

**BENCHMARKING THE COMPETITIVENESS OF THE
CANADIAN ANIMAL HEALTH INDUSTRY**

A REPORT BY BUSINESS DECISIONS LIMITED

MAY 2007

THE EXECUTIVE SUMMARY

THE STUDY

In Canada, the animal health industry is regulated primarily by the Federal government through a number of executive agencies. The Veterinary Drugs Directorate (VDD), part of Health Canada, regulates most animal pharmaceuticals. The Veterinary Biologics Section (VBS), a section of the Canadian Food Inspection Agency (CFIA), regulates veterinary vaccines and biologicals, and the Pest Management Regulatory Agency (PRMA) an agency of Health Canada is responsible for a small number of specialist pharmaceuticals – specifically, externally-applied anti-parasite products many of which are based on crop protection technologies.

Risks to human health, animal welfare and the environment posed by the technologies used by the animal health industry are managed through a complex set of ex ante and ex post controls. There is widespread agreement amongst companies on the need to regulate the products and activities of the Animal Health Industry in order to create customer confidence and protect public health from unsafe products. Strong legal protection for intellectual property also provides a powerful incentive to innovate.

Evidence from a number of sources, however, suggests that many of these objectives are not being achieved in Canada. There are, it is suggested, two major problems: significant delays in the ‘ex ante’ assessment of new or improved products (most notably by the VDD), and the presence in Canada, unlike other OECD countries, of a major market for animal health products that have not been formally approved for use (the “unapproved market”). Canada and Canadians may therefore be accepting greater than anticipated levels of risk, whilst at the same time the scale of benefits may have been reduced.

In the light of these concerns, the Canadian Animal Health Institute (CAHI) and the International Federation for Animal Health (IFAH) commissioned Business Decisions Limited (BDL) to examine the impact of regulatory factors on the competitiveness of the Canadian animal health industry, and to compare the results primarily with those from similar studies carried out by BDL for the US and Australian animal health industries.

Our principal sources of evidence are five major quantitative surveys with companies, one carried out in Canada and the others in Australia, the EU, Japan, and the USA. The sample achieved in Canada represents around 90% of total sales in the industry¹. The sample achieved in the other four countries represents between 80% and 95% of local market sales. More than 120 in-depth interviews were also undertaken with companies of different sizes and types in Canada, Australia, the EU, Japan, and the USA.

THE INDUSTRY

Animal Health companies supply Canadian farmers and pet owners with a comprehensive range of pharmaceuticals, vaccines, and diagnostics developed and produced using complex chemical, pharmacological, and biological technologies. Animal health products improve the health, welfare, and productivity of animals, whilst at the same time ensuring food safety, protecting human health, supporting sustainable agriculture, and helping to preserve the environment.

¹ In all three countries, this measure is based on sales of products approved for use by national regulators. Canada, unlike the USA and Australia, also has a major animal health market based on sales of products that have not been approved for use by Canadian regulators – the “unapproved market”.

Moreover, Canada, one of the world's leading exporters of agricultural products, relies upon animal health products to ensure a globally competitive agricultural sector. These products are critical inputs for farmers, playing a major role in determining effectiveness, and efficiency, as well as the safety, and quality of food.

Continued delivery of this extensive range of benefits depends, however, on the competitiveness of the animal health industry in Canada.

Despite its importance for Canada and Canadians, the animal health sector is relatively small. But it creates substantial socio-economic benefits through exploiting investments in science, leading to important product-based innovations. Measured on the basis of expenditure on research and development (R&D), animal health is a high-tech industry.

THE FINDINGS

The Importance of Good Regulation

- Governments are heavily involved in shaping the business environment for animal health companies in Canada, as well as in other OECD countries. This occurs for two reasons. On the one hand, governments act to protect citizens from the potential hazards posed to human health (and the food supply) and animal welfare by the chemical and biological technologies used by animal health companies. On the other hand, governments also act to ensure that citizens gain from the benefits that the animal health industry's products can deliver.
- Taking these two factors into account, most governments establish a "risk-benefit" trade-off. There is a social acceptance of some risk, set against the potential delivery of major social benefits by the private sector.
- Companies accept the need for regulation and see it as a necessary pre-condition for competitiveness. They recognise that good public policy can deliver major benefits for animal health companies. Government action is capable of protecting intellectual property; creating intangible assets (through pre-market licensing); setting high quality thresholds for market participation; and strengthening consumer confidence.
- Our research, however, shows that relatively few companies based in Canada believe that the existing regulatory framework creates benefits for them. In contrast, companies in the USA and Australia are much more positive than companies in Canada about the benefits of the regulatory framework. This is an unusual finding. There appears to be a gap between a conceptual understanding of the benefits of public policy for animal health companies and the day-to-day experience of animal health companies in Canada. This is due, companies argue, to regulatory failings, most notably slow and unpredictable risk assessment processes and high levels of competition from products that are not approved for use in Canada but may, because of legislative loopholes, be sold there legally (the "unapproved market"). These weaknesses have created a lack of effective intellectual property protection, a lack of market confidence, and have the potential to contribute to poor public trust.

Competitiveness, Innovation, and Regulations

- The ability of companies to develop major new products to meet customer needs is the major driver of long-term competitive success in the Canadian, Australian, and US animal health industries.

