IFAH Global Benchmarking Survey (GBS) 2011

Contents

- Survey Statistics
- Key Recommendations
- Major Challenges
- Major Trends
- Regulatory environments by region

Survey statistics

- Recurring survey (every 5 years) in the major regulatory regions
- 60 companies responded from 5 regions
- 72 interviews average 1.5 hours each
- 21,000 individual data points and up to 400 free-text responses
- Members provide 85%-90% of the veterinary products in their markets
- USA and Europe each account for approximately one third of global sales

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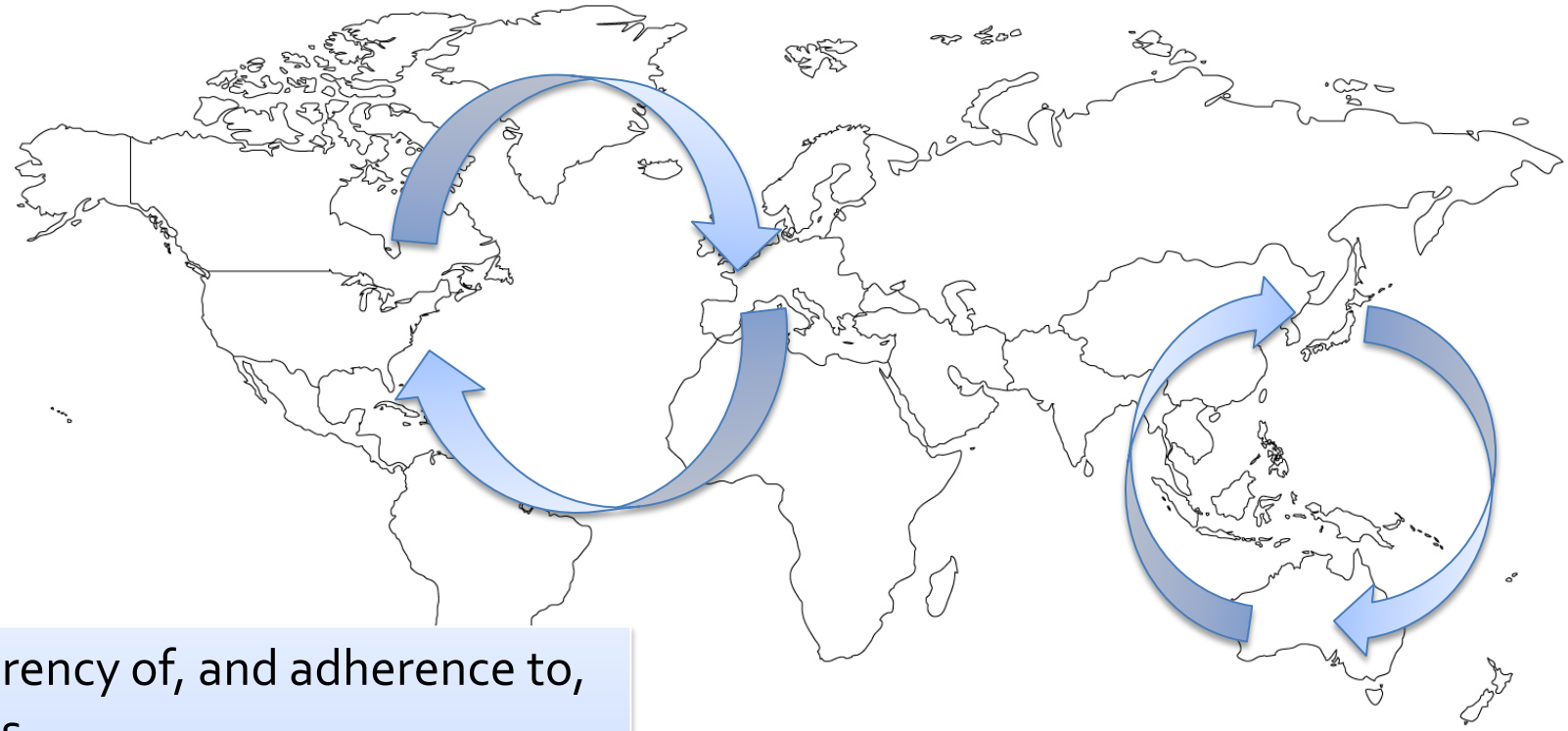
Key recommendations

1. Best practice in one region to be considered in others.



- Transparency of, and adherence to, timelines
- Consultation between industry and regulators
- Acceptance of foreign data / dossiers

