IFAH GLOBAL BENCHMARKING SURVEY

2011

Summary of the reports by BioBridge Ltd
For IFAH BOARD

For endorsement
Issued October 2012

Introduction

The IFAH Global Benchmarking Survey (GBS) 2011 is the fourth survey conducted by IFAH at 5-year intervals, the second to include 5 regions, and it is the most comprehensive to date. The companies participating provide a full range of products and cover most species, in all regions. Compared with 2006 there is a broader market focus of companies that reflects the high level of merger and acquisition activity.

The benchmarking survey comes at a time when governments are examining the roles and costs of their regulatory agencies. Benchmarking data plays an important role in supporting informed decision-making during this review period.

Several conflicting trends and challenges can be found in the sector. There are some signs that a move towards more efficient regulation is possible. Companies see evidence of acceptance of overseas data and standards though this is incomplete and not consistent across the regions. There also seems to be a move towards simplification of procedures for approving minor product modifications. Access to, and openness of regulatory reviewers has increased markedly in some regions, including Canada and Europe.

Yet significant concerns and challenges outweigh positive changes. The most serious of these are over-caution in agency staff leading to a zero-risk approach; lack of acceptance of overseas data, dossier formats, and approvals from other regions despite the existence of VICH and JECFA; increasing costs for maintenance of existing products; and spiralling demands for pharmacovigilance data and ecotoxicology information.

As well as providing updated analysis and review of regulatory practices and policy and their impact on the future of the industry, the benchmarking survey provides the opportunity to work globally towards a benefit:risk assessment framework. It provides the opportunity to analyse best practice cases in one region and present them, working with IFAH member associations, to other regions, providing regulators with confidence that efficiencies can be gained in systems and procedures without compromising quality, safety or efficacy at a time when governments are weighing the direct and indirect cost of red tape.

Key recommendations

The current time offers an unparalleled opportunity for industry and governments to work globally towards a benefit:risk assessment framework. Joint action with a wider variety of stakeholders should be pursued to ensure that political pressure results in balanced outcomes that facilitate the entry of products to the market.

Improvements sought are:

- 'Best practice' approaches in one region to be introduced in others. For example transparency of timelines, consultation between industry and regulators and acceptance of foreign data and dossiers in line with international standards.

- Training and information sharing to improve knowledge of veterinary medicine and medicines, and joint workshops on innovation between industry and regulators.

- Continued dialogue to enhance or introduce a risk assessment approach that allows regulators to respond flexibly to the different actual risks of products.

- Much-needed work on collecting, interpreting and managing pharmacovigilance data. Joint seminars could avoid unrealistic expectations and introduce systems that are proportionate to real in-use risks.

- In regions/countries where they are not currently in place, introduction of processes such as timelines for regulatory responses and systems for tracking dossier progress, preferably on-line. Predictability and transparency does not compromise quality, safety or efficacy.

- Introduction of conditional approvals in those regions where they are not currently available e.g. CVM-regulated products in USA, pharmaceutical products in Japan.

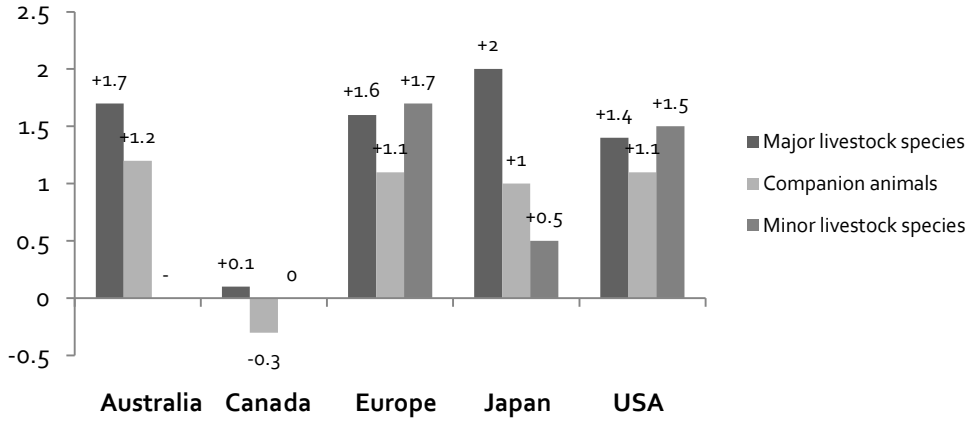
- Reinforcement of the message that fragmented markets cannot stand up to over-regulation. This is particularly the case in Australia and Canada.

Major global challenges

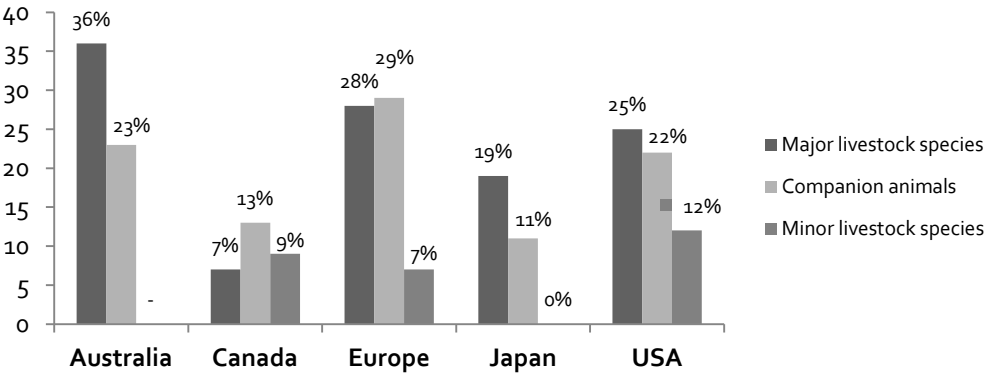
Time & cost

- Since 2006 the time and cost to gain registrations has continued to rise in all regions except Canada. This is largely due to initiatives within regulatory agencies in the region.

Increase in Time to gain registrations since 2006 (years)



Increase in cost to gain registration since 2006



- 64%-94% of companies consider the costs due to demands on existing products disproportionate. In particular, the proportion of R&D spent on Mandatory Defensive R&D continues to be a concern.

Mandatory Defensive R&D (MDR&D) as a % of total R&D costs (average)	AUSTRALIA	CANADA	EUROPE	JAPAN	USA
	14%	26%	GMN 27%; local 51%	15%	16%

- The involvement of human health agency regulators continues to have a disproportionate and inappropriate impact on the costs and time required for animal health product regulation.

Zero-risk trend

- A lack of acceptance of high-quality data still exists, even when compliant with VICH guidelines. Exceptions include Canada; and for companion animal products, Australia.

- Industry is in strong support of the need for an effective pharmacovigilance system, which should be risk-based and kept proportionate to the risks and resources of the animal health sector; but increasing demands for pharmacovigilance data are seen as imposing considerable pressure without adding to real knowledge about safety. Pharmacovigilance and Post-marketing Surveillance systems are seen as a large 'black cloud' by industry. Joint seminars on practical aspects of collecting, interpreting and managing pharmacovigilance data might be of assistance to avoid unrealistic expectations and demands by regulators and introduce systems that are proportionate to real in-use risks.

- The increasingly zero-risk approach is especially problematic when more than one agency is involved in a review process, such as for biologicals in Australia (APVMA and AQIS) or products for food-producing animals in Canada (Health Canada is involved in assessing consumer safety).

Ease of use of the regulatory process

- Transparency of the regulatory process was one of the two criteria in which some agencies performed worst. Applicants did not know what was happening to their submissions and were unable to anticipate any part of the process.

- Differences in the requirements for specific studies e.g. bioequivalence or residues add cost and complexity to product development.

- The regulatory impacts of mergers and acquisitions were greater than expected. These ranged from complexity, costs and variable requirements for re-labelling, to revalidation of manufacturing and control and provision of new product performance data.

A case study provided by one global multinational reveals the scale of the regulatory challenge:

> In 2006, 8% of the R&D budget was spent in the EU on Mandatory Defensive R&D. By 2011, 20% of a much larger total global R&D spend for this company was required, partly as a result of the work needed for product acquisitions, partly in defending existing products, and partly in dealing with referrals arising as a result of generics and Directive 2004/28/EC.

Limited knowledge

- There is widespread concern that agency staff lacks sufficient knowledge of diseases, disease management, animal rearing and nutrition, the practicalities of product use in the field and the realistic significance of adverse reactions.

- Companies are not confident that regulators have the expertise to understand the innovations that industry might wish to introduce, in particular biotechnologies and nanotechnology, leading to increased time to market.

- The lack of clarity in risk assessments is also causing concern in industry.

