



Drug & Feed Additives – differences between Canada & the US: are we being left behind?

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Prepared for CMC Technical
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Szkotnicki, President, CAHI



Canadian Animal Health Institute

- Trade assoc. representing the manufacturers and distributors of animal medications in Canada.
- 19 full members & 38 associate members.
- Representing over 95% of the licensed animal health product sales.
- \$560 million dollar business in Canada; 2% of the global animal health market.



Canadian Animal Health Institute

- Objectives
 - Foster & maintain a competitive regulatory environment
 - Actively promote the proper use of medications
 - Enhance the public's understanding of the contributions made by the animal health industry
 - Work closely with the veterinary profession & food animal sector



Federal Regulatory Programs for Animal Health Products

Product Category	Government Authority	Legislation
Drug	Veterinary Drugs Directorate, Health Canada	Food and Drugs Act
Biologics	Veterinary Biologics Section, CFIA	Health of Animals Act
Feed Additives	Feeds Section, CFIA	Feeds Act
Pesticides	Pest Management Regulatory Agency, Health Canada	Pest Control Products Act



Situation Assessment & Challenges

IFAH Regulatory Benchmarking Study

- Examined relationship between competitiveness and external business environment, including regulations
- Employed a proven methodology – used in the USA and the EU in 1997 and 2001
- Compared Canada, USA, Australia, Japan, and the European Union (2006)
- Used two principal sources of evidence:
 - *Five major quantitative surveys with companies (80-95% of sales in each area)*
 - *Over 120 depth interviews*
- Provides a unique source of quantitative and qualitative evidence



What Canadian Business Said

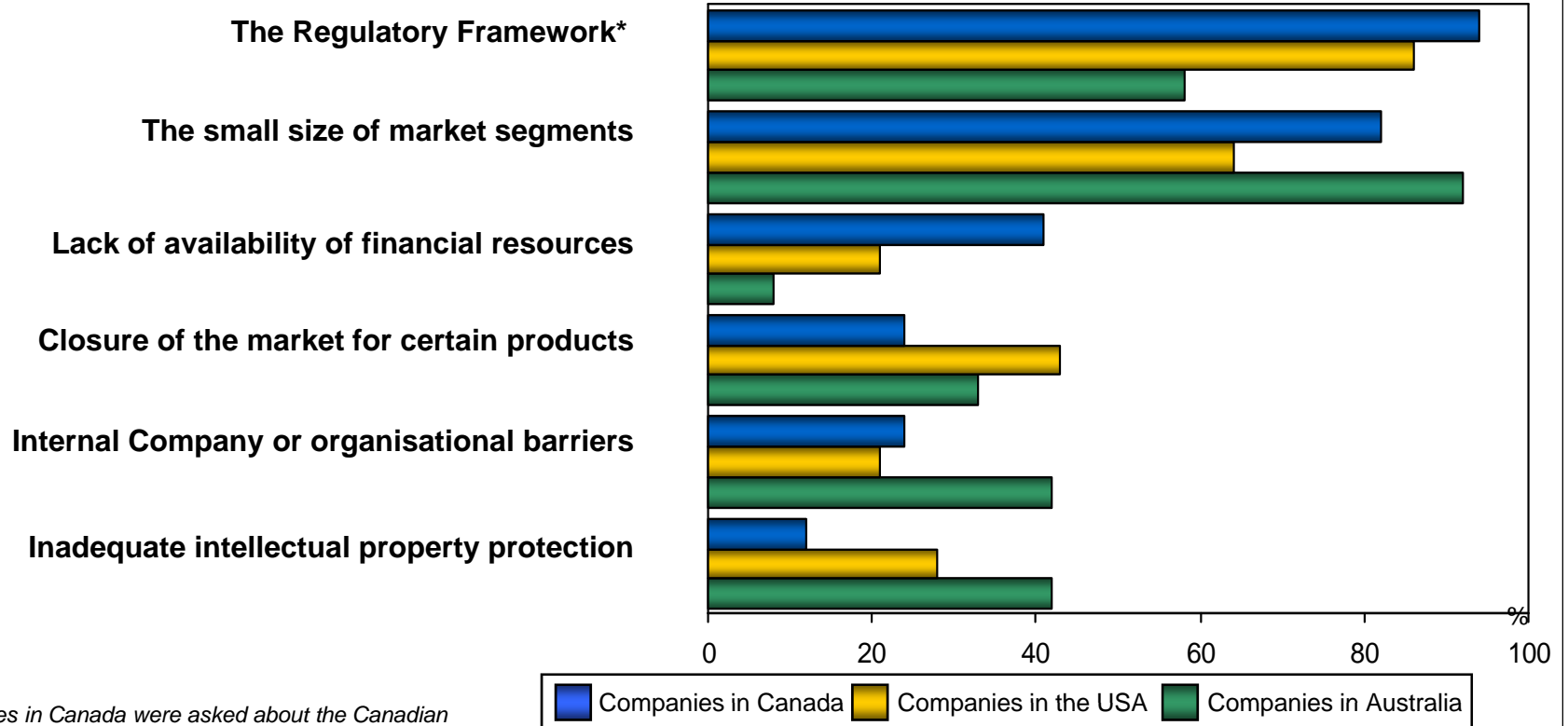
- Product innovation is the major driver of long-term competitiveness (100% of companies)
- Companies need to achieve critical success factors (time-to-market, cost, predictability) to innovate effectively
- Regulatory framework is the biggest obstacle to innovation and ultimately availability (94% of companies in Canada)
- Regulatory factors also reduce market incentives – major “unapproved market” permitted in Canada
- Regulations have triggered reductions in investment in Canada