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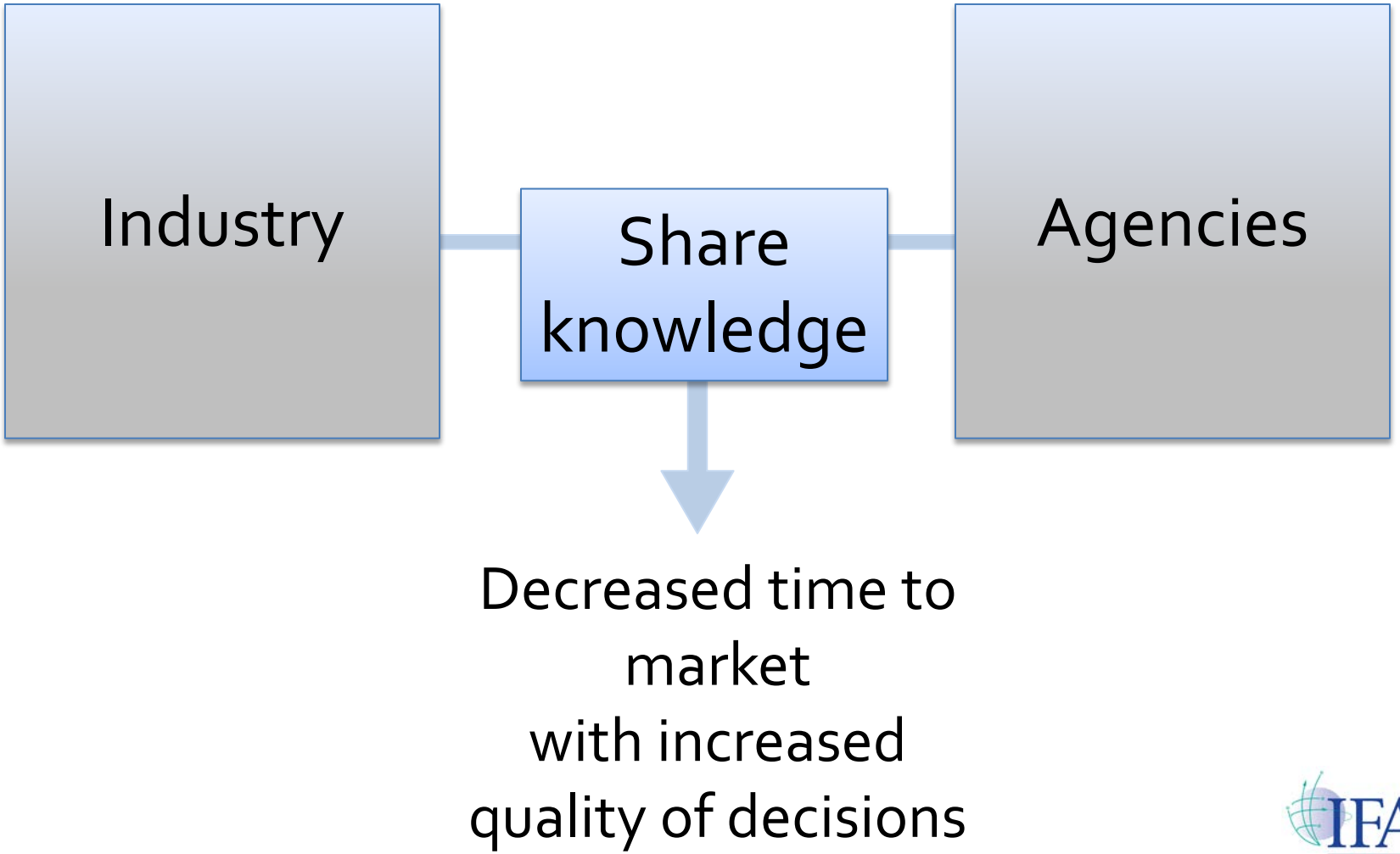
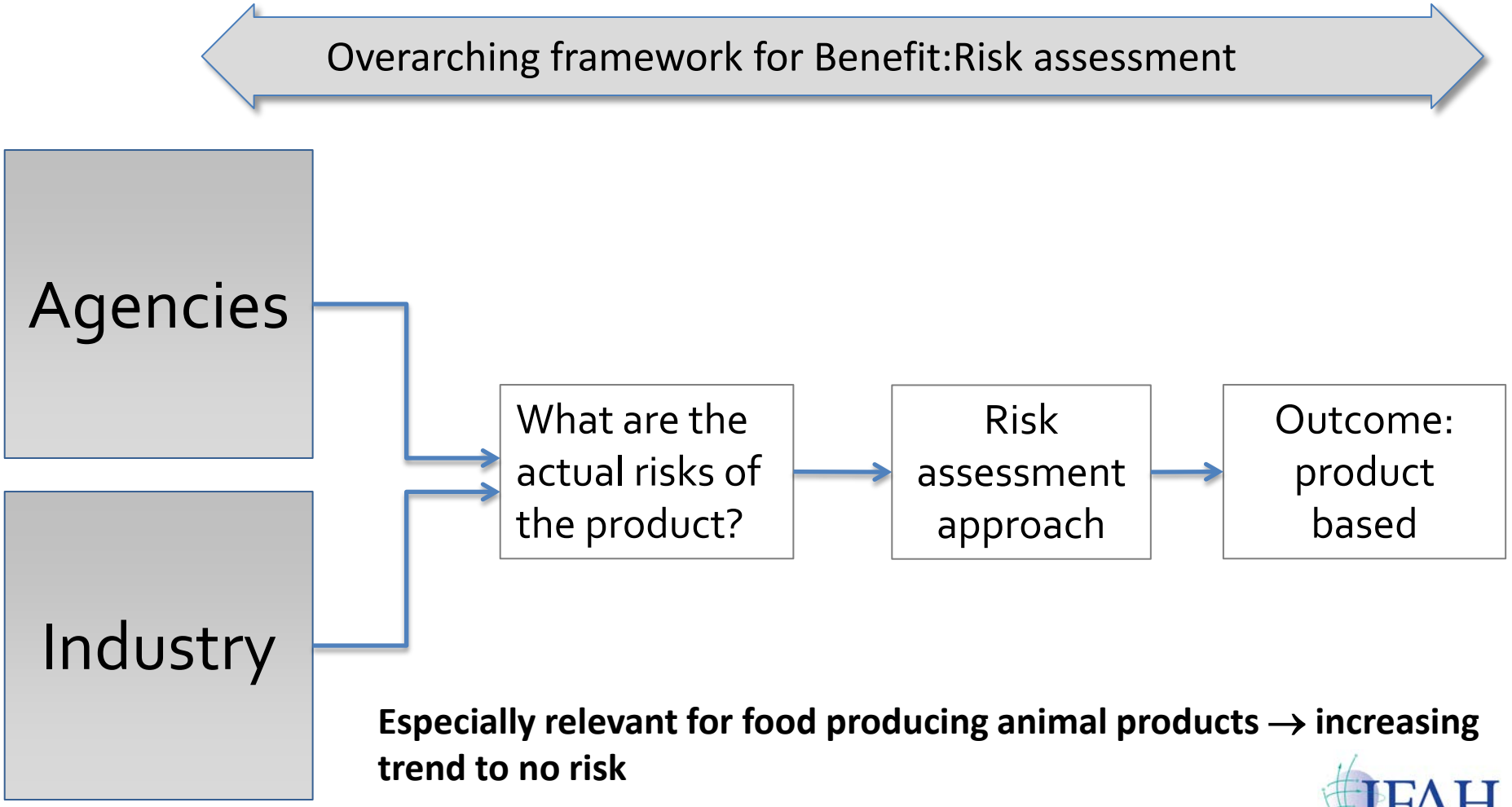
2. Sharing of information on veterinary knowledge and joint workshops on innovation.