Major global trends

Market

- Slowing growth in the farm animal sector in Europe and USA, much stronger growth in China, India and parts of South America. Long-term growth in other emerging markets.
- Increasing negativity towards food animal antibiotics in Europe and USA, seen as highly counter-productive in the context of increasing global food demand.
- The companion animal sectors follow general economic buoyancy, and are therefore expected to grow in emerging markets.

Operational activities

- Companies will increasingly plan innovation programmes globally and apply stricter return-on-investment criteria and risk assessments.
- Some companies report the benefits of pre-submission discussions as part of their overall development plans.
- Although innovation is firmly on the agenda, improvements in existing products, and efficiencies in production, sales, and distribution are also regarded as vital to success.

Technology and innovation

- Replacement or supplementation of treatment with prevention products via vaccine technologies and biotechnology in Europe and USA, particularly in food animals.
- Biological products more acceptable from a public and policy standpoint as well as being easier to gain regulatory approvals, than pharmaceuticals.
- Continued innovation in product delivery expected.

Regulatory

- The regulatory trends regarded as positive in all regions, and on which companies want IFAH and the regional associations to build are: full acceptance of VICH-compliant data, acceptance of JECFA assessments and established Codex standards, moves towards electronic submission a move from zero risk to benefit:risk assessment and an increase in predictability.

Regional regulatory environments – specificities, challenges and improvements

Australia

Industry and regulators could benefit from more constructive relations; in such a case, IFAH can support AHA in rebuilding trust. As in other regions, there are widespread concerns with lack of timeliness, predictability and consistency for processes within APVMA.

Challenges

- For biologicals, the Australian Quarantine and Inspection Service is overcautious, highly inflexible and sometimes inconsistent, causing significant delays.
- For products with residue implications, Export Slaughter Intervals are not being imposed based on any science-based studies of risk. Outcomes for some products have been rendered commercially impractical.
- Rules concerning trials for ectoparasiticides are excessive. This is one of most important product classes in Australia.

Improvements

- The introduction of the Electronic Application and Registration System.
- The creation of 'Tiger Teams' in which junior evaluators can learn from more experienced ones has led to faster approval of simple dossiers.
- An increased willingness to review dossiers in a phased approach.
- Use of international guidelines by the regulators, and reduction in the burden in approval for minor changes in manufacturing and formulation including change to the management of labels.

Canada

The situation in Canada has improved considerably since 2006. Companies have experienced the smallest increases in total costs and time to market and indeed in some cases these have decreased.

However the Canadian animal health business is relatively small and the industry is sensitive to factors that may represent an inappropriately high burden in relation to market returns. Several situations act as a deterrent to new products coming to the market.

Challenges

- Lack of action to curb abuse of 'own-use' imported unapproved drug products and importation and use of APIs through direct application or compounding by veterinarians and pharmacists.
- The approach by manufacturing, quality and inspection staff, which is not aligned to the rest of the VDD. There is no harmonization with other regions and the framework does not prevent abuse of API uses.
- Antimicrobial resistance and environmental regulations have extremely negative impact scores of -70% and -90% respectively, the highest level of concern of all regions involved. The Environmental Impact Assessment process in Canada is not harmonized with other

VICH member countries, resulting in a concern about predictability and timely availability of product in a small market.
- Manufacturing requirements for animal health medicines that equal those of human medicines, making them more stringent than any other region. Harmonisation with other regions is urgently needed.

Improvements
- The management of submissions has improved, especially at the VDD.
- Time from initial submission to approval has shortened significantly since 2006.
- The Canadian Centre for Veterinary Biologics has also improved submission review performance.
- At VDD, there are signs of a move away from zero-risk to a benefit:risk assessment.
- Health Canada has introduced the Interim Low Risk Veterinary Health Product Notification Program, developed with CAHI. It allows low risk products for use in companion animals and horses not for slaughter to undergo a pre-market notification process rather than a full submission.
- The attitude towards cooperation and problem-solving has improved dramatically.

Europe

With the European Commission focus on 'Better Regulation' and the on-going review of the veterinary medicinal product legislation, the overall outlook is positive. Although industry supports a proportionate pharmacovigilance system, concern over increasing demands is shared globally. European industry and some regulators fear this could become the next 'bureaucratic monster'. Separate concerns exist about increasing data demands for environmental risk assessments and antimicrobial resistance.

Challenges
- Political pressure on food animal antimicrobials is seriously affecting the ability of the industry to provide new products. Fewer companies can afford to engage in new product development.
- Provisions for generic products in Directive 2004/28/EC forces originator companies to standardise product literature across the EU, causing referrals, extra time and costs.
- IFAH-Europe consistently points out that there is effectively less data protection as a result of Directive 2004/28/EC.
- Procedures still give opportunities for member states to disagree with marketing authorisation on grounds that are often rejected on appeal at European level.
- There is still no alignment of best practice across national agencies. This affects all stages of the regulatory chain and appears to be based on a lack of trust between agencies.

Improvements
- Regulators are willing to engage in dialogue with industry on specific concerns that have been raised by IFAH-Europe, e.g. rationalisation of cross-EU labelling and packaging.
- Variations regulation has reduced regulatory burdens for industry and has also begun to help with best practice standardisation across the EU.

Japan

Challenges

- Despite a decrease in time between the investigation committee and decision committee stage of the JMAFF procedure, too many committees are involved in review.
- Processes do not take place in parallel, but sequentially if more than one agency is involved in assessing a product.
- Lack of the opportunity for pre-submission discussion on biologicals with the National Veterinary Assay Laboratory.
- Continued insistence on full Japanese translation of dossiers is very costly and adds time.
- Inflexibility in requesting local study requirements even when products do not need these. Sometimes these include ADME (absorption, distribution, metabolism and excretion) studies, toxicity and even general pharmacology studies. These are scientifically excessive for the product type and use.

Improvements

- Moves towards accepting high quality test results from other sectors, species or regions, by all agencies.
- Provision in advance of discussion points for JMAFF hearings.
- Decrease in time between investigation committee and division committee stages of JMAFF's procedure.
- Revision of the Pharmaceutical Affairs Law to allow domestic and overseas manufacturing sites to be treated equally.
- Reduction in restrictions on minor formulation and manufacturing changes for existing products.
- There has been mutual acceptance of GLP inspections among EU, US and Japan.

USA

Challenges

- EPA scored the lowest overall of the US agencies and often scored the lowest when compared with agencies in other regions. This situation requires deeper analysis and a specific action program to help move the regulatory system forward.
- CVB is showing an increasing reliance on biometrics rather than clinical outcomes; this may reflect assessor inexperience with respect to animal diseases and field conditions.
- The End Review Amendment is used as a compendium of points that could have been answered with less stress during earlier stages of the process.
- Very lengthy overall approval process times with few obvious reasons.
- There are some concerns about how biotechnology-derived products will be treated in the future in terms of lines of responsibility between the three agencies.

Improvements

- ADUFA III gives the opportunity to raise awareness of a number of concerns that relate to the operation of the CVM (such as those mentioned above).
- There is an increase in openness and interfacing between regulatory staff and industry.
- The CVM's InnoVation Exploration Team (iVET) initiative, though very recent, is regarded positively. This seeks to bring a company together with a team of agency scientists and reviewers in the pre-submission stage to help the agency understand the scientific characteristics of a product before it enters the review process.

- The USDA revised requalification rules for the foundation seed antigens of vaccines, reducing time and costs of repeat studies.

Survey and interview statistics

The survey required analysis of over 21,000 individual data points and up to 400 free-text responses. Interview reports summarised 72 interviews of on average 1.5 hours each.

Region	Number of IFAH member companies invited	Number of companies responding	Return rate	Number of interviews undertaken
Australia	10	9	90%	6
Canada	19	14	74%	11
EU	14	11*	79%	14
Japan	12	12	100%	11
USA	14	14	100%	16
Total IFAH regions	69	60	88%	-
European national associations	-	5	-	-
IFAH's corporate members	11	-	-	14
Total interviews	78	-	-	72

** Two companies were subject to acquisitions during the survey*

The companies in IFAH's 2011 benchmarking survey provide a more comprehensive range of products and cover most species, in all regions.

Market focus of the business	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Comprehensive product line	**55%**	**38%**	**50%**	**64%**	**33%**
Focused on selected species	11%	31%	19%	0%	20%
Focused on specific product types	11%	15%	0%	18%	27%
Focused on specific types of disease	11%	8%	12%	9%	0%
Selected products for specific species/diseases	11%	8%	19%	9%	20%
Product focus of the business	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
A mix of all types	22%	31%	25%	**36%**	**40%**
Primarily pharmaceuticals	22%	**46%**	**50%**	**36%**	20%
Primarily biologicals	11%	0%	6%	28%	13%
Primarily medicinal in-feed products	11%	8%	13%	0%	13%
Primarily pesticide-based products	**33%**	0%	0%	0%	7%
Other combinations:	0%	15%	6%	0%	7%

Members of the IFAH's regional associations provide 85%-90% of the veterinary products in their markets. Local companies were also represented – from 12% to 50% of contributing companies.