Major Obstacles to Successful New Product Development Canada/USA/Australia Comparison

Major Obstacles

(% of companies identifying obstacle as signif.)



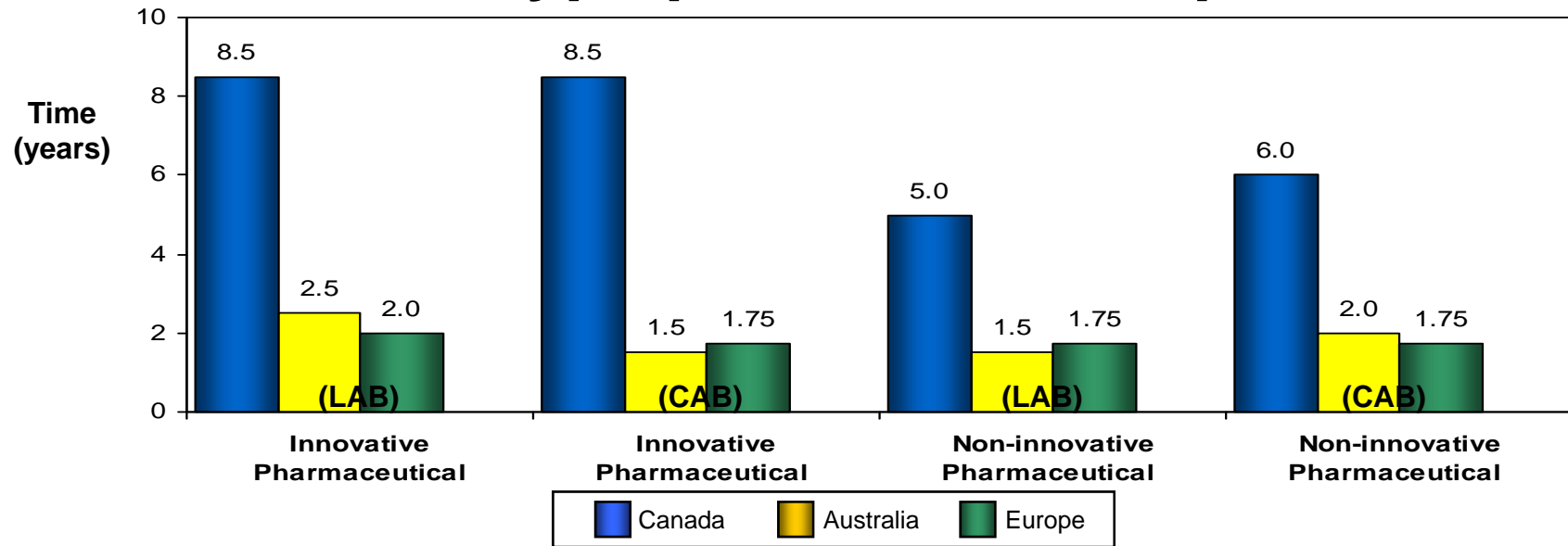
* **Note:** Companies in Canada were asked about the Canadian Regulatory Framework; companies in the USA were asked about the US Regulatory Framework; and companies in Australia were asked about the Australian Regulatory Framework