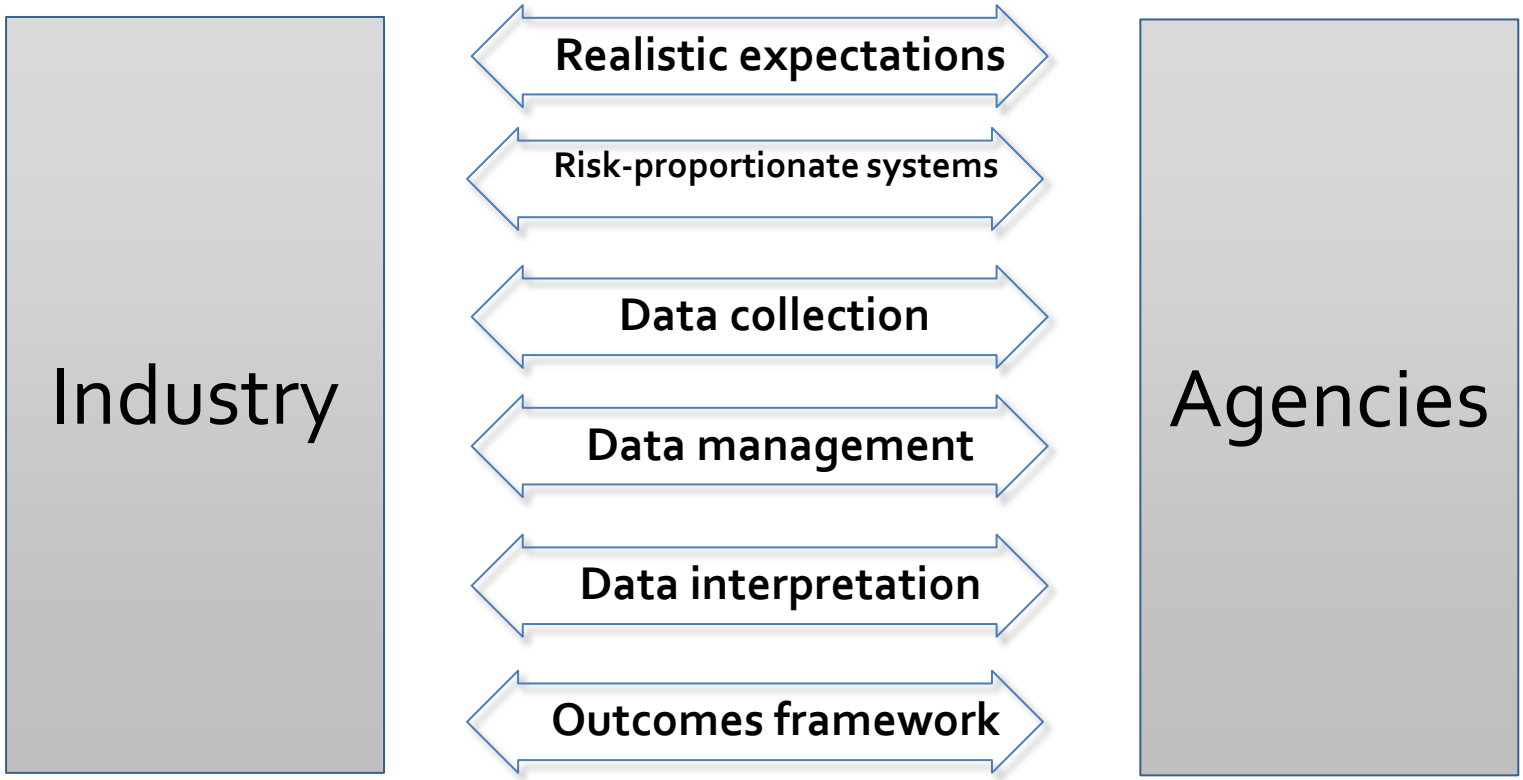


3. Continued dialogue between industry and regulators to introduce a realistic risk assessment approach.



Especially relevant for food producing animal products → increasing trend to no risk