The survey confirms that Australia and Canada are markets with more limited opportunities for high sales than elsewhere. When it comes to global sales, 88% and 45% of regional respondents in these two countries reported a turnover of more than US$500M, compared with 46%-55% of companies in other regions. However, for regional sales, only 11% and 9% reported a turnover of >US$100M, compared with 60% in Europe, 67% in the USA and 36% in Japan.

USA and Europe each account for approximately one third of global sales, significantly higher than other regions. Japan's regional share of global sales is over twice that of Australian and Canadian respondents.

Region	***Regional sales (approximate)***	***Regional sales as % of global sales***
USA	*US$5.4B*	*36%*
Europe	*€4.5B*	*35%*
Japan	*>¥110B*	*9.4%*
Canada	*C$523M*	*4.4%*
Australia	*A$690M*	*4.2%*

USA respondents employ almost 30% of their workforce within their region, compared with over 40% for the Europe respondents and much smaller percentages elsewhere.

Region	***Regional employment (approximate)***	***Regional employment as % of global employment***
Europe	*>16,000*	*42%*
USA	*9,900*	*29.5%*
Japan	*>1,800*	*6.2%*
Canada	*773*	*2.9%*
Australia	*900*	*2.7%*

Further detailed information can be found in the individual Benchmarking reports for each region and in the Appendix attached.

The team and acknowledgements

The BioBridge team included Dr Bruce Chick for Australia, Dr Earle Nestmann for Canada, & Meredith Lloyd-Evans (Project Director), Sue Addison and Peter H Jones for Europe, Dr Atsuo Hata and Dr Yuki Ujimasa for Japan and Dr Johnny Jacobsen and Jane Eagleson for USA. Alex Greenberg of AlcheraBio provided the IT component, without which the survey would not have taken place so efficiently. Acknowledgements are due to Dr Gareth Harris who project-managed for IFAH; to the members of IFAH's Regulatory Strategy and Leadership Teams, who gave their time to ensure that IFAH's aims would be fulfilled by the BioBridge methodology and survey specifications; to the staff of IFAH and the regional associations, who provided tremendous help; to Masao Osaka of Boehringer Ingelheim Vetmedica Japan, who provided valuable assistance with the final stages of the Japan report; and above all to all the survey respondents and interviewees, who have provided the raw information in over 150 sessions, from which these IFAH GBS reports are composed.

The information in this report has been compiled from many sources, nearly all of which cannot be attributed for reasons of confidentiality. Although Meredith Lloyd-Evans and BioBridge cannot guarantee the accuracy of the statements in this report, which represents the views of the industry, the findings of surveys and the outcomes of interviews, any inaccuracies are not the responsibility of IFAH or its member associations. July 2012

Acronyms

ADUFA	Animal Drug User Fee Act (USA), ADUFA III being the third, adjusted phase of the act under negotiation in 2012.
AHA	Animal Health Alliance (Australia) Ltd., the national association of the animal health industry in Australia
AHI	Animal Health Institute, the national association of the animal health industry in the United States of America
API	Active Pharmaceutical Ingredient
APVMA	Australian Pesticides and Veterinary Medicines Authority, the Australian regulatory body for veterinary medicines (biologics and pharmaceuticals)
AQIS	Australian Quarantine and Inspection Services; involved in the assessment of veterinary biologics
CAHI	Canadian Animal Health Institute, the national association of the animal health industry in Canada
CFIA	Canadian Food Inspections Agency, the organization which houses the Canadian Center for Veterinary Biologics
Codex Alimentarius	The international food standards setting program of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO)
CVB	Center for Veterinary Biologics (USA), of the United States (US) Department of Agriculture (USDA)
CVM	Center for Veterinary Medicine of the Food and Drug Administration (FDA)
EPA	The US Environmental Protection Agency
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration of the United States of America, part of the US Department of Health and Human Services
Health Canada	Federal department responsible for helping Canadians maintain and improve their health, while respecting individual choices and circumstances
IFAH	International Federation for Animal Health, the global association for the animal health industry
IFAH-Europe	International Federation for Animal Health Europe, the regional association of the animal health industry in the European Union
JECFA	The Joint FAO/WHO Expert Committee on Food Additives, an international expert scientific committee of FAO and WHO, whose tasks include risk assessments for Codex Alimentarius.
J-MAFF	Japan Ministry of Agriculture, Forestry and Fisheries
JVPA	Japan Veterinary Products Association, the national association of the animal health industry in Japan
NVAL	National Veterinary Assay Laboratory, Japan; involved in the regulatory process for veterinary biologics in Japan
US, USA	United States, United States of America
USDA	United States Department of Agriculture, the government branch that houses the Centre for Veterinary Biologics, among others.
VDD	Veterinary Drugs Directorate of Health Canada, Canada, the regulatory body for veterinary pharmaceuticals in Canada
VICH	International Co-operation on Harmonisation of Technical Requirements for Registration of Veterinary Products
WHO	World Health Organisation of the United Nations

Appendix: Inter-regional key data summary 2011

COMPANY PROFILES

Number of companies in survey in 2011

AUSTRALIA	CANADA	EUROPE	JAPAN	USA
9	14	11+5	12	14

Data is expressed as a % of companies responding or choosing a specific criterion, except where noted otherwise.

Headquarters of the animal health business	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
In Australia	12%	0%	0%	0%	0%
In Canada	0%	29%	0%	0%	0%
In Europe	**63%**	**50%**	**80%**	33%	**50%**
In Japan	0%	0%	0%	**50%**	0%
In the USA	25%	21%	20%	17%	**50%**
Market focus of the business	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Comprehensive product line	**55%**	**38%**	**50%**	**64%**	**33%**
Focused on selected species	11%	31%	19%	0%	20%
Focused on specific product types	11%	15%	0%	18%	27%
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Primarily biologicals	11%	0%	6%	28%	13%
Primarily medicinal in-feed products	11%	8%	13%	0%	13%
Primarily pesticide-based products	**33%**	0%	0%	0%	7%
Other combinations: C, E, U: pharma+bios. C: pharma + unregulated products	0%	15%	6%	0%	7%
Geographic focus of the world-wide animal health business	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Global	**88%**	**79%**	**69%**	**50%**	**71%**
In the country/region plus some regional exports/subsidiaries	0%	7%	25%	25%	29%
Mainly in the country/region only	12%	14%	6%	25%	0%
Number of employees world-wide in animal health	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
>500	**78%**	**55%**	**69%**	**58%**	**77%**
250-500	0%	0%	6%	8%	0%
<250	22%	45%	25%	33%	23%
Number of employees in country/region in animal health	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
>500	0%	0%	**60%**	9%	**47%**
250-500	0%	0%	7%	9%	15%
<250	**100%**	**100%**	33%	**82%**	38%

Total annual gross turnover in animal health	**A** **A$M/B**	**C** **C$M**	**E** **€M**	**J** **YenB**	**U** **US$**
	<100M 11%	**<100M 45%**	**<100M 33%**	**<60 50%**	<100M 17%
	100M-500M 0%	100M-500M 9%	100M-500M 27%	60-100 17%	101M-500M 25%
	501M-2B 55%	**>500M 45%**	501M-1B 7%	>100 33%	501M-1B 8%
	>2B 33%		**>1B 33%**		**>1B 47%**
Annual gross turnover in animal health in country/region	**A** **A$M**	**C** **C$M**	**E** **€M**	**J** **YenB**	**U** **US$M**
	<100M 89%	**<100M 91%**	**<100M 40%**	**<100 100%**	<100 33%
	100M-500M 11%	100M-500M 9%	**100M-500M 40%**	100-500 0%	100-500 17%
	>500M 0%	>500M 0%	>500M 20%	>500 0%	**>500 50%**

Total annual gross turnover in animal health in US$ 2010	**A** **A$1.09=US$1**	**C** **C$1.03=US$1**	**E** **€0.75=US$1**	**J** **87.78¥=US$1**	**U**
<100M	11%	45%	33%	27%	17%
100M-500M	0%	9%	13%	27%	25%
501M-1B	55%	0%	20%	0%	8%
>1B	33%	45%	33%	**46%**	**47%**
Annual gross turnover in animal health in country/region in US$	**A** **A$1.09=US$1**	**C** **C$1.03=US$1**	**E** **€0.75=US$1**	**J** **87.78¥=US$1**	**U**
<100M	89%	91%	40%	64%	33%
100M-500M	11%	9%	40%	36%	17%
>500M	0%	0%	20%	0%	50%