Source: Business Decisions Limited 'Survey of Animal Health Companies in Canada, the USA and Australia' (2006)



Timeliness of VDD Decision-Making

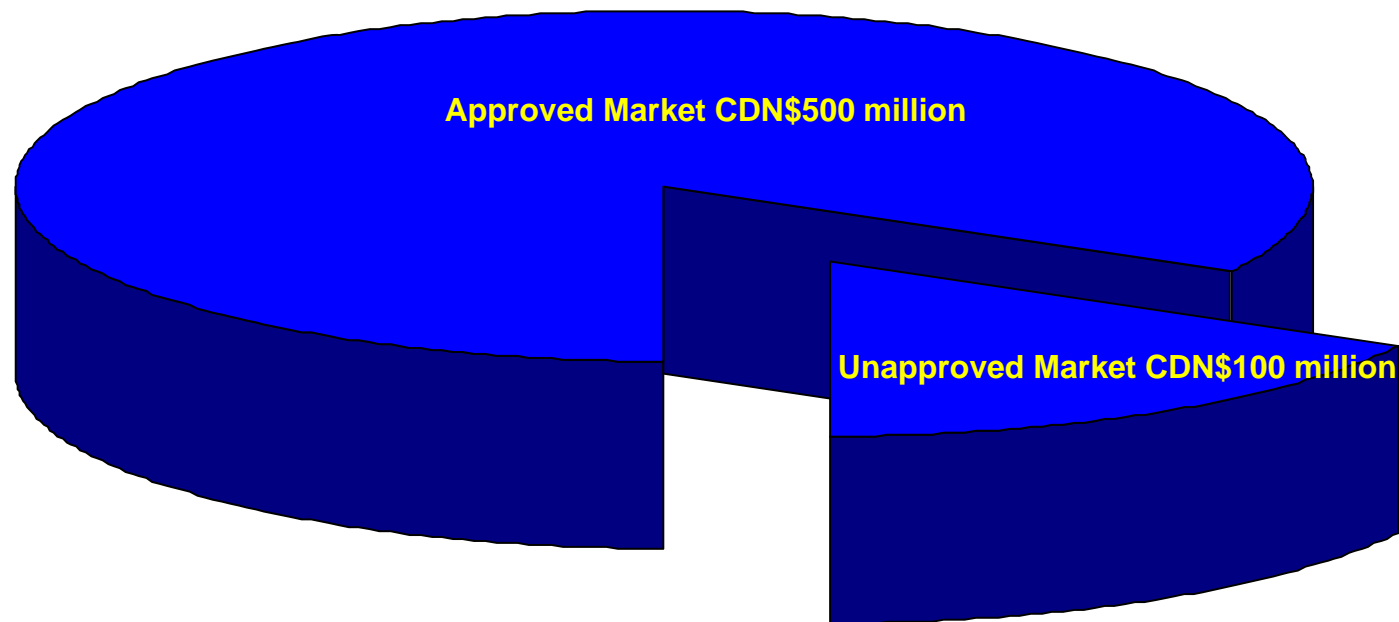
Estimate of expected time needed to carry out mandatory risk assessment and management for four archetype pharmaceutical products



* **Note:** Estimates for Europe assume complete dossier review (with no other previous agency review), while estimates for Canada and Australia assume dossier has already been reviewed and approved in the USA (and additional national tests have been completed)