4. Reach an adequate framework for animal health pharmacovigilance.



→ Increased requirements
→ Unpredictable outcomes
→ Increased regulatory burden

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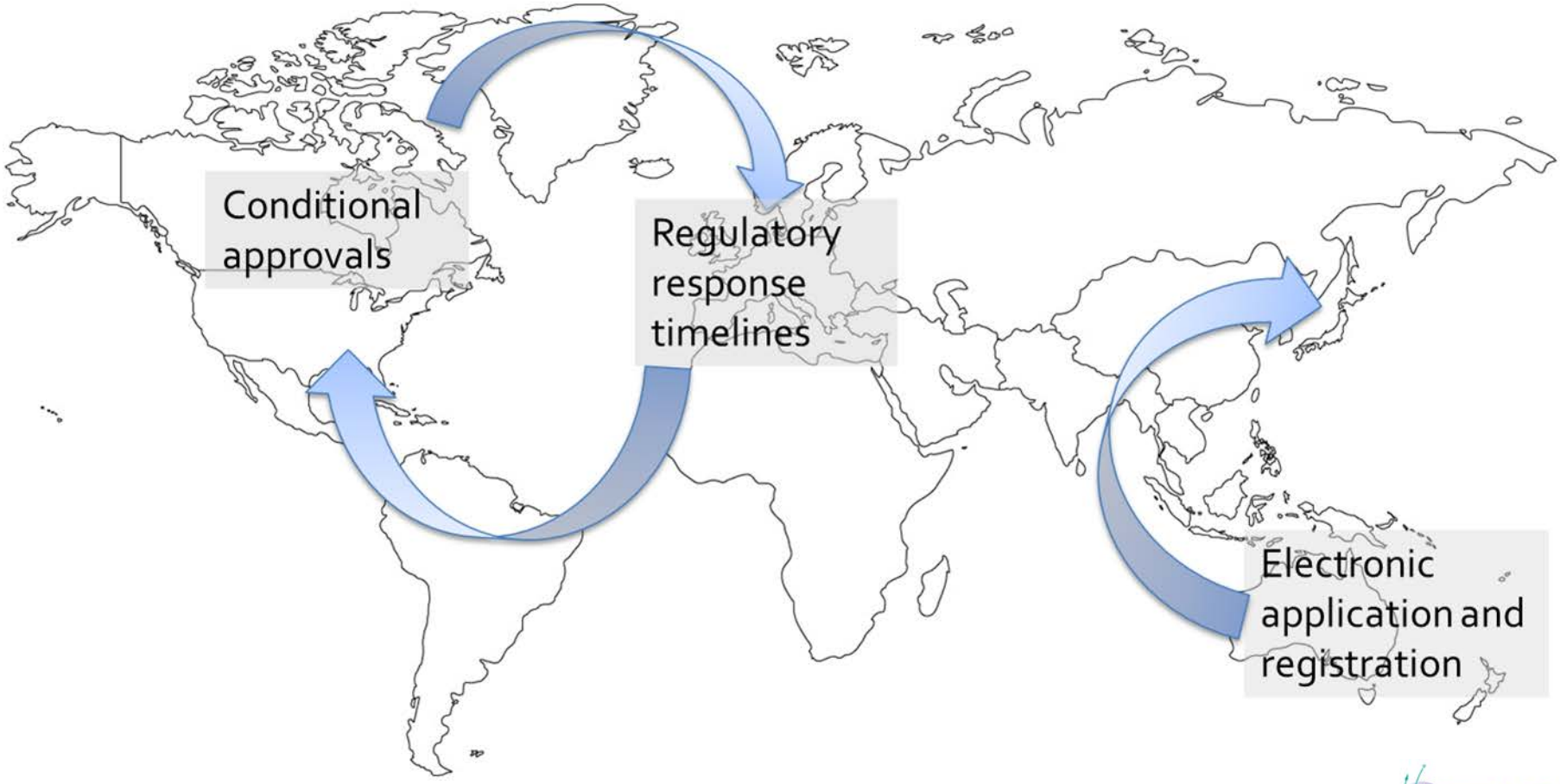
5. Where not in place, introduction of common processes such as timelines for regulatory responses, systems for tracking dossier progress preferably on line.



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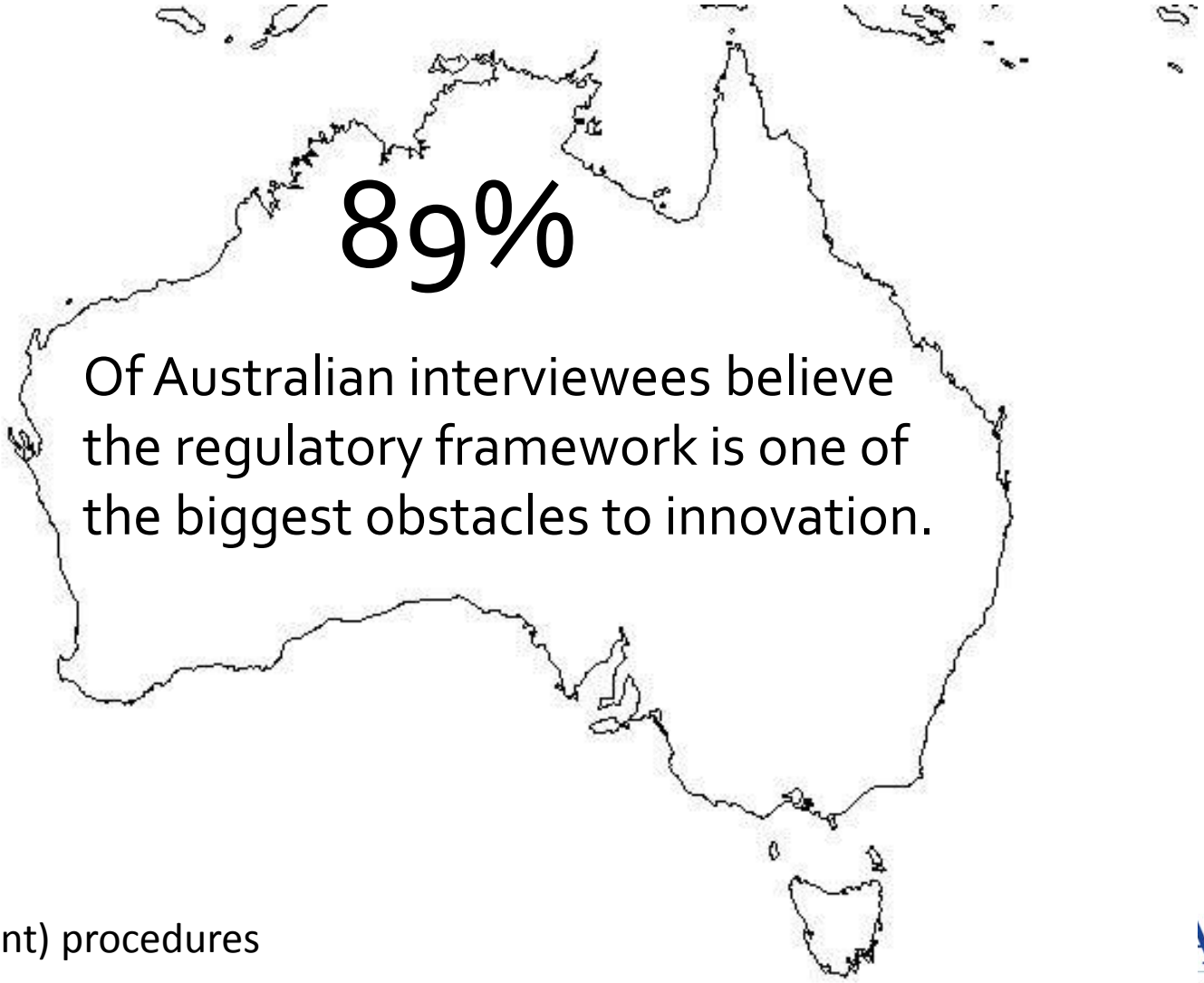
6. Message that <u>small or fragmented markets</u> cannot stand up to over-regulation or inefficient regulation was reinforced.