COMPETITIVENESS IN THE ANIMAL HEALTH INDUSTRY IN 2011

Drivers of competitive success in the short term	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Reducing the costs of production and distribution	**78%**	**50%**	**53%**	**55%**	**79%**
Exploiting existing products more profitably	**100%**	**64%**	**77%**	**91%**	**79%**
Improving the efficiency of sales and marketing activities	**89%**	**86%**	35%	**73%**	**79%**
Providing new services to meet customer needs	**67%**	36%	**77%**	**91%**	**57%**
Developing major new products to meet customer needs	44%	**64%**	41%	55%	50%
Entering new geographic markets	11%	29%	35%	27%	21%
Reducing competition through Mergers and acquisitions	0%	36%	**59%**	0%	0%
Other: C: GMP harmonisation	0%	7%	0%	0%	0%
Drivers of competitive success in the long term	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Developing major new products to meet customer needs	**100%**	**71%**	**89%**	**100%**	**93%**
Improving the efficiency of sales and marketing activities	**67%**	**64%**	24%	**55%**	**71%**
Reducing the costs of production and distribution	**67%**	21%	41%	**82%**	**64%**
Exploiting existing products more profitably	**67%**	**71%**	**47%**	36%	**64%**
Providing new services to meet customer needs	56%	**57%**	**77%**	**55%**	64%
Entering new geographic markets	44%	21%	**47%**	27%	29%
Reducing competition through Mergers and acquisitions	0%	43%	41%	9%	7%
Other: C: simultaneous approvals in Europe, US, Canada	0%	7%	0%	0%	0%

Government Regulations and contribution to competitiveness of the industry	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Reassured the public about the safety of animal health products	**63%**	38%	**31%**	**90%**	**71%**
Provided confidence to invest (added to certainty and predictability)	25%	**62%**	19%	20%	**50%**
Prevented dangerous products entering the market	**38%**	8%	**44%**	**80%**	**43%**
Provided a stable business environment	25%	**46%**	**50%**	**40%**	**43%**
Protected investments in innovation	**38%**	15%	19%	20%	36%
Improved product quality	**50%**	**54%**	**38%**	**70%**	29%
Improved access to other geographic markets	0%	15%	25%	30%	29%
Created new market segments	13%	0%	19%	0%	21%
Speeded up time-to-market	0%	**62%**	25%	0%	21%
Triggered innovation in new production processes	13%	8%	13%	10%	0%
Helped redirect resources to innovation	25%	23%	13%	30%	0%
Other: U: Minor Use-Minor Species	-	-	-	-	7%

INNOVATION IN THE ANIMAL HEALTH INDUSTRY IN 2011

Innovation – important factors and obstacles

Important factors for successful innovation	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Access to creativity & ideas	**89%**	**77%**	**82%**	**91%**	**93%**
Minimising time-to-market	**44%**	**77%**	**88%**	**73%**	**79%**
Access to critical skills	44%	46%	**41%**	**82%**	**50%**
Minimising uncertainty	**56%**	**62%**	**47%**	**55%**	**50%**
Controlling development costs	22%	38%	35%	9%	50%
Access to capital	**56%**	**62%**	41%	18%	43%
Integrating activity across functions	22%	15%	24%	45%	14%
Access to other markets	0%	23%	6%	18%	14%
The impact of the regulatory environment on the AH industry's ability to innovate	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Very positive	0%	0%	0%	0%	0%
Positive	10%	18%	0%	28%	7%
Neutral	10%	**45%**	6.5%	18%	21%
Negative	**60%**	18%	**87%**	**36%**	**64%**
Very negative	20%	18%	6.5%	18%	7%
Important obstacles to successful innovation	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
The regulatory framework	**89%**	**64%**	**63%**	**64%**	**86%**
Inadequate intellectual property protection (for patents or commercial data)	33%	29%	**63%**	18%	**50%**
Lack of availability of financial resources	44%	21%	25%	27%	**50%**
Small size of market segments	**89%**	**79%**	38%	**82%**	**43%**
Closure of the home and/or other geographic markets for certain products	44%	7%	**57%**	**45%**	29%
Negative consumer attitudes	44%	21%	**76%**	36%	21%
Lack of skilled staff	11%	**43%**	13%	36%	21%
Internal company organisational or cultural barriers	33%	29%	25%	36%	14%
Poor technology transfer mechanisms between academia and business	0%	**36%**	19%	36%	14%
Lack of access to specialist biotechnology companies	11%	7%	0%	18%	14%

Negative effects of Government Regulations on innovation	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Increase costs of development	**89%**	**59%**	**87%**	**100%**	**93%**
Create significant uncertainty or unpredictability	**89%**	**70%**	**53%**	**73%**	**86%**
Increase development time	**78%**	**59%**	**73%**	**82%**	**79%**
Re-direct resources into defensive R&D	**33%**	49%	**87%**	**55%**	**43%**
Restrict collaborative R&D ventures	0%	0%	0%	0%	21%
Reduce access to new ideas, particularly in biotechnology	11%	12%	0%	18%	14%
Limit the use of innovative marketing methods	11%	10%	7%	9%	14%
Close markets for specific products	33%	42%	47%	18%	14%
Divert management time	33%	**52%**	13%	27%	0%
Reduce cash flows from existing products	11%	12%	27%	18%	0%
Other: U: Barrier to import due to USDA/FDA non-tariff barriers to trade					7%

R&D in the Animal Health Industry

R&D priorities	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
New products	**100%**	**90%**	**100%**	**89%**	**79%**
New active ingredients/antigens	**75%**	60%	44%	**78%**	**71%**
Improved products	63%	**80%**	**69%**	56%	64%
New drug or biologicals delivery methods	38%	20%	19%	22%	21%
New production processes	13%	0%	19%	22%	14%
New drug/biologicals development tools	0%	0%	6%	11%	14%
Where new product test data is generated for major livestock species	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Completely or mostly in the region	44%	27%	**71%**	**50%**	**75%**
Core data outside the region and final data in the region	**56%**	**55%**	29%	**50%**	25%
All data outside the region, complying with VICH	0%	18%	0%	0%	0%
Where new product test data is generated for companion animals	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Completely or mostly in the region	11%	11%	**71%**	40%	**83%**
Core data outside the region and final data in the region	**44%**	**44%**	29%	**60%**	17%
All data outside the region, complying with VICH	**44%**	**44%**	0%	0%	0%
Where new product test data is generated for minor livestock species	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Completely or mostly in the region	-	11%	**75%**	**55%**	**78%**
Core data outside the region and final data in the region	-	**56%**	17%	45%	22%
All data outside the region, complying with VICH	-	33%	8%	0%	0%
The proportion of R&D carried out in the region that is contracted out	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
	57%	**52%**	**40%**	**47%**	**53%**
Expenditure on R&D	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
% of annual world-wide turnover spent on R&D	**7.7%**	**5.5%**	**7.7%**	**6.3%**	**6.1%**
% of world-wide R&D spend undertaken in region	**<10%**	**26%**	**64%**	**59%**	**61%**
% of world-wide R&D spent on Pharmaceutical R&D	**72%**	**78%**	**76%**	**68%**	**65%**
% of world-wide R&D spent on Biologicals R&D	**28%**	**22%**	**24%**	**32%**	**35%**
% of world-wide R&D spent on Companion Animals	**44%**	**50%**	**40%**	**53%**	**40%**
% of world-wide R&D spent on Production Animals	**56%**	**50%**	**60%**	**47%**	**60%**

Change in regional share of new product R&D since 2006	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Decreased a lot	0%	**9%**	0%	0%	0%
Decreased slightly	0%	**9%**	**27%**	0%	**7%**
Little change	**78%**	**64%**	**60%**	**89%**	36%
Increased slightly	11%	9%	13%	11%	**43%**
Increased a lot	11%	9%	0%	0%	14%
The most important causes of the change in regional share of new product R&D	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Acquisition of companies with development programs	**50%**	**20%**	**45%**	33%	**50%**
Increased base cost of conducting R&D in region	**38%**	**30%**	**55%**	**83%**	**50%**
Deterioration in regulatory environment	**63%**	0%	**18%**	33%	**33%**
Greater availability of CROs/research organisations	25%	20%	**36%**	50%	**25%**
Decreased base cost of conducting R&D in region	13%	**50%**	0%	0%	17%
Less availability of CROs/research organisations	13%	10%	9%	17%	17%
Improved regulatory environment	**38%**	**40%**	0%	0%	17%
Moved R&D elsewhere	25%	10%	18%	17%	17%
Divestment of companies with development programs	0%	0%	9%	17%	8%
Other: A: respondents are domestic companies; compatible research now in USA; less focus on local needs in R&D programme. C: new R&D centre, corporate HQ, all R&D ex-Canada, poor economic environment. E: local competences and activities; local R&D tax regimes. J: M&As, R&D all elsewhere	38%	50%	27%	33%	0%