Estimated Scale of Market for Unregulated Animal Health Products in Canada

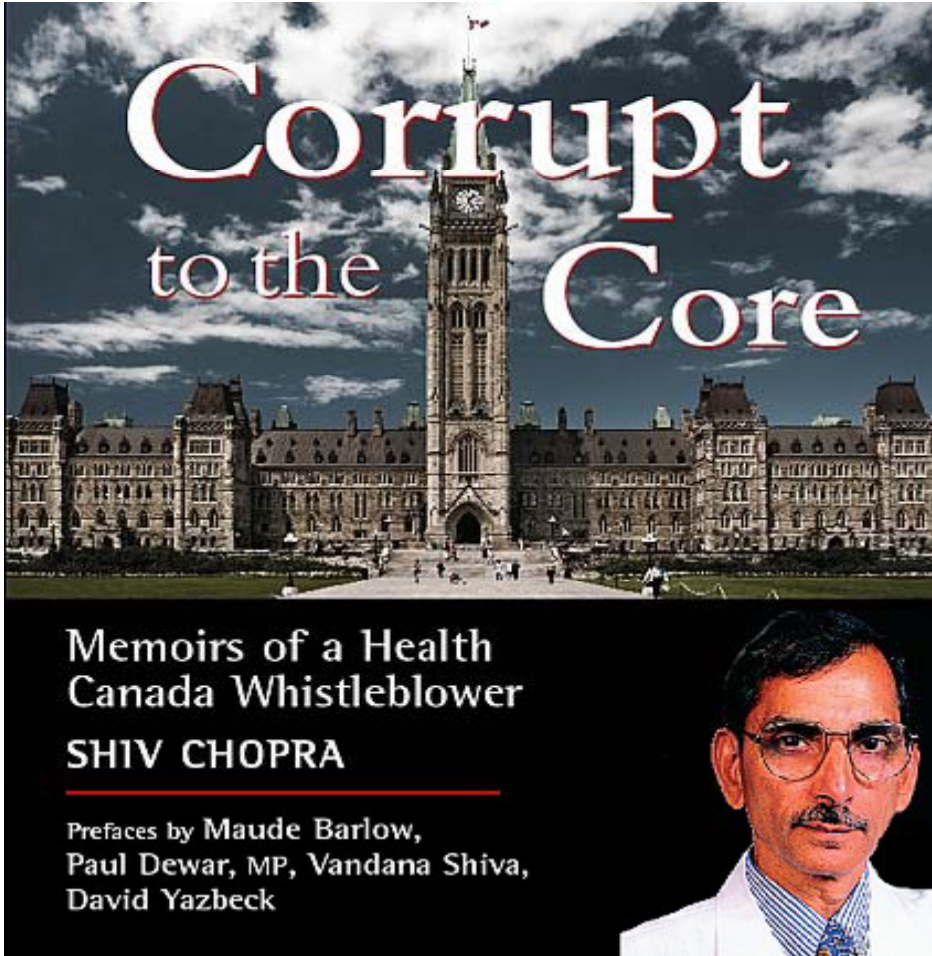


* 1/3 of the sale of licensed animal drugs



Strategic Decisions and Regulation

- Major strategic decisions taken by companies over last five years have been negatively affected by regulations:
 - *Fewer breakthrough products launched (60% of companies)*
 - *Product availability reduced - 85% of companies have reduced overall product range; 75% have reduced coverage of species/indications*
 - *Focus on older technologies (77% focus on existing or older technologies)*
- Long-term problem for animal companies & Canadians



Testimonials:
Read this eye opening book for a shocking answer.

David Suzuki, Ph.D., Canadian Environmentalist

Shiv Chopra is a hero ... who took on the powers at Health Canada.

Maude Barlow, Chairperson, Council of Canadians

Recipient, Swedish Right Livelihood Award
In all my years as a rebel-rouser, I never heard anyone announce publicly, in advance and again and again, that they were going to blow the whistle

Ralph Nader, Former Presidential Candidate, U.S.A., Speaking at a conference on Science in the Public Good.