Aus/Can
- Multiple species
- Multiple agencies



Europe
- Multiple species
- Multiple agencies
- Multiple (inefficient) procedures

Major challenges

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1. Average registration time (yrs)*

Registration time Major new FAP	AUS	CAN	EU	JP	USA**
Pharmaceuticals	2.3	2.6	1.7	3.2	9.4
Biologics	2.3	1.4	1.5	2.3	4.3
Pesticide-based product	2.8	2.5	2.0	3.0	6.0

Registration time Major new CAP	AUS	CAN	EU	JP	USA**
Pharmaceuticals	1.8	2.3	1.5	2.1	6.4
Biologics	1.8	1.2	1.5	2.0	4.1
Pesticide-based product	2.1	1.7	1.4	3.0	3.5

Registration time Major new [MU]MS	AUS	CAN	EU	JP	USA**
Pharmaceuticals	-	2.0	1.7	2.4	6.0
Biologics	-	-	1.5	-	5.5
Pesticide-based	-	-	2.0	-	-

*** Registation times based on first regulatory submission**

**** USA = phased review applications (note: incorporates complete duration of development program)**

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2. Average registration costs (US$M) (2010)

The approximate cost New FAP	AUS*	CAN	EU	JP	USA
Pharmaceutical product	48	1.23	29.0	1.6	38.8
Biological product	77	0.003	20.0	1.3	10.8
Pesticide-based product	30	-	46.7	-	14.0

The approximate cost New CAP	AUS*	CAN	EU	JP	USA
Pharmaceutical product	34	0.25	16.0	1.7	21.6
Biological product	24	0.003	18.4	1.2	11.8
Pesticide-based product	28	-	32.5	-	22.6

The approximate cost New MUMS product	AUS	CAN	EU	JP	USA
Pharmaceutical product	-	-	11.7	0.7	21.6
Biological product	-	-	8.0	-	11.8
Pesticide-based product	-	-	20.0	-	22.6

*** Includes manufacturing and specific regulatory requirements that contribute to the increased costs**

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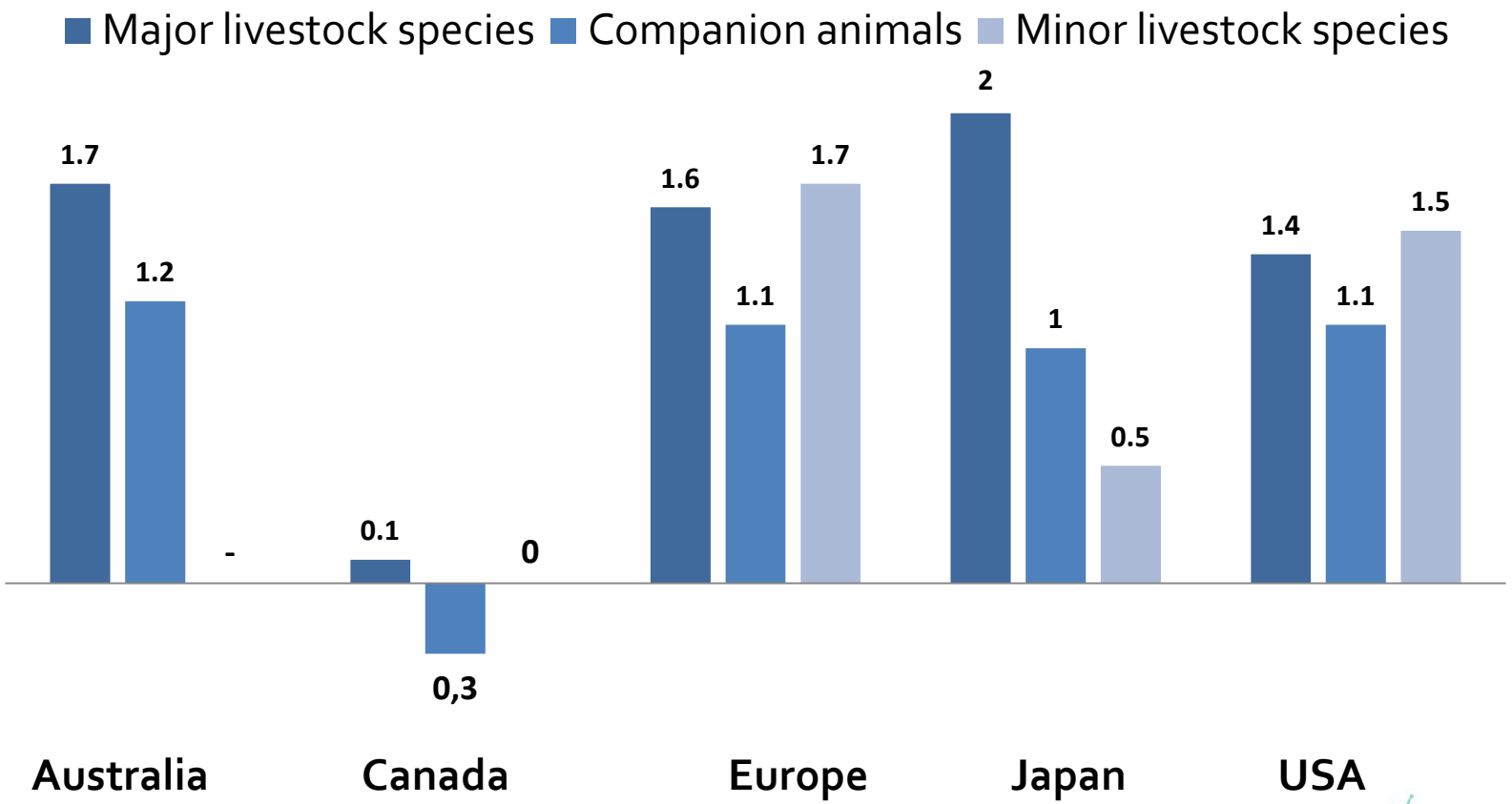
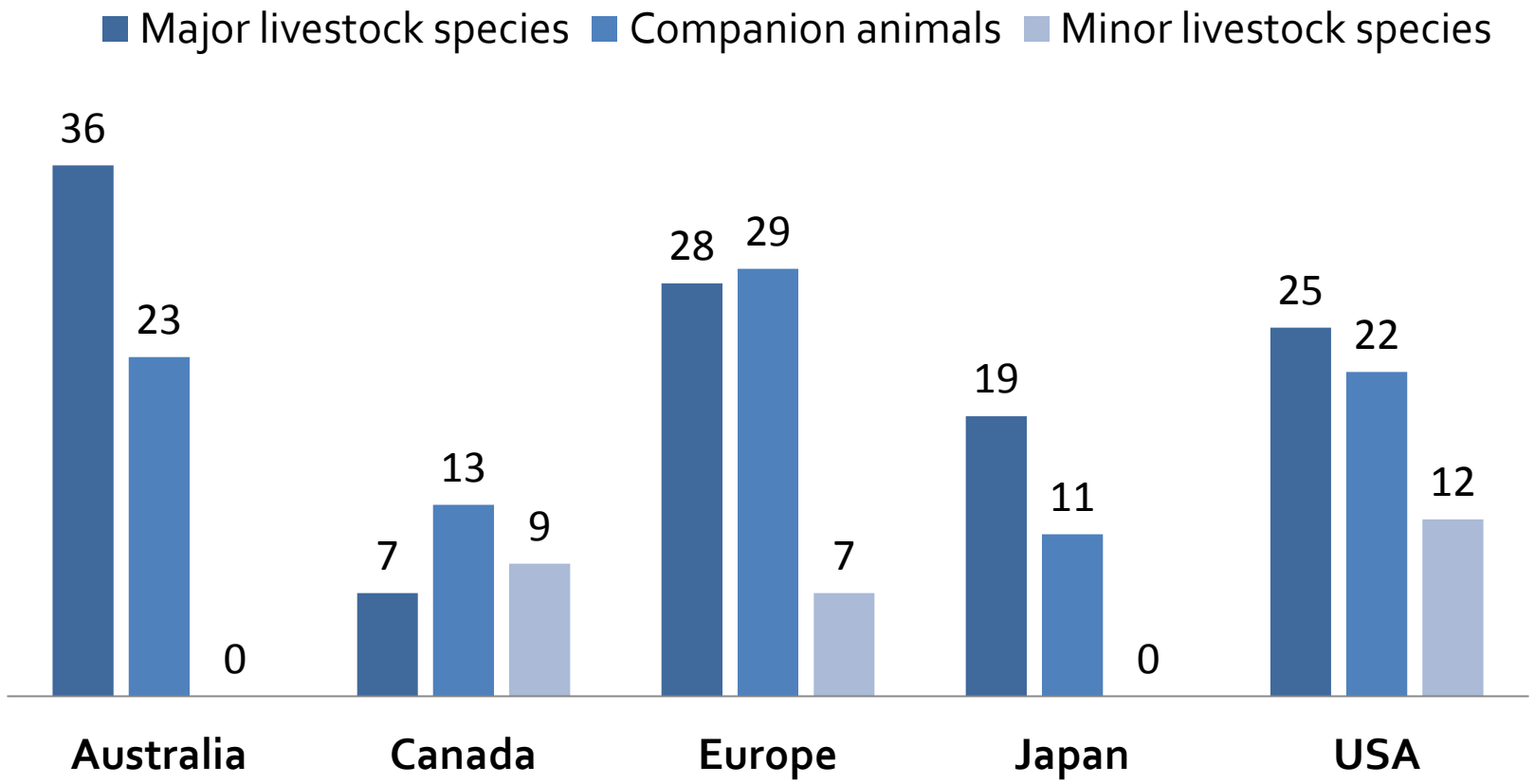
3. Increased registration time since 2006 (yrs)