Mandatory Defensive R&D

Mandatory Defensive R&D (MDR&D) as a % of total R&D costs (average)	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
	14%	26%	GMN 27%; local 51%	15%	16%
Change in expenditure on MDR&D over the past 5 years	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Decreased a lot	0%	0%	0%	0%	0%
Decreased slightly	0%	0%	0%	0%	0%
Little or no change	**44%**	45%	**50%**	36%	22%
Increased slightly	**44%**	0%	44%	**45%**	**64%**
Increased a lot	11%	**55%**	6%	18%	14%
The most important causes of the change in MDR&D spend	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Regulator product review activities have increased	**100%**	**80%**	**93%**	**38%**	**93%**
Deterioration in regulatory environment	**86%**	**80%**	**79%**	**38%**	**71%**
Acquisition of companies with products on the market	**57%**	**80%**	**43%**	**38%**	**50%**
Improved regulatory environment	**43%**	**60%**	29%	15%	**43%**
Regulator product review activities have decreased	0%	20%	7%	**31%**	29%
Divestment of companies	14%	40%	**36%**	15%	7%
Other: A: global rather than local opportunities leading to little change; additional approvals leading to increased costs. C: Application of new GMP rules for Establishment licence (API testing sites)	29%	20%	-	-	-

IMPACTS OF REGULATION ON INNOVATION – TIME, COSTS AND SPECIFIC FACTORS

Impact of regulatory factors on time

The average length of time to gain registration for a major new FAP in years	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Pharmaceuticals	2.3 yrs	2.6 yrs	1.7 yrs	3.2yrs	9.4 yrs
Biologics	2.3 yrs	1.4 yrs	1.5 yrs	2.3yrs	BCL 2.8 yrs GMO 5.4 yrs NMS 4.3 yrs Combi 3.6 yrs
Pesticide-based product	2.8 yrs	2.5 yrs	2.0 yrs	3.0 yrs	6.0 yrs
For USA BCL = Biologics Conditional License; GMO = genetically-modified organism requiring risk assessment; NMS = new master seed; Combi = new combination of approved master seeds					
The average length of time to gain registration for a major new CAP in years	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Pharmaceuticals	1.8 yrs	2.3 yrs	1.5 yrs	2.1 yrs	6.4 yrs
Biologics	1.8 yrs	1.2 yrs	1.5 yrs	2.0 yrs	BCL 2.9 yrs GMO 5.0 yrs NMS 4.1 yrs Combi 2.8 yrs
Pesticide-based product	2.1 yrs	1.7 yrs	1.4 yrs	3.0 yrs	3.5 yrs
The average length of time to gain registration for a major new [MU]MS in years	AUSTRALIA	CANADA	EUROPE	JAPAN	USA
Pharmaceuticals	-	2.0 yrs	1.7 yrs	2.4 yrs	6.0 yrs
Biologics	-	-	1.5 yrs	-	BCL 3.5 yrs GMO 6.0 yrs NMS 5.5 yrs Combi 3.0 yrs
Pesticide-based product	-	-	2.0 yrs	-	-
Impact of regulatory factors on the average length of time needed to develop a major new product – changes over the past 5 years	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Major livestock species	+1.7 yrs	+0.1 yrs	+1.6 yrs	+2.0 yrs	+1.4 yrs
Companion animals	+1.2 yrs	-0.3 yrs	+1.1 yrs	+1.0 yrs	+1.1 yrs
Minor livestock species	-	0 yrs	+1.7 yrs	+0.5 yrs	+1.5 yrs
The role of internal processes in any change in time, as a % (average of those reporting a time increase)	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
FAP	30%	19%	28%	24%	31%
CAP	27%	32%	24%	24%	29%
[MU]MS	-	50%	24%	-	28%

Impact of regulatory factors on costs

The approximate cost of developing a recent new FAP	**AUSTRALIA A$M**	**CANADA C$M**	**EUROPE €M**	**JAPAN ¥100M**	**USA US$M**
Pharmaceutical product with new active ingredient	52	1.27	21.6	1.4	38.8
New biological product	84	0.003	15.1	1.18	10.8
New medicinal in-feed product	0.2	0.63	3.7	-	26.7
New pesticide-based product	33	-	35.0	-	14.0
The approximate cost of developing a recent new CAP	**AUSTRALIA A$M**	**CANADA C$M**	**EUROPE €M**	**JAPAN ¥100M**	**USA US$M**
Pharmaceutical product with new active ingredient	37	0.26	12.0	1.48	21.6
New biological product	26	0.003	13.8	1.03	11.8
New medicinal in-feed product	-	-	-	-	-
New pesticide-based product	31	-	24.4	-	22.6
The approximate cost of developing a recent new [MU]MS product	**AUSTRALIA A$M**	**CANADA C$M**	**EUROPE €M**	**JAPAN ¥100M**	**USA US$M**
Pharmaceutical product with new active ingredient	-	-	8.8	0.6	8.0
New biological product	-	-	6.0	-	3.0
New medicinal in-feed product	-	-	-	-	12.0
New pesticide-based product	-	-	15.0	-	-
The approximate cost of establishing a new species use for an existing FAP	**AUSTRALIA A$M**	**CANADA C$M**	**EUROPE €M**	**JAPAN ¥100M**	**USA US$M**
Pharmaceutical product	0.9	0.54	3.2	0.63	11.3
Biological product	5	0.0015	5.1	1.5	3.4
Medicinal in-feed product	1.3	0.23	1.5	-	10.5
Pesticide-based product	5.4	0.8	3.5	-	4.0
The approximate cost of establishing a new species use for an existing CAP	**AUSTRALIA A$M**	**CANADA C$M**	**EUROPE €M**	**JAPAN ¥100M**	**USA US$M**
Pharmaceutical product	2.9	0.26	2.1	0.37	6.7
Biological product	5	0.0015	4.0	1.0	4.1
Medicinal in-feed product	-	-	1.0	-	-
Pesticide-based product	6.8	0.5	2.0	-	2.5
The approximate cost of establishing a new species use for an existing [MU]MS product	**AUSTRALIA A$M**	**CANADA C$M**	**EUROPE €M**	**JAPAN ¥100M**	**USA US$M**
Pharmaceutical product	-	-	1.7	-	4.0
Biological product	-	-	-	-	2.5
Medicinal in-feed product	-	-	0.5	-	3.0
Pesticide-based product	-	-	1.5	-	-

The approximate cost of developing a recent new FAP in US$M (annual average 2010)	**AUSTRALIA A$1.09= US$1**	**CANADA C$1.03= US$1**	**EUROPE 0.75€= US$1**	**JAPAN 87.78¥= US$1**	**USA**
Pharmaceutical product with new active ingredient	48	1.23	29.0	1.6	38.8
New biological product	77	0.003	20.0	1.3	10.8
New medicinal in-feed product	0.18	0.61	4.9	-	26.7
New pesticide-based product	30	-	46.7	-	14.0
The approximate cost of developing a recent new CAP in US$M	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Pharmaceutical product with new active ingredient	34	0.25	16.0	1.7	21.6
New biological product	24	0.003	18.4	1.2	11.8
New medicinal in-feed product	-	-	-	-	-
New pesticide-based product	28	-	32.5	-	22.6
The approximate cost of developing a recent new [MU]MS product in US$M	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Pharmaceutical product with new active ingredient	-	-	11.7	0.7	8.0
New biological product	-	-	8.0	-	3.0
New medicinal in-feed product	-	-	-	-	12.0
New pesticide-based product	-	-	20.0	-	-
The approximate cost of establishing a new species use for an existing FAP in US$M	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Pharmaceutical product	0.83	0.52	4.3	0.7	11.3
Biological product	4.6	0.0015	6.8	1.7	3.4
Medicinal in-feed product	1.2	0.23	2.0	-	10.5
Pesticide-based product	5.0	0.8	4.7	-	4.0
The approximate cost of establishing a new species use for an existing CAP in US$M	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Pharmaceutical product	2.7	0.26	2.8	0.4	6.7
Biological product	4.6	0.0015	5.3	1.1	4.1
Medicinal in-feed product	-	-	1.3	-	-
Pesticide-based product	6.2	0.48	2.7	-	2.5
The approximate cost of establishing a new species use for an existing [MU]MS product in US$M	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Pharmaceutical product	-	-	2.3	-	4.0
Biological product	-	-	-	-	2.5
Medicinal in-feed product	-	-	0.7	-	3.0
Pesticide-based product	-	-	2.0	-	-