Here is a full account of how government corruption endangers the public food supply.
Paul Dewar, M.P., Canadian House of Commons

A courageous writing; [it] provides a dose of resilience to all who care about the integrity of science, independence of government regulations ... and the freedom of citizens from hazardous food and medicines.

Vandana Shiva, Ph.D., Environmental Activist
Recipient, Swedish Right Livelihood Award



Regulatory Challenges - Drugs

- Submission backlog
- Poor morale within the VDD
- Risk adverse
- Poor operational processes
- Unpredictable & untimely



Situation Assessment & Challenges

ANAC Regulatory Survey – June 2006

Results ...

- 90 day performance std. > met 32% of the time; 68% time not met



ANAC Regulatory Survey

- Delays in decision making were problematic for a new feed or ingredient with safety or efficacy requirements, standard ingredient, significant changes for supplm't or macro premix for top dressing or with a mixing rate, mineral feed, salt to which other elements have been added & specialty products.



ANAC Regulatory Survey

- Reasons for delays ...
 - > Requests for additional scientific evidence/data, issues around the use of nutraceuticals & functional feeds/nutrients with application being handed over to VDD, & the removal or replacement of an ingredient to satisfy requmts. Non specified reasons.



Canadian Approach - Feeds

- Functional feeds, functional nutrients & nutraceuticals considered to be pharmaceuticals
- Frustration that the regulatory process is not enabling



Natural Health Product Human Background

- Natural Health Products Directorate – Jan.2004
 - Vitamins & minerals
 - Herbal remedies
 - Homeopathic medicines
 - Traditional medicines such as Chinese
 - Probiotics
 - Other products like amino acids & essential fatty acids



Functional Foods & Nutraceuticals

Food Directorate, HC

- Functional Food – physiological benefit &/or reduces the risk of chronic disease.
- Nutraceutical – product isolated or purified from foods sold in medicinal form for physiological benefit or protection against chronic disease.



United States

- Health claims > FDA drug evaluation
- No health claims > Unregulated
- GRAS list – 2000 chemicals/products database unregulated
- FDA & industry consultations underway
- No compliance action for product considered of low regulatory priority



Feed Additive Regulatory Challenges

1. Performance
2. Predictability
3. Governance of animal health product review – authority & technical requm'ts
4. Interpretation of the definition of a nutritional to address utility & functional claims
5. Regulatory amendments to address Table 4 limitations



Moving Forward - Providing Solutions

- ✓ Canadian Veterinary Pharmaceutical regulatory programmes need to be competitive globally, if they are to meet the needs of animal owners, food consumers, and producers of meat and livestock, and meet current government standards for competitiveness
- ✓ Focus on primary and underlying causes
- ✓ Our Goal: To have Canadian veterinary pharmaceutical review programmes that ensure producers and veterinarians access to drugs and biologics no later than 6 months after approval in the USA. This would ensure the competitiveness of our food animal producers, veterinary access to safer, more targeted medicines, and continued investment in the Canadian veterinary pharmaceutical industry, without compromising safety.



Reforms – Veterinary Drug Review Process

2007 Reforms Rec'm	2008 Reforms Init'd
Eliminate the Submission Backlog	Backlog was eliminated Mar. 31, 2009 at the latest.
Phased Submissions	Examining a process for phased submissions through the IND process



Reforms – Veterinary Drug Review Process continued...

2007 Reforms Rec'd	2008 Reforms Init'd
Streamlined review for companion animal submissions	Pilot project with U.S. CVM licensed products
Streamlined review for chemistry & manufacturing	QOS and CIPD programs being implemented
Harmonized review generic guidelines	New guidelines to be released for consultation Spring 2009



Reforms – Veterinary Drug Review Process continued...