The time to gain registrations has significantly increased in all regions except Canada.



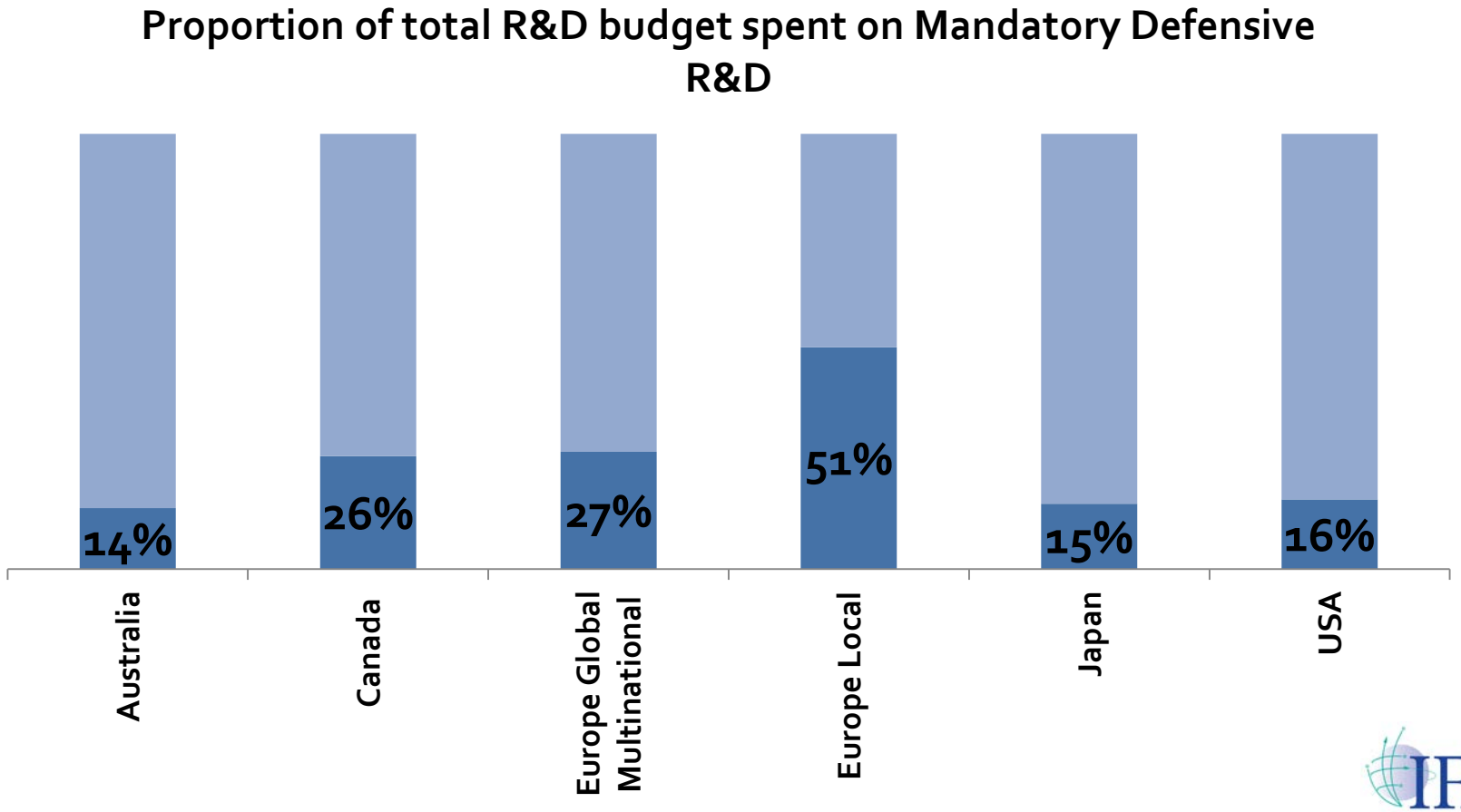
4. Increased registration costs since 2006 (%)