Impact of regulatory factors on the average cost of developing and registering a major new product – changes over the past 5 years	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Major livestock species	**+36%**	**+7%**	**+28%**	**+19%**	**+25%**
Companion animals	**+23%**	**+13%**	**+29%**	**+11%**	**+22%**
Minor livestock species	**-**	**+9%**	**+7%**	**0%**	**+12%**

SPECIFIC REGULATORY PROCESSES AND IMPACTS ON SUCCESSFUL INNOVATION

The impact of Government Regulations on the industry's ABILITY TO INNOVATE successfully	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Marketing Authorisations	APVMA -10%	VDD +70% CFIA +60%	MRP +13% DCP +33% CP +80%	J-MAFF +27%	+29%
Protection of Intellectual Property-patents	-20%	+50%	+27%	+64%	+43%
Protection of Intellectual Property-commercial data	-20%	+10%	+27%	+55%	+50%
Good Laboratory Practice	+20%	+10%	-7%	+36%	-7%
Biotechnology regulations	-10%	0%	-20%	-9%	0%
Maximum Residue Limits	-60%	-20%	-13%	-27%	-14%
Disease Resistance Risk Management/Regulations (e.g. Antimicrobials)	0%	-70%	-40%	-64%	-57%
Environmental Regulations (Ecotox)	-40%	-90%	-80%	-27%	-43%
Good Manufacturing Practice (J: inc. overseas site inspection)	+40%	+20%	-	0%	-
Good Clinical Practice	+40%	-	-	+18%	-
Access to regulators for advice/discussion	+60%	-	-		-
Electronic submission requirements	0%	-	-		-
Post-marketing monitoring and surveillance requirements	-10%	-	-		-
Other (A: inconsistency & lack of clarity in review process)	-10%	-			
Clinical trials material import/movement regulations	-60%	-	-		-
Biological material import/movement regulations	-70%	-	-		-
Trade Regulations	-70%	-	-		-
Pharmaceutical manufacturing and compounding rules		-70%			
'Own-Use' policy/laws		-80%			
Safety and Risk Assessment (Food Safety Commission)	-	-	-	-36%	-
Animal Drug User Fee (ADUFA) rules	-	-	-	-	+29%
Minor Use Minor Species rules	-	-	-	-	+29%
USDA/APHIS adoption of VICH GCP regulations	-	-	-	-	0%
USDA/APHIS Conditional Product Licenses	-	-	-	-	+43%
USDA/APHIS expanded biometrics standards	-	-	-	-	-29%

EXPLOITATION OF EXISTING PRODUCTS

Obstacles to the exploitation of existing products	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Pressure from competitors (including parallel imports and generics)	**56%**	**77%**	**65%**	**73%**	**85%**
The region's regulatory framework for maintenance/extension of licences	**67%**	**54%**	**94%**	**55%**	**54%**
Small size of market segments	**78%**	**69%**	**59%**	**73%**	**54%**
Inadequate intellectual property protection (commercial data & patents)	44%	23%	47%	18%	**46%**
Legal restrictions on advertising, labels, trademarks and communication	44%	15%	47%	36%	38%
Negative consumer attitudes	33%	8%	18%	36%	23%
Lack of availability of financial resources	11%	23%	6%	18%	23%
Closure of the national or, for Europe, European market and/or other geographic markets for certain products	22%	15%	12%	18%	8%
Demand volatility in certain segments	33%	23%	6%	36%	8%
Lack of skilled staff	0%	8%	12%	18%	8%
Other: E: Regulations on packaging/labelling make small markets uneconomic U: illegal compounding; distribution constraints; and CVB applying new requirements to existing vaccines			6%		23%
Importation and use of unapproved drugs/OUI and API	-	62%	-	-	-
Impacts of government regulations in region on existing products	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Create disproportionate costs for maintaining/extending marketing authorisations	**71%**	**58%**	**94%**	**64%**	**64%**
Increase the cost of production	14%	42%	29%	**55%**	**57%**
Divert financial resources away from the development of new, innovative products	0%	17%	**53%**	0%	**57%**
Divert management time	29%	**58%**	29%	**55%**	**43%**
Remove profitable products from the market	43%	17%	**47%**	45%	36%
Create significant uncertainty	**86%**	**50%**	18%	45%	36%
Restrict the extension of existing technologies to additional species/indications	**71%**	33%	18%	27%	29%
Increase the cost of distribution and marketing	0%	25%	24%	36%	21%
Limit the use of innovative marketing methods	0%	33%	6%	45%	14%
Fail to protect intellectual property (patents & commercial data) adequately	43%	42%	**47%**	9%	14%
Other: U: restrictions on imports of biologicals					7%

Specific regulatory processes and impacts on exploiting existing products

The impact of Government Regulations on the industry's ability to exploit existing products successfully	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Licence Maintenance	APVMA +13%	VDD +42% CFIA +17%	CP +53% NP -41%	J-MAFF +27%	0%
Protection of Intellectual Property–patents	+13%	+8%	+18%	+73%	+29%
Protection of Intellectual Property–commercial data	-38%	-8%	-6%	+73%	+43%
Good Manufacturing Practice	+38%	0%	0%	+9%	-7%
Pharmacovigilance/AERP	+13%	-8%	-29%	+18%	-36%
Manufacturing [Licensing Scheme] Variation/Changes Rules	+13%	-17%	-24%	0%	-43%
Environmental Regulations (Ecotox)	-13%	-42%	-65%	-36%	-64%
Packaging/Labelling Modification Rules	-38%	-33%	-59%	0%	-71%
Maximum Residue Limits	-50%	-17%	-12%	-64%	-36%
Disease Resistance Regulations (AMR/Antimicrobial Resistance Risk)	-50%	-25%	-24%	-64%	-57%
Import Regulations	-13%		-41%	+27%	-
Other: The need for excessive data for even modest product extensions.	-13%	-	-	-	-
Establishment Licensing requirements	-	-50%	-	-	
Harmonization measures within Europe	-	-	+18%	-	-
Good Laboratory Practice	-	-	-	+18%	
Good Clinical Practice	-	-	-	0%	
Accreditation of Foreign Manufacturer	-	-	-	0%	
Post-Marketing Surveillance rules J-MAFF	-	-	-	-9%	
Safety and Risk Assessment FSC	-	-	-	-45%	
Animal Drug User Fee (ADUFA) rules	-	-	-	-	+14%
Regulations regarding Combination Products	-	-	-	-	-21%

REGULATORY PREDICTABILITY

Regulatory predictability and new products

The current procedure for approving new products	**A AVPMA**	**C VDD**	**C CFIA**	**E CP**
Expert assessment of applications to approve new products is based on best available science	56%	-	-	80%
Expert assessment of applications to approve new products is firmly rooted in the principles of Benefit:Risk Assessment	22%	-	-	67%
Expert assessment of applications to approve new products is based on a consistent application and interpretation of Regulatory Guidelines	22%	-	-	87%
Final approval of new products is based on the expert assessment of safety, quality, and efficacy	11%	-	-	73%
The process of approving new products is transparent, efficient and predictable (C: Submission tracking is transparent to the sponsor)	11%	42%	43%	80%
The process of Scientific Advice is useful and efficient	-	-	-	47%
Questions sent to companies are based on relevant science	-	58%-83%	75%-100%	-
Assessors/officials are easy to contact	-	67%-92%	80%-100%	-
Responses by assessors/officials to submissions by companies are timely	-	50%-83%	75%-86%	-

	J J-MAFF	**J MHLW & FSC**	**U CVM**	**U USDA**	**U EPA**
Expert assessment of applications to approve new products is based on best available science	Quality & Efficacy 50%	Safety 67%	73%	86%	50%
Expert assessment of applications to approve new products is firmly rooted in the principles of Benefit:Risk Assessment			45%	57%	50%
Expert assessment of applications to approve new products is based on a consistent application and interpretation of Regulatory Guidelines	-	-	55%	57%	17%
Final approval of new products is based on the expert assessment of safety, quality, and efficacy	83%	-	82%	100%	50%
The process of approving new products is transparent, efficient and predictable	58%	-	55%	43%	0%
The process of Scientific Advice is useful and efficient	-	-	-	-	-
The "hearing process" within J-MAFF is efficient, timely and predictable	67%	-	-	-	-

