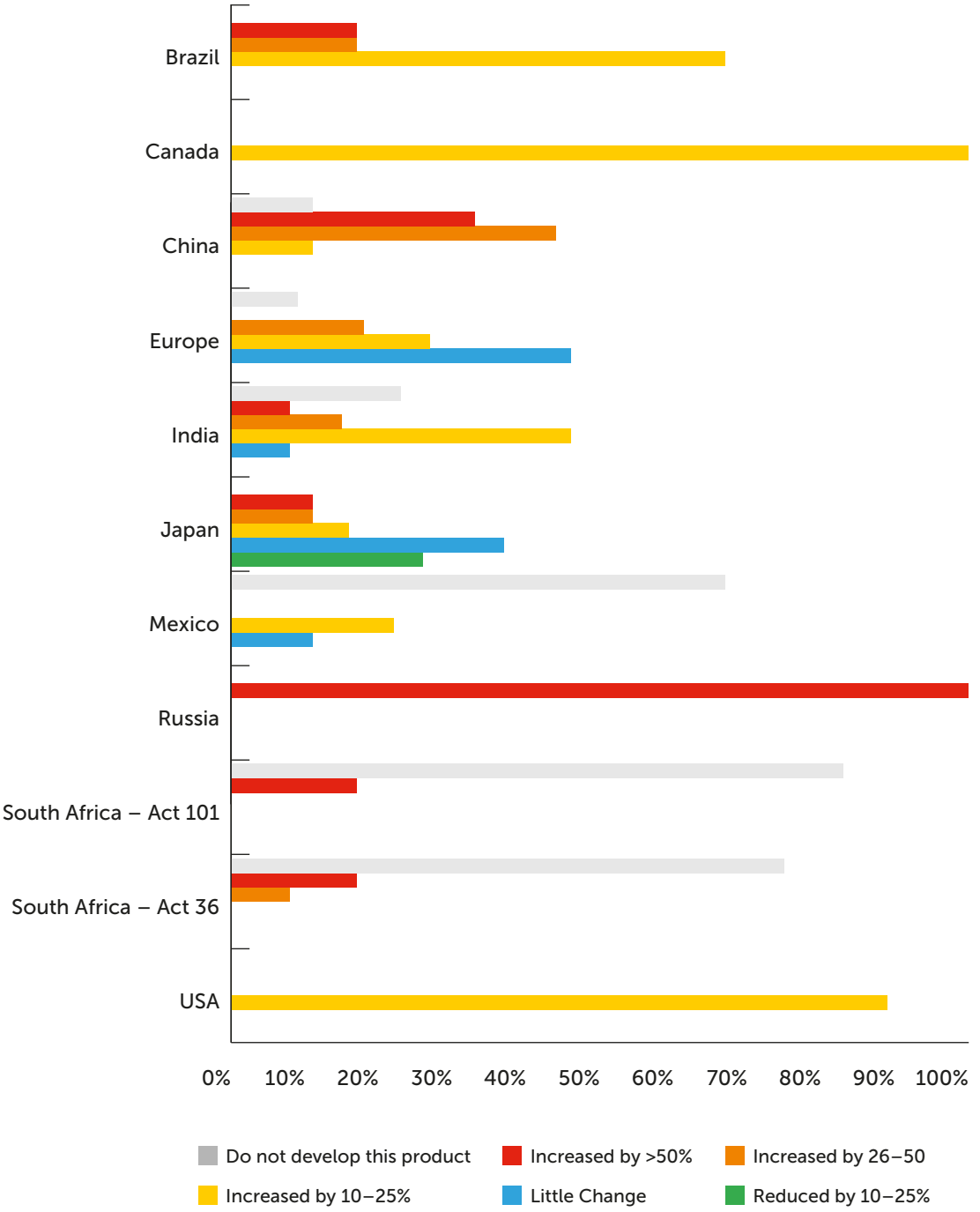
There has been a general trend in the global benchmarking surveys for new product development costs to increase. Although the rate of increase has slowed down in the VICH countries, it has risen significantly in transition countries that are upgrading their regulatory systems to international standards. The largest changes since the previous survey in 2015 were seen in Brazil, China, Russia and South Africa. The least change has been seen in Canada, Europe and USA.