The cost of gaining registrations has increased significantly in some regions.



5a. Registration costs (mandatory defense)

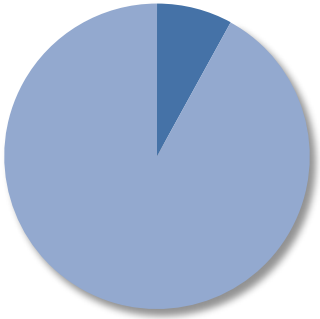
The costs due to demands on existing products consume considerable R&D budget limiting investment on innovation.



5b. Registration costs (mandatory defense)

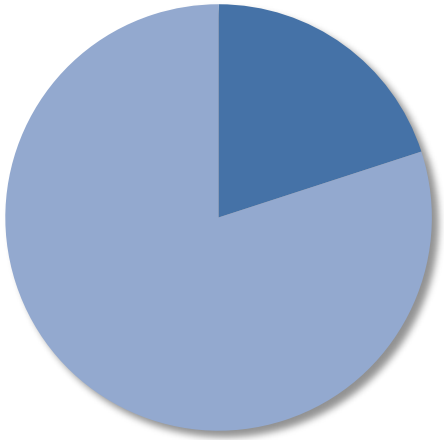
The growing cost of Mandatory R&D in one global multinational.

EU Mandatory R&D Budget as Proportion of Total R&D Spend 2006



8 %

EU Mandatory R&D Budget as Proportion of Total R&D Spend 2011



20%

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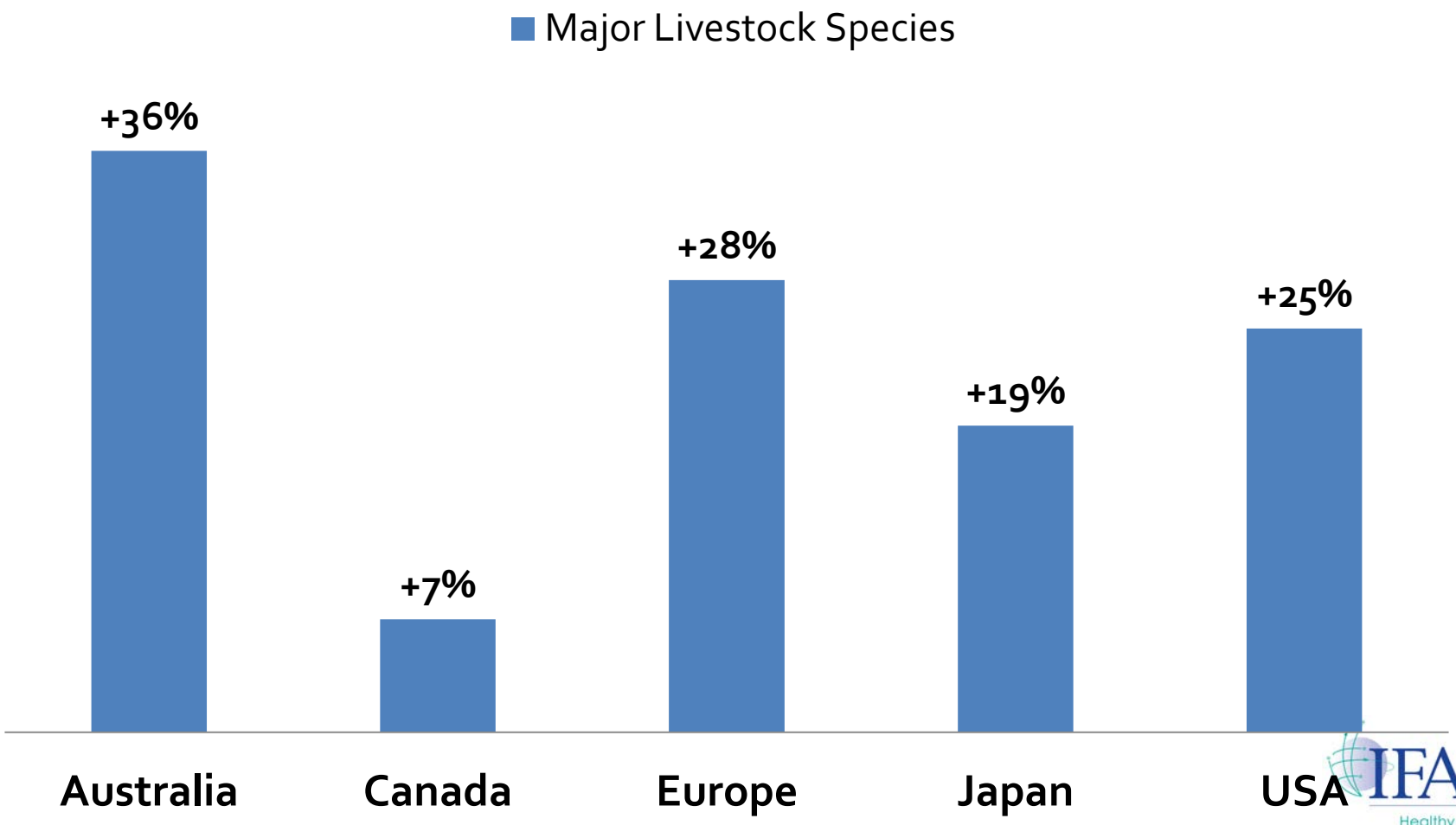
6. Impact of regulatory factors on development costs since 2006