Regulatory predictability and existing products

The current procedure for maintaining existing products on the market	**A AVPMA**	**C VDD**	**C CFIA**	**E CP**
New tests or reviews are based only on a rigorous science-based analysis of pharmacovigilance data OR relevant advances in knowledge of risks based on best available science	56%	-	-	67%
Expert assessment is based on best available science and risk assessment	56%	-	-	92%
The process of reviewing existing products is transparent, efficient and predictable	22%	-	-	83%
A clear and transparent division exists between risk assessment and risk management decisions	11%	-	-	58%

The current procedure for maintaining existing products on the market	**J J-MAFF**	**J MHLW & FSC**	**U CVM**	**U USDA**	**U EPA**
New tests or reviews are based only on a rigorous science-based analysis of pharmacovigilance data OR relevant advances in knowledge of risks based on best available science	83%	-	20%	14%	17%
Expert assessment is based on best available science and risk assessment: *Q = quality; E = efficacy; S = safety*	Q & E 83%	S 83%	40%	71%	33%
The process of reviewing existing products is transparent, efficient and predictable	-	-	-	-	-
A clear and transparent division exists between risk assessment and risk management decisions	41%	-	40%	57%	67%

REGULATORY QUALITY

Regulatory quality and new products

Approval of new products	**A AVPMA**	**C VDD**	**C CFIA**	**E CP**	**E DCP/ MRP**	**E NP**
The calibre of scientific assessors for quality (purity/potency for biologics) is of the highest possible competence	89%	58%	71%	78%	75%	40%
The calibre of scientific assessors for safety is of th highest possible competence	78%	75%	71%	86%	75%	33%
The calibre of scientific assessors for efficacy is of the highest possible competence	78%	92%	86%	78%	75%	33%
Safety, quality and efficacy guidelines are applied on the basis of practical and rigorous assessment of risks and benefits	22%	50%	86%	93%	56%	33%
The process of approving new products is transparent, efficient and predictable	11%	42%	71%	86%	50%	33%
The regulatory authorities deal with pre-submission stages helpfully and promptly	44%	67%	71%	86%	69%	13%
The regulatory authorities deal with submission helpfully and promptly	11%	75%	71%	93%	69%	40%
The regulatory authorities deal with further interactions promptly	11%	83%	71%	93%	31%	40%
Overall, scientific assessment of risks and benefits is clear and respected by other regulators internationally	44%	25%	43%	72%	31%	33%

Approval of new products	**J J-MAFF**	**J MHLW & FSC**	**U CVM**	**U USDA**	**U EPA**
The calibre of scientific assessors for quality/purity-potency is of the highest possible competence	92%	-	55%	43%	50%
The calibre of scientific assessors for safety is of the highest possible competence	83%	83%	64%	71%	33%
The calibre of scientific assessors for efficacy is of the highest possible competence	83%	-	82%	71%	50%
Safety, quality/purity and efficacy guidelines are applied on the basis of practical and rigorous assessment of risks and benefits	42%	50%	45%	86%	50%
The process of approving new products is transparent, efficient and predictable	42%	33%	36%	29%	17%
The regulatory authorities deal with pre-submission stages helpfully and promptly	33%	8%	82%	100%	50%
The regulatory authorities deal with submission helpfully and promptly	58%	17%	91%	43%	33%
The regulatory authorities deal with further interactions promptly	50%	17%	91%	86%	33%
Overall, scientific assessment of risks and benefits is clear and respected by other regulators internationally	17%	25%	36%	43%	50%

Regulatory quality and existing products

Existing products	**A AVPMA**
The calibre of scientific assessors for safety is of the highest possible competence	89%
The calibre of scientific assessors for quality is of the highest possible competence	78%
Safety, quality and efficacy guidelines are applied on the basis of practical and rigorous assessment of risks and benefits	56%
Overall, scientific assessment of risks and benefits is clear and respected by other regulators internationally	44%
The regulatory authorities deal with pre-submission stages helpfully and promptly	44%
The regulatory authorities deal with further interactions promptly	11%
The regulatory authorities deal with submission helpfully and promptly	0%
The calibre of scientific assessors for efficacy is of the highest possible competence	-

REGULATORY REFORM 2006-2011

Regulatory reforms anticipated in 2006 and impacts on innovation	AUSTRALIA		CANADA VDD		EUROPE		JAPAN J-MAFF		USA	
	A	I	A	I	A	I	A	I	A	I
Remove redundant and overlapping guidelines	25%	0%	-	-	71%	29%	10%	0%	27%	45%
Harmonise test requirements internationally (incl. VICH)	50%	75%	45%	45%	93%	50%	90%	30%	73%	45%
Accept relevant high quality test results from other sectors, species or regions	25%	38%	64%	18%	64%	21%	60%	10%	27%	27%
Provide specific incentives to develop new products for small markets	13%	13%	45%	27%	64%	7%	50%	0%	46%	27%
Use consultation & impact assessment when developing new guidelines	75%	25%	-	-	86%	50%	100 %	0%	27%	18%
Implementation of an effective dispute resolution procedure for scientific issues	0%	13%	-	-	-	-	-	-	18%	18%
Change test requirements only with scientific justification	25%	25%	18%	18%	71%	29%	70%	10%	9%	18%
Base test requirements only on best available science and risk assessment	38%	63%	18%	18%	71%	50%	50%	0%	9%	18%
Adapt test requirements to reflect small size of markets	0%	0%	-	-	57%	21%	0%	0%	27%	18%
Tailor test requirements to specific risks posed by each product	0%	0%	9%	9%	71%	14%	20%	0%	27%	18%
Base quality standards solely on animal health industry requirements	13%	13%	18%	9%	64%	36%	30%	10%	0%	9%
Remove political involvement in testing and approval	0%	0%	0%	18%	64%	21%	30%	10%	9%	9%
Harmonise test or guideline interpretation and implementation within the region	-	-	-	-	71%	43%	-	-	-	-
Outsource the initial dossier review to a dedicated agency (example NVAL in 2011; PMDA in 2006)	-	-	-	-	-	-	10%	10%	-	-
Define and enforce compounding and manufacturing rules	-	-	0%	36%	-	-	-	-	-	-
Prohibit importation of animal health products for "own use"	-	-	0%	36%	-	-	-	-	-	-
Establish and enforce globally competitive product review procedures	-	-	36%	27%	-	-	-	-	-	-
Introduce phased reviews of new innovative products	-	-	45%	18%	-	-	-	-	-	-
Improve accountability and transparency of decision-making processes in regulatory agency/ies	13%	25%	-	-	-	-	-	-	-	-

Note: A = percentage of companies noting reform as having been achieved by 2011; I = percentage of companies regarding the reform as high impact (ranks 1-4)

Regulatory reforms anticipated in 2006 and impacts on exploiting existing products	AUSTRALIA		CANADA		EUROPE		JAPAN		USA	
	A	I	A	I	A	I	A	I	A	I
Reduction of restrictions on minor formulation and manufacturing changes	43%	43%	75%	63%	54%	69%	90%	80%	50%	20%
Basing need for dossier reviews solely on pharmacovigilance or relevant scientific advances	14%	43%	13%	25%	23%	46%	10%	10%	20%	10%
Provision of justification prior to retrospective application of new guidelines to well-established products	-	-	25%	38%	8%	23%	20%	60%	-	-
Providing additional legal protection for data for new indications or species	43%	14%	13%	38%	31%	23%	10%	10%	10%	10%
Adaptation of packaging and labelling requirements to small size of markets	57%	14%	-	-	8%	23%	0%	0%	10%	0%
Basing test requirements only on best available science and risk assessment	0%	29%	25%	25%	8%	23%	20%	50%	20%	30%
Basing Disease/Antibiotic Resistance rules only on best available science (e.g. Antimicrobials)	0%	0%	38%	50%	8%	15%	10%	10%	0%	0%
Ensuring that all types of products are subject to full regulatory approval requirements	29%	43%	13%	25%	15%	0%	20%	10%	0%	10%
Adapting test requirements to small size of markets	0%	14%	25%	38%	0%	0%	20%	20%	0%	0%
Limit Post Marketing Surveillance to product safety issues only	-	-	-	-	-	-	10%	40%		
Establishing a scientific and predictable process for assessing and using pharmacovigilance data	-	-	50%	38%	-	-	-	-	-	-
Basing Establishment Licensing reviews on assessment of relevant risks	-	-	38%	38%	-	-	-	-	-	-
Requiring all animal health companies to pay user fees	29%	14%	-	-	-	-	-	-	60%	50%
Speeding up the review time by increasing the number of review/support staff	0%	29%	-	-	-	-	-	-	80%	80%
Ensuring equitable reviews through staff training	0%	14%	-	-	-	-	-	-	30%	30%
Changing the definition of "minor use" in MUMS to allow an increase in the number of animals treated	0%	0%	-	-	-	-	-	-	10%	0%
Remove restrictions on intra-EU trade in animal health products	-	-	-	-	7%	36%	-	-	-	-