2007 Reforms Rec'd	2008 Reforms Init'd
Address importation and use of nonlicensed products in animal medicine	Own Use Importation Task Force call for a restricted import permit program (RIPP). Progressive licensing initiative to strengthen controls around importation of APIs



Canadian Animal Health Product Regulatory Advisory Committee (CAHPRAC)

- **GOAL:** implement initiatives to improve regulatory efficiency & cost effectiveness
- **WHO:** Senior officials of Health Canada & CFIA & animal industry reps plus CAHI members
- **WHAT:** animal drugs, biologics, feed additives and animal natural health products



Canadian Animal Health Product Regulatory Programs

- Health Canada and CFIA animal medications programs have improved and continue to improve performance delivery
- Work still needed to facilitate better governance re. feeds, drugs and the fit for bioactives and veterinary natural animal health products



vNHPs - Health Canada

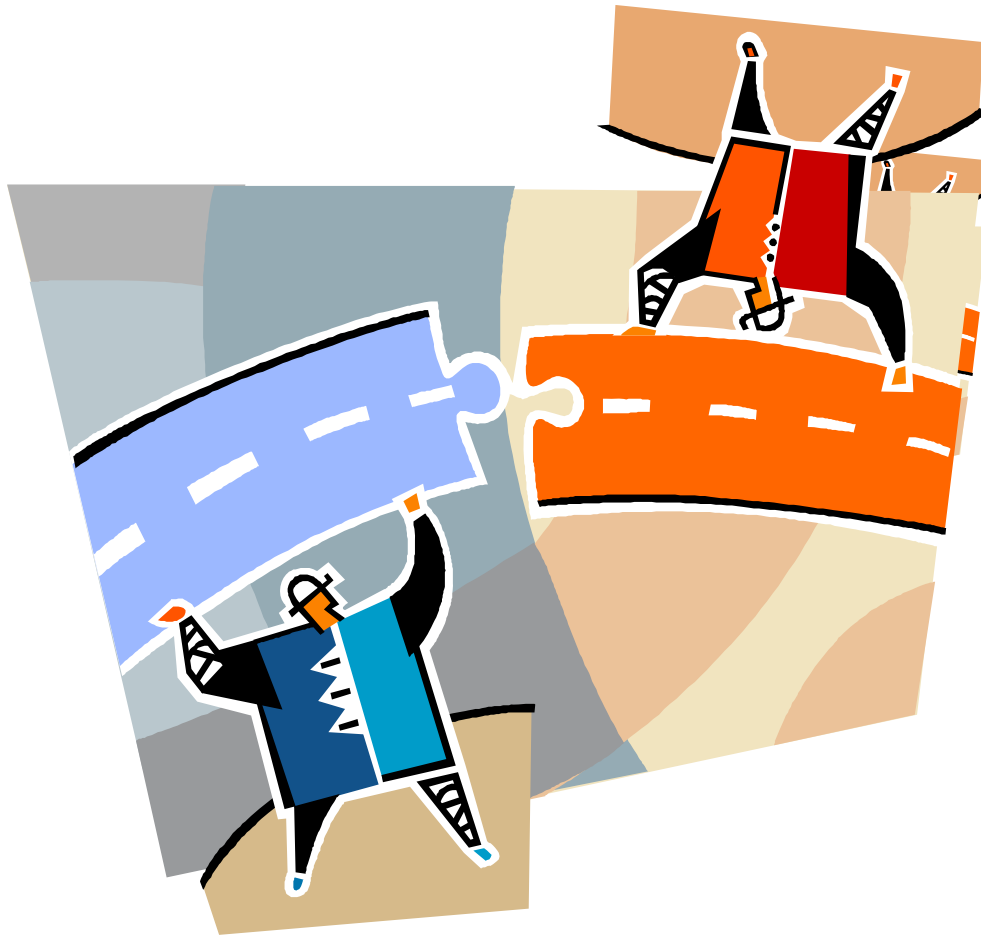
- VNHP Advisory Committee
- Regulatory process proportional to the risk
- Timeframe???



In the absence of noncompetitive veterinary medicinal regulation,...

Inconsistency of regulation results in ...