Figure 12: Company perception of change in NPD Cost since 2015 – Pharmaceuticals / food-producing animals



N.B. Canada and Russia show a single coloured bar depicting a local group consensus opinion.

Figure 13: Company perception of change in NPD Cost since 2015 – Pharmaceuticals / companion animals



N.B. the data for Canada and Russia is a single value agreed by consensus in the local workshop.

The future and suggestions for action

This report has recognised the progress that has been made in modernising regulatory frameworks. Although well advanced in some countries, progress is in its infancy in others. Consequently, there are calls for several countries to continue down this path and in particular to improve standards in regulatory practice that will bring improvements to regulatory efficiency, predictability and transparency. This will concomitantly bring improvements in the availability of authorised veterinary medicines giving veterinarians and animal owners access to safe and quality assured products.

The modernisation of regulatory frameworks should be seen as an opportunity to better adapt regulatory systems to the specific characteristics of the veterinary sector and to bring regulatory activities under a single agency specific for veterinary medicines, avoiding lengthy regulatory pathways involving several government ministries.

There are also calls for countries to continue to move towards regulatory convergence with the adoption of international standards, participation in international regulatory initiatives, such as VICH and PIC/S, and continue to pursue international standards of good regulatory practice. This includes strong stakeholder engagement through good lines of communication with applicants and public consultations on draft guidelines and legislation.

Regulatory science must also adapt to new scientific approaches and novel technologies in order to not hinder innovation and encourage investment.

The important role to be played by greater international cooperation in future systems cannot be underestimated. The participation of national regulatory agencies in international initiatives (such as VICH and PIC/S) and alignment with international standards helps to build trust and mutual respect, facilitating the emergence of resource-efficient approaches such as joint reviews, work-sharing, recognition of the decisions of trusted agencies and reduced duplication of inspections and audits.

Regulatory convergence should also lead to the removal of different approaches towards the regulation of imported products and locally developed products.

Modernised regulatory systems, including improved pharmacovigilance, should go hand-in-hand with less emphasis on post-authorisation administrative tasks, such licence renewals and short licence validity (e.g. 5 years).

The ability to respond rapidly to new emerging disease threats requires an agile and flexible regulatory system; greater emphasis should be placed on nuanced regulatory approaches, such as conditional approvals, fast-track approvals and mutual reliance on decisions taken in other trusted jurisdictions.

More emphasis is needed on the application of the principles of the "3Rs" in the reduction of the mandatory use of animals in regulatory science, both at the product development stage and for routine batch release. HealthforAnimals calls for the global acceptance of the removal of unwarranted use of test animals by deleting or waiving (according to the criteria in the VICH guidelines) of *in-vivo* batch safety testing of vaccines in target species or laboratory animals.

Industry requests for regulatory improvements

Australia 2020

- Maintenance of legislated timeframes for regulatory procedures.
- Greater use of international assessments and regulatory cooperation to deliver efficiency benefits to regulatory procedures.
- Improved guidance material for applicants to support mutual understanding of requirements and consistent interpretation.

Brazil 2020

- Clearer rules from modernization of the regulatory framework, including on categorization, predictability of standards and dossier evaluation.
- Transparency of information (mainly regarding the dossier evaluation queues) and agility.
- Sharing of responsibility between authority and industry technical experts in order to make the best technologies and products available to customers.
- Best scientific and risk assessment evaluation made available.
- New tests or product reviews should only be requested based on a rigorous analysis of pharmacovigilance data or relevant advances in scientific knowledge.
- Final approval of new products should be based on expert evaluation of safety, quality and effectiveness, and on a practical but thorough assessment of the benefit – risk balance.
- Public-private partnership for product evaluation (e.g. FEA).
- Significant reduction in process analysis deadlines within MAPA, especially for new products.
- Transition to use of only digital channels for sending processes.
- Focus effort on removing the dossier evaluation backlog and reduced to applications submitted only in the last two years.
- Continue effort to bring more efficient regulatory procedures.
- Pursue further updates to regulations in order to clarify and harmonize with international legislation.
- Lead discussions about pharmacovigilance.