The involvement of human health agencies continues to have a disproportionate and inappropriate impact.



7a. Zero risk trend

The trend towards a zero-risk approach is seen as highly significant.

- Lack of acceptance of high quality data e.g. for food producing animals
- Increasing demands for pharmacovigilance data without a clear outcome or framework e.g. specialized PSURs, increase regulatory burden
- Zero-risk approach compounded when more than one agency involved e.g. perception of higher requirements following US/EU collaborative assessments
- Regulatory burden after mergers and acquisitions greater than expected e.g. huge numbers of product transfers etc.

7b. Zero risk trend

An appropriate benefit:risk approach is one of the industry's most widely held hopes.

Hopes & Expectations	Australia	Canada	Europe	Japan	USA
Increasing trend to move from a zero-risk approach to a benefit:risk assessment.	+56%	+100%	+59%	+92%	+83%

8. Provide knowledge to authorities

There is widespread support to share knowledge with agency staff

- Support the sharing of knowledge of disease, disease management and practicalities of product use with agency staff.
- Support expanding agency expertise in scientific innovation.
- Support agency staff improving the clarity-of risk assessments.

Major trends

1. Market

- Slowing growth in farm animal sector in Europe and USA.
- Strong 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 other developed nations.
- Companion animal sectors to follow general economic trends – growth in emerging markets expected.

2. Operational activities

- Innovation programmes to be planned globally.
- Stricter ROI criteria and risk assessments for development plans.
- Some success with pre-submission discussions.
- Improvements in existing products and greater operational efficiencies seen as key to success.

3. Technology & innovation

- Replacement / supplementation of treatment with prevention products e.g. vaccines, probiotics, increasing husbandry standards
- Biological products more acceptable to public and now generally easier to gain approval than pharmaceuticals.
- Continued innovation in product delivery expected e.g. needleless injectors, oral vaccines, transdermal

4. Regulatory

Trends regarded as positive in all regions:

- ✔ Full acceptance of VICH-compliant data.
- ✔ In general, acceptance of CODEX agreements and standards.
- ✔ Moves towards electronic submission. (e.g. AUS, US, EU)
- ✔ Move from zero-risk to benefit:risk (e.g. EU)

Regulatory environments by region

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Australia

- Lack of trust between industry and regulators.
- Lack of timeliness, predictability and consistency in APVMA.

Challenges

- Australian Quarantine and Inspection Service (AQIS) causes significant delays
- Export Slaughter Intervals not imposed based on science-based risk studies.
- Ectoparasiticide rules excessive.

Improvements

- Introduction of Electronic Application and Registration system.
- Creation of 'Tiger Teams' in which junior evaluators can learn from more experienced ones .
- Phased dossier review.
- Use of international guidelines and reduction in burden for minor changes.

Canada

- Considerable improvement since 2006 in some agencies.
- Small market sensitive to over-regulation.

Challenges

- Lack of action on importation and use of non-registered pharmaceuticals.
- Unaligned manufacturing, quality and inspection staff at the Veterinary Drugs Directorate (VDD).
- Antimicrobial and environmental regulations.
- Manufacturing requirements that equal those of human health.

Improvements

- Management of submissions improved.
- Time from submission to approval shortened significantly.
- Improved review performance at Canadian Centre for Veterinary Biologics.
- Introduction of Low Risk Veterinary Health Product Notification Program.
- Move towards benefit:risk approach at VDD.
- Industry / regulator co-operation and problem-solving.

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Europe

- Introduce highly efficient regulatory systems to reduce administrative burden.
- Support pharmacovigilance, but avoid it becoming the next 'bureaucratic monster.'

Challenges

- Political pressure on food animal antimicrobials now critical.
- Directive 2004/28/EC forces originators to standardise product literature across the EU when a generic is authorised, causing a massive burden.
- Opportunities for unreasonable disagreement by Member States on marketing authorisations still exist ("*1 MS can de-rail the procedure*").
- Insufficient alignment of best practice across national agencies.

Improvements

- Regulators willing to engage with industry on specific concerns.
- Variations regulation.
- European Commission 'Better Regulation' initiative.

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Japan

Challenges

- Too many committees involved in J-MAFF review process.
- Processes sequential, not parallel.
- Lack of pre-submission discussion on biologicals with the NVAL.
- Continued insistence on full Japanese translation of dossiers.
- Inflexibility in applying local study requirements when not required.

Improvements

- Increasing acceptance of high quality test results from other sectors and regions.
- Decrease in time between investigation and division committee stages of J-MAFF.
- Revision of the Pharmaceutical Affairs Law to allow domestic and overseas manufacturing sites to be treated equally.
- Reduction in restrictions on minor changes for existing products.
- Provision in advance of discussion points for J-MAFF hearings.

USA

Challenges

- EPA: performance lowest of the surveyed agencies.
- CVB: increasingly reliant on biometrics not clinical outcomes.
- CVM: End Review Amendment is used as a compendium of points that could have been answered with less stress during earlier stages of the process; lengthy overall approval process times with few obvious reasons.
- Lack of clear lines of responsibility between the three agencies for biotechnology-derived products.

Improvements

- Greater openness and interface between regulators and industry.
- CVM Innovation Exploration Team Initiative promising.
- USDA requalification rules for foundation seed antigens.