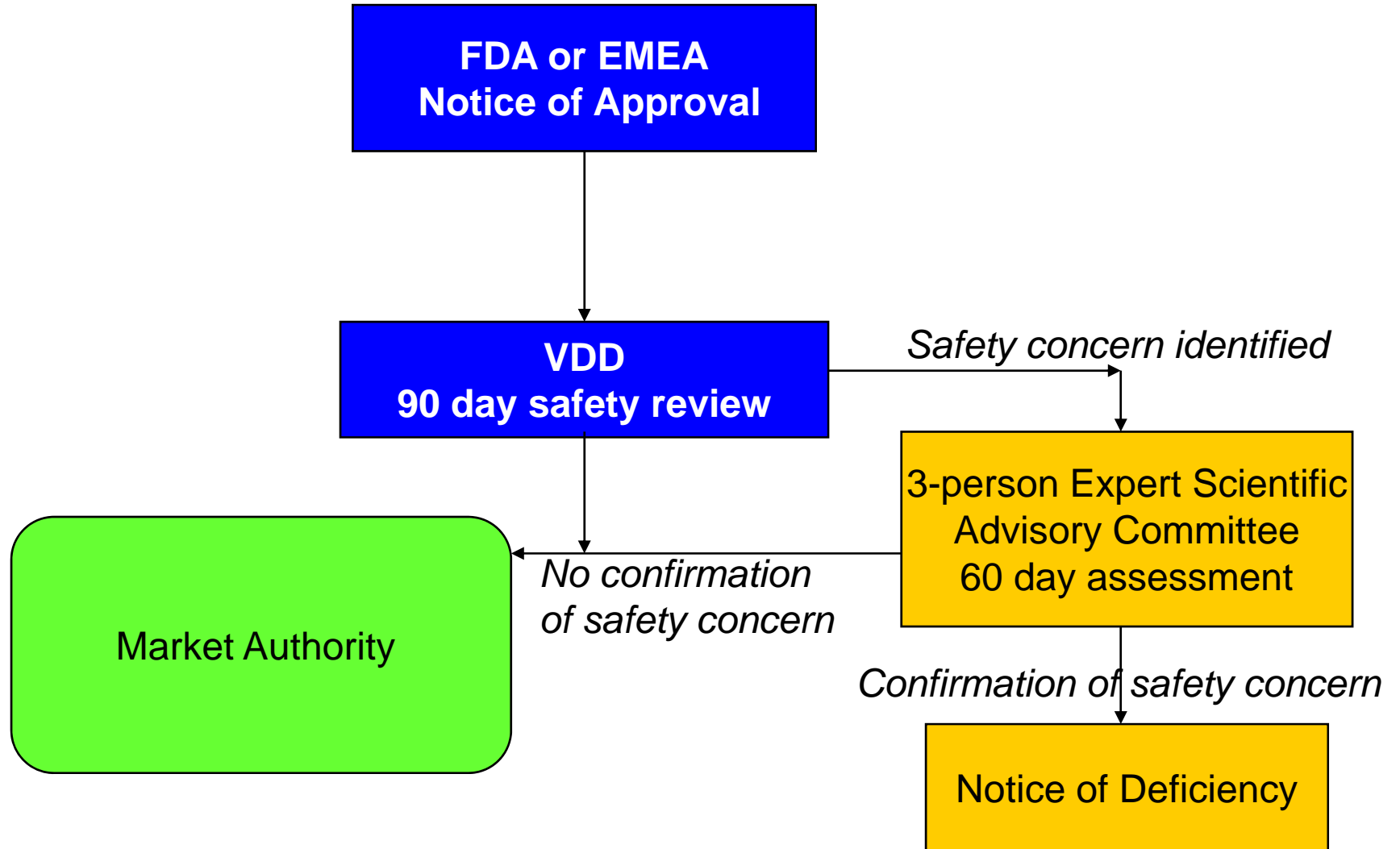
- Use of regulated & nonregulated product
- Lack of harmonization with trading partners
- Canadian producers forced to compete with producers in other countries that have access to health management tools not available in Canada
- Issues of food safety, animal welfare, trade, producer competitiveness and a disinterest in innovation