Canada 2020

- VDD (Veterinary Drugs Directorate).
- Move to risk benefit assessments.
- Updating of guidance documents (GLs) to support single review passes for products.
- Use of foreign decisions.
- Move to dose ranges and alignment in the maximum residue assessment.
- Remove redundant need for endotoxin testing to align with the EU.
- Alignment with the interpretation of VICH guidelines.
- ROEB (Regulatory Operations & Enforcement Branch).
- Robust triaging of foreign site assessments.
- Improve timeliness of reviews.
- Work with manufacturers on observations before going public.
- Inspectors need to better understand veterinary requirements.
- Better oversight and more inspection of compounding facilities to ensure the safety and efficacy of compounded products and a level playing field.

China 2020

- Greater harmonisation of regulatory requirements and standards with other countries.
- In-parallel registration procedures with other countries, for innovation product and products which is urgent demands by farmers or veterinarians.
- Introduce the MAH management and allows CMO.
- Classification on variation registration process, such as major, and minor changes. Priority registration clarification via a detailed regulation.
- Specific Regulation for MUMS registration procedures.
- Clear and reasonable transition periods for the implementation of (new) regulations for multinational companies.
- Clear review and approval timelines and facilitation measures for GMOs.
- Improve the authority quality confirmatory testing or finished product quality specification process issues settlement caused by poor communications with the industry or inefficient internal communications within the authority.
- Stakeholder consultation in the drafting of regulations.
- More efficient and transparent communication mechanisms.
- Speed up the authority testing process.

European Union 2020

- Practical implementation of the new regulation, and better implementation of existing principles (e.g. mutual recognition and fully harmonised approaches across Member States).
- Training, preparation and understanding of new technologies and new therapeutic paradigms to support innovation.

- Creation of more opportunities for industry and regulatory agencies to collaborate more closely.
- Regulation that is better adapted, where appropriate, to the characteristics of the veterinary medicines sector (e.g. more veterinary specific aspects to GMP) and to biologicals.
- Greater harmonisation between regions and more mutual recognition agreements.

India 2020

- The registration validity of imported products should be equal to the validity of locally manufactured products i.e. five years with renewal based on company declaration and registration fee payment.
- Avoid duplication of check list documents for Market Authorization and Registration applications.
- Specific guidelines and check list for submissions of Veterinary products.
- Greater harmonization of requirements with global standards (VICH Guidelines)
- More predictable regulatory processes with continuous engagement of Authority and applicant to clarify scientific issues with open dialogue.
- A tracking system for the approval process is needed (as single window system with fixed timelines); minimize the timelines.
- Better coordination between CDSCO and DAHD with time bound response system.
- Reduce registration fees to be more proportionate to the sector.
- One to one meeting with the stakeholders (CDSCO) to discuss and resolve issues.
- Frequency of technical meetings at GEAC should be increased.
- Exclusive Veterinary Experts panel for evaluation and NOC for Veterinary products approvals.

Japan 2020

- Conduct a food health impact assessment of new active ingredients before applying for a product approval.
- Acceptance of evaluation results by EU / US.
- Abolition of post-marketing surveillance and replacement by pharmacovigilance system.
- For biologicals, change the regulation from during development to quality inspection after approval.
- Abolition of safety / titre tests in quality monitoring.
- Acceptance of quality inspection results.
- Elimination of efficacy studies in pre-application clinical trials.
- Promote notification system for in-vitro diagnostic drugs.
- Acceleration of regulatory approval processes for use of GMO.
- Further promotion of VICH activities.
- Allow paid clinical trials.
- Mandatory priority use of antibacterial substances for animals by veterinarian. (cascade construction).