Note: A = percentage of companies noting reform as having been achieved by 2011; I = percentage of companies regarding the reform as high impact (ranks 1-4)

THE OVERALL IMPACT OF POLITICS AND THE REGULATORY FRAMEWORK ON BUSINESS

Politics, regulation and business

Industry's experience of political involvement in the regulatory process	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
No	0%	**45%**	12.5%	**30%**	9%
Yes	**100%**	**55%**	**87.5%**	**70%**	**91%**
Problems created by political involvement in the region's regulatory process [E4]	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Increases the cost of developing new products	**67%**	14%	27%	**89%**	**54%**
Increases the time needed to develop new products	**56%**	14%	6%	**78%**	**46%**
Increases the cost of maintaining existing products	11%	**43%**	**33%**	**67%**	**38%**
Creates uncertainty for future product development	**78%**	**43%**	**73%**	**56%**	**62%**
Prevents approval of new products that are available in other geographic markets	**78%**	29%	**47%**	33%	23%
Restricts the species or indications covered by certain products	11%	29%	27%	22%	8%
Requires products to be removed from markets without scientific evidence	11%	**57%**	**53%**	22%	23%
Allows products to be placed on the market without scientific evidence	11%	29%	7%	11%	8%
Restricts the use of certain product or process technologies	33%	14%	13%	11%	15%
Reduces investment in the development of new technologies	11%	0%	13%	0%	23%
Other (C: Importation of APIs and illegal compounding is still continuing because of political lobbying in favour of this)	-	14%	-	-	-

Business decisions and the impact of regulations

CAPEX

Sales and purchases	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Buy businesses in Region	43%	20%	50%	55%	42%
Influence of Regulations					
No influence	67%	100%	75%	83%	80%
Some influence	0%	0%	25%	17%	20%
Significant influence	33%	0%	0%	0%	0%
Sell or close businesses in Region	14%	0%	13%	0%	17%
Influence of Regulations					
No influence	100%	0%	0%	0%	100%
Some influence	0%	0%	50%	0%	0%
Significant influence	0%	0%	50%	0%	0%
Production	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Invest in production inside Region	38%	40%	75%	45%	67%
Influence of Regulations					
No influence	33%	75%	42%	80%	50%
Some influence	67%	25%	33%	0%	50%
Significant influence	0%	0%	25%	20%	0%
Invest in production outside Region	71%	50%	63%	27%	67%
Influence of Regulations					
No influence	100%	80%	50%	100%	63%
Some influence	0%	20%	40%	0%	37%
Significant influence	0%	0%	10%	0%	0%

R&D location	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Locate R&D Facilities inside region	14%	40%	13%	0%	33%
Influence of Regulations					
No influence	0%	100%	0%	0%	75%
Some influence	100%	0%	50%	0%	25%
Significant influence	0%	0%	50%	0%	0%
Locate R&D Facilities outside region	29%	40%	31%	9%	25%
Influence of Regulations					
No influence	50%	75%	60%	100%	67%
Some influence	20%	25%	20%	0%	33%
Significant influence	50%	0%	20%	0%	0%

MARKETS

Market focus	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Increase (geographic) market focus in Region	43%	50%	38%	36%	50%
Influence of Regulations					
No influence	67%	60%	50%	100%	83%
Some influence	33%	40%	17%	0%	17%
Significant influence	0%	0%	33%	0%	0%
Restrict (geographic) market focus in Region	0%	10%	**6%**	9%	0%
Influence of Regulations					
No influence	0%	100%	0%	100%	0%
Some influence	0%	0%	0%	0%	0%
Significant influence	0%	0%	100%	0%	0%
Product range	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Increase product range in Region	100%	50%	63%	64%	67%
Influence of Regulations					
No influence	50%	20%	70%	86%	88%
Some influence	25%	60%	20%	0%	12%
Significant influence	25%	20%	10%	14%	0%
Reduce product range in Region	29%	10%	**31%**	18%	33%
Influence of Regulations					
No influence	50%	100%	0%	0%	25%
Some influence	50%	0%	60%	50%	25%
Significant influence	0%	0%	40%	50%	50%
Species and indication	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Increase coverage of species or indications in Region	71%	70%	50%	73%	58%
Influence of Regulations					
No influence	40%	43%	63%	88%	71%
Some influence	60%	57%	38%	13%	29%
Significant influence	0%	0%	0%	0%	0%
Reduce coverage of species or indications in Region	29%	10%	44%	0%	17%
Influence of Regulations					
No influence	50%	0%	29%	0%	0%
Some influence	0%	0%	14%	0%	50%
Significant influence	50%	100%	57%	0%	50%

Breakthrough products	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Introduce more 'breakthrough' products in Region	57%	60%	44%	45%	50%
Influence of Regulations					
No influence	25%	17%	29%	60%	83%
Some influence	25%	67%	57%	20%	17%
Significant influence	50%	17%	14%	20%	0%
Introduce fewer 'breakthrough' products in Region	50%	20%	13%	9%	17%
Influence of Regulations					
No influence	25%	50%	0%	0%	0%
Some influence	0%	0%	100%	100%	50%
Significant influence	75%	50%	0%	0%	50%

INNOVATION AND TECHNOLOGIES

R&D budgets	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Switch R&D budgets to labs inside region	14%	30%	44%	9%	17%
Influence of Regulations					
No influence	100%	100%	57%	0%	100%
Some influence	0%	0%	29%	0%	0%
Significant influence	0%	0%	14%	100%	0%
Switch R&D budgets to labs outside Region	25%	30%	38%	9%	25%
Influence of Regulations					
No influence	0%	100%	67%	0%	67%
Some influence	50%	0%	17%	100%	33%
Significant influence	50%	0%	17%	0%	0%
Innovation focus	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Focus on new technologies in Region	63%	30%	50%	36%	83%
Influence of Regulations					
No influence	60%	33%	50%	50%	80%
Some influence	40%	67%	38%	25%	0%
Significant influence	0%	0%	15%	25%	20%
Focus on existing/older technologies in Region	57%	50%	38%	27%	75%
Influence of Regulations					
No influence	75%	20%	67%	33%	67%
Some influence	0%	40%	17%	33%	22%
Significant influence	25%	40%	17%	33%	11%
Technology avoidance	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Develop certain product technologies in Region	43%	40%	25%	18%	67%
Influence of Regulations					
No influence	100%	75%	25%	50%	88%
Some influence	0%	0%	75%	0%	12%
Significant influence	0%	25%	0%	50%	0%
Avoid certain product technologies in Region	63%	10%	44%	9%	58%
Influence of Regulations					
No influence	60%	0%	0%	0%	0%
Some influence	40%	0%	71%	0%	43%
Significant influence	0%	100%	29%	100%	57%

HOPES AND EXPECTATIONS

The industry's view on the possible impacts of recent or current trends and changes in regulatory approach	**AUSTRALIA**	**CANADA**	**EUROPE**	**JAPAN**	**USA**
Increasing trend to move from a zero-risk approach to a benefit:risk assessment	+56%	+100%	+59%	+92%	+83%
Acceptance of JECFA agreements for residues of non-contentious molecules	+89%	+100%	+47%	+83%	+25%
Moves towards electronic submission	+67%	+83%	+59%	+75%	+67%
Moves towards a common technical document	+100%	+83%	+6%	+58%	+75%
Increasing transparency with respect to data disclosure	+67%	+9%	-47%	+42%	-8%
Trend to wider participation in regulatory process, including public comment	+11%	-9%	-59%	+33%	-8%
Increasing globalisation of post-marketing surveillance outcomes	0%	-9%	-41%	+8%	-67%
Increasing requirements for post-marketing surveillance & pharmacovigilance	-33%	-17%	-47%	-58%	-92%
Agency strategies on antimicrobials management	-	-	-24%	-	
The harmonisation of the summary of product characteristics (e.g. via referrals) in Europe	-	-	+6%	-	-
Agency initiatives on 'Better Regulation'	-	-	+59%	-	CVB +67% CVM +25%
Acceptance of notification of minor changes	-	-	-	+100%	-
Conditional approval of new animal drug (Under Discussion)	-	-	-	+83%	-
Consultation with NVAL on pre-application of new animal drug including clinical trial design	-	-	-	+83%	-
Acceptance of English documents for New Animal Drug Application without translation into Japanese	-	-	-	+75%	-
Acceptance of orphan animals drugs in same way as MUMS in the US regulation	-	-	-	+42%	-
Expansion of classification of quasi-animal drug (Under Discussion)	-	-	-	+42%	-
Integration of evaluation offices into National Veterinary Assay Laboratory only	-	-	-	+17%	-