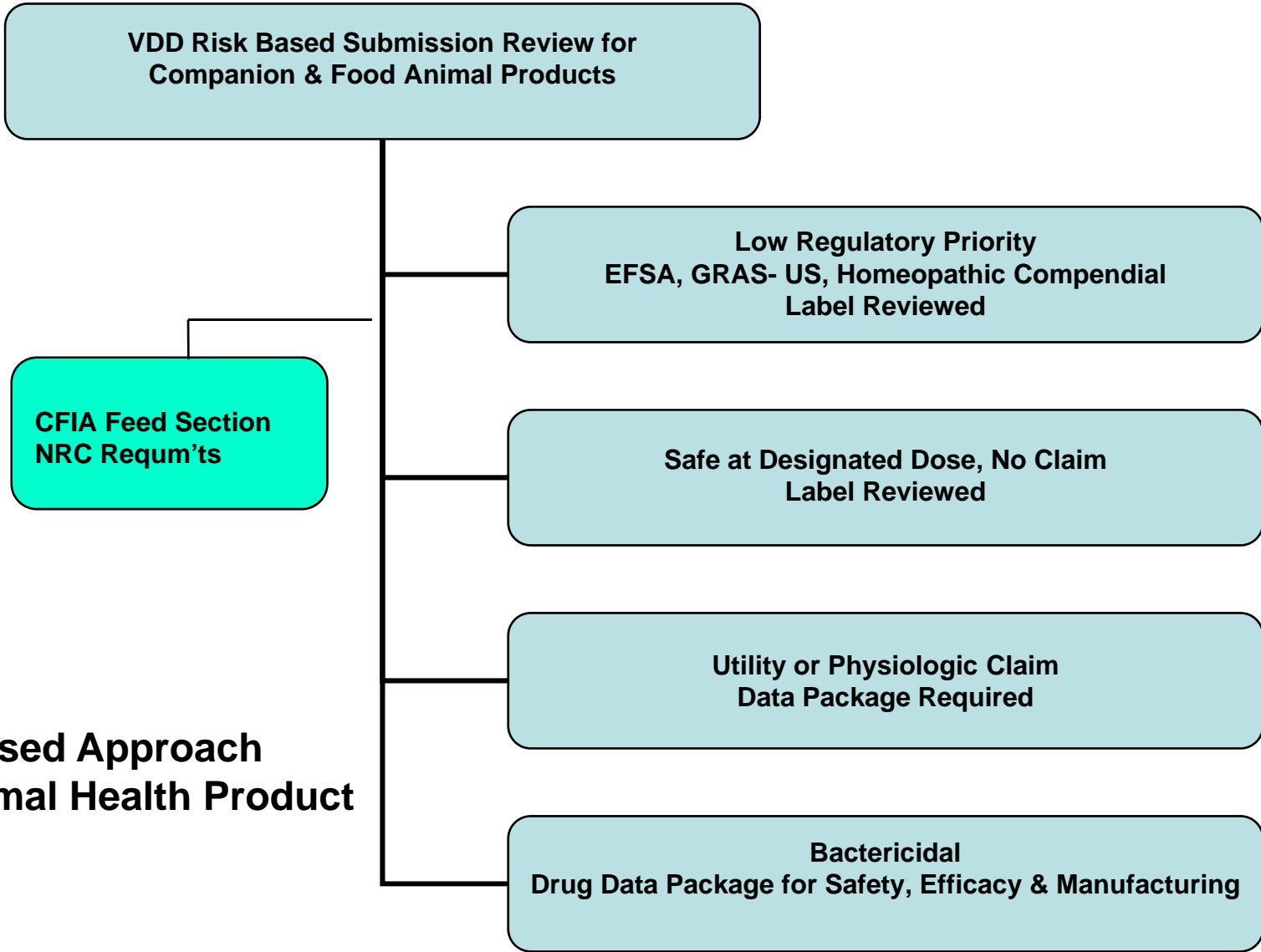


***Staying
Ahead of
the Curve***



ALTERNATIVE REGULATORY APPROACH





Risk Based Approach For Animal Health Product Review



Questions and Discussion