Mexico 2020

- More attention and follow-up to citizen complaints considering that currently there are no provisions neither in SENASICA[1] nor SADER[2] for legal action.
- Reduction in the approval times for Biologicals by providing on-site approval with no dependency on the Federal government.
- Extensions of product registration validity to 10 years from 5 to reduce costs, lead-times and procedural delays.
- Better analysis for optimal periods to implement label changes thus avoiding production downtime and wasteful destruction of old labels.
- Harmonisation of reporting and procedures for better uniformity within Mexican regulatory bodies.

Russia 2020

- Further development of interactions between the industry and the regulatory system is required.
- The short-term goal is to simplify market access for existing products.
- Abolish the need of target animal testing of veterinary medicines in Russia as in Europe.
- Widespread innovative products launches and global increase of presence of multi-national companies on the Russian market requires serious legislation improvement and change of the approach to market regulation.

South Africa 2020

- The dual registration system for Veterinary Medicines and Stock Remedies must be resolved, with one act for veterinary products.
- Regulatory predictability and certainty are lacking and must be a priority moving forward.
- Measures are required to ensure Data Protection and Integrity, as well as patent protection for innovator products.
- Defensive R&D expenditure is expected to be significant for the foreseeable future. A risk-based approach to R&D requirements is needed, particularly for well-established molecules and products.

[1] SENASICA, Servicio Nacional de Sanidad, Inocuidad y Calidad (National Service for Health, Inoculations and Quality)
[2] SADER, Secretaria de Agricultura y Desarrollo Rural (Secretary of Agriculture and Rural Development)

- Evaluation guidelines are required for External Technical Evaluators to bring consistency in product assessment reports.
- Regional regulatory harmonisation in sub-Saharan Africa is important for growth of this market. Common dossier formats, common labels and mutual recognition should be encouraged.
- The compounding legislation should be reviewed for gaps and to ensure that the rights of innovators are addressed.

USA 2020

FDA

- Stricter regulation of compounding from bulk substances to prevent pharmacies from marketing unapproved medicines that compete with NADA approved drugs.
- Regulatory innovation efforts comparable to FDA's human side, e.g. "Food and Drug Administration Safety and Innovation Act" of 2012 that led to new regulatory pathways like breakthrough innovation or accelerated approval or the "Generating Antibiotic Incentives Now Act" that provides incentives for developing novel antimicrobial therapies such as patent term extensions. Revised EU legislation has recently also established incentives for new veterinary antimicrobials.
- Eliminate the requirement for raw data submission just as human pharma does not require this level of data submission.
- Coordinate residue models between FDA and Food Safety and Inspection Service (FSIS). FSIS and major trading partners care about the multi-reside method not the single.
- Increase coordination between CODEX and Foreign Agricultural Service. Investing more in CODEX gives USDA leverage to avoid future trade barriers.
- Current MUMS regulations do not encourage real development for minor uses/species.
- More detailed guidance on CMC requirements for biopharma products.
- Improvement in efficiency and outcome of CMC reviews.
- Good implementation of expanded conditional approval.
- More risk-based evaluation of data packages; consideration of what is necessary in submissions and efficiency improvements within CVM related to regulatory reform.
- Better avenues for communications to be able to keep work moving forward.

EPA

- EPA to follow FDA process and procedures for Sponsor meetings (formal memorandum of conference (MOC), timelines, etc.)
- Commitment to timelines established under the Pesticide Registration Improvement Act without the need for renegotiation of timelines.

USDA

- Eliminate redundant review of export labels that have already been approved by other regulatory authorities. CVB oversight could be eliminated or significantly reduced. Production of quality products is inherent in the CVB's oversight of manufacturing processes, facilities, confirmatory testing, and serial release processes.
- Eliminate 9 CFR regulations requiring Batch Safety Testing.
- Predictable policy change implementation through consistent application of due process for policy review and impact assessment that includes industry input to implementation of guidance documents.
- Changes to CVB lab test methods that impact regulatory disposition of pre-license serials and licensed products confirmatory testing should not be implemented without consulting with industry in an effort to fully understand consequences to testing outcomes. Changes of this nature should be published so industry has an opportunity to comment and transition.
- Stop applying draft guidance or current thinking without first communicating to industry the intent and inquiring what an adequate transition period would be for industry.
- Additional engagement from CVB on international harmonization.
- Key countries for outreach Turkey, China, Japan, Brazil, Russia, Thailand.
- There was interest in additional outreach on the 3Rs. VICH is a very slow process. What else can be done?
- Expansion of VSM 800.213 to include viable products that do not replicate in target species for live recombinant platforms well established in multiple species. Currently, VSM only addresses Licensing Guidelines for Production Platform-Based, Non-Replicating, Nonviable Products (March 12, 2018)

GENERAL

- The regulatory agencies need to embrace new approaches and move towards the benefit offered by new approaches versus the inherent risk just because it is new (e.g. 3R's).
- Reduction in the number of terminal studies.
- Increased reliance on in-vitro bioequivalence and other in-vitro options. This results in less or no animal use, less expense, often less variance on results, and decreased time to obtain and report data.

Glossary

Definitions

- Innovation is defined as new APIs (active pharmaceutical ingredients), new combinations of APIs, antigens products, technologies and services that bring new benefits to the market.
- R&D costs included all relevant internal costs, such as personnel, apportioned establishment costs, and allocated research costs, and those for outside resources such as CROs (Contract Research Organizations), field trials etc, and expenditure on defensive R&D.
- Mandatory defensive R&D expenditure was undertaken as a direct result of legal requirements by the regulatory authorities if the company is to maintain existing products in the market, including compliance with requirements for license renewals.
- 'Pharmaceuticals' should include pharmaceuticals, in-feed therapeutic products and in-water therapeutic products, biocides and animal pesticides, and biopharmaceuticals only if regulated by the same agency as therapeutics.
- 'Biologicals' should include vaccines, antibodies, antitoxins, antisera, and biopharmaceuticals only if regulated by the same agency as biologicals.
- Minor Species were considered according to any definition applied by the appropriate regulatory agency/agencies.
- Internal regulatory processes were internal review committees, enhanced quality management procedures for regulatory process, additional oversight processes for external R&D and other internal procedures that impact product development and regulatory activity.
- To estimate the cost for developing a new product, all relevant internal costs, such as personnel, apportioned establishment costs, and allocated research costs should be included, plus those for outside resources such as CROs, field trials etc.
- 'Safety' includes all aspects (target species, human, consumer, environmental).

Abbreviations

Abbreviation	Expansion
AH	Animal Health/animal health
AM[s], AMR	Antimicrobial[s], Antimicrobial Resistance
API	Active pharmaceutical ingredient
APVMA	Australian Pesticides and Veterinary Medicines Authority
CMC	Chemistry, Manufacture and Controls
CRO	Contract research organization
CVB	IN USA, APHIS's Center for Veterinary Biologics (Animal and Plant Health Inspection Service)
CVM	In USA, the FDA's Center for Veterinary Medicines
EAEU	Eurasian Economic Union
EMA	European Medicines [Evaluation] Agency
EPA	US Environmental Protection Agency
EU	European Union
FDA	US Food & Drug Administration
GBS	Global Benchmarking Survey
GCP, GLP, GMP	Good Clinical Practice, Good Laboratory Practice, Good Manufacturing Practice
GM, GMO	Genetically-modified/genetic modification, genetically-modified organism
JECFA	Joint FAO/WHO Expert Committee on Food Additives
MAPA	Brazil's Ministry of Agriculture, Livestock and Supply
MDR&D	Mandatory Defensive R&D
MUMS	Minor Uses-Minor Species
NPD	New Product Development – from discovery to final approval
PIC/S	Pharmaceutical Inspection Conventions / PI Cooperation Scheme
R&D	Research and Development
SAHPRA	South African Health Products Regulatory Authority
USDA	US Department of Agriculture
VICH	Veterinary International Cooperation on Harmonization (of Technical Requirements for Registration of Veterinary Medicinal Products)

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This report and reports on the other markets included in the benchmarking survey are available at: HealthforAnimals.org/GBS2020

Health for Animals
global animal health association