- Within companies, innovation is a process. Success depends on being able to meet a series of critical success factors. Internal and external obstacles can impede the ability of companies to meet these requirements.
- Companies identify that the *external* business environment creates the most significant obstacles to innovation in the Canadian Animal Health Industry. Specifically, companies in the Canadian Animal Health Industry identify the following obstacles to innovation: the Canadian Regulatory Framework (94% of companies); the small size of market segments (82%); and lack of availability of financial resources (41%). Companies based in the USA hold similar views, whilst companies in Australia see market-based factors as being greater obstacles than regulatory ones.
- Our surveys show that large numbers of animal health companies in Canada have experienced problems in the innovation process because of regulation. Specifically, regulations have: increased development time (82% of companies); created significant uncertainty (82%); increased the costs of development (65%); diverted management time (65%); and re-directed resources into defensive R&D (53%).
- In the five year period between 2001 and 2006, companies in Canada believe that regulatory factors **increased the average length of time** needed to develop a major new product for food producing animals by nearly a year and by a similar amount for companion animal products and products for minor species.
- Evidence from our surveys shows that, in the opinion of companies in Canada, regulatory factors have caused the **average cost of developing a major new product** for the Livestock sector to increase by around 10% in real terms over the last five years. Companies also believe that regulatory factors have caused the average cost of developing a major new product for pets to increase by a similar amount in real terms over the last five years.
- Our survey shows that companies in the Canadian Animal Health Industry are currently spending around 20 per cent of their total R&D budgets on mandatory **‘Defensive’ R&D**. Moreover, nearly 50% of companies believe that the level of Defensive R&D has increased significantly in the last 5 years. Companies in the Australian Animal Health Industry are currently spending around 25-30 per cent of their total R&D budgets on mandatory ‘Defensive’ R&D. In contrast, companies in the USA currently spend around 15% on Defensive R&D.

Competitiveness, Existing Products and Regulation

- The exploitation of existing products is the most important driver of short-term competitiveness in the Animal Health Industry. This is because it enhances returns to investors, provides cash for re-investment in new products, and sustains the sales and marketing infrastructure needed for launching new products.
- Our survey of companies in Canada shows that exploiting existing products is strongly influenced by regulatory-based factors. In particular, companies identify the regulatory framework for maintaining/extending licences as the biggest single obstacle to exploiting products more profitably. Companies based in the USA share this view. However, in Australia, market-based factors are more important than regulatory obstacles.

- Our surveys show that, in the opinion of animal health companies in Canada, regulations create four major problems for the exploitation of existing products. Specifically they: create significant uncertainty (59% of companies); create disproportionate costs for maintaining/extending marketing authorisations (59%); divert financial resources away from the development of new, innovative products (53% of companies); restrict the extension of existing technologies to additional species/indications (53%); and, divert management time (53%).

Regulatory Decision-making and Competitiveness

- In Canada and most other OECD countries, primary risk management laws are implemented through technical regulatory decision-making processes. Evidence from depth interviews suggests that companies require regulatory decision-making processes to meet three criteria: timeliness, quality, and predictability.
- Evidence from expert analysis of archetype product development projects suggests that the expected time needed by regulators in Canada to make risk assessment and management decisions is significantly greater than that needed in Australia, Europe and Japan for the same group of products². There is no evidence that the additional time needed in Canada results in a higher standard of protection for human health, animal welfare, or the environment than that achieved by regulators elsewhere. Canada's failings are long-standing and result from poor regulatory quality and risk aversion within agencies. Indeed, an unintended consequence of delays at the VDD and VBS is to increase risk, because slow regulatory processes provide incentives for suppliers of unapproved products to enter the market.
- Canada's poor performance is brought into sharp relief when compared quantitatively to the time needed in Europe. Our analysis shows that on average, Europe's regulators and politicians are expected to take less than **2.0 years** to carry out risk assessment and risk management on a group of four archetype pharmaceutical products, whereas the average in Canada, for the same group of four products, is expected to be between **5.0 and 8.5 years** at the VDD.
- In contrast, the performance of the VBS, Canada's regulator for veterinary vaccines is more complex. Although, expert evidence suggests that risk assessment and management processes are expected to take significantly longer in Canada than in the European Union, the VBS continues to approve and accept advanced GM technologies, unlike regulators in Australia and Japan. Indeed, it is suggested that Canada has become a world leader in licensing innovative genetically modified vaccines for animals.
- Regulators can create significant regulatory unpredictability through failures of decision-making processes and of regulatory outcomes. Processes are unpredictable if guidelines are interpreted inconsistently or if the time needed for decision-making varies or if requirements change during product development cycles. Decision-makers create uncertain outcomes when non-scientific factors determine test requirements or the approval of new products or access to existing products.

² In order to produce accurate and fair comparisons of the expected time needed to assess in different countries the risks posed by similar products, we developed a series of six archetype new product development programmes. Based on programmes that are typical of the global animal health industry, experts estimates were developed of the expected time needed to carry out the complete product development cycle for each archetype in five countries – Australia, Canada, Europe, Japan, and the USA. Estimates were drawn up by local, national experts. Estimates for Canada assume that companies 'import' global technology. These are forward-looking estimates. They play a critical role in informing the decision-making of animal health companies, because of the use of discounted cash flow tools to measure the impact of delays on expected market values and investment costs.

- Companies believe that the regulatory processes used by the VDD are, in too many cases, highly unpredictable in terms of dossier requirements and time. There is also evidence that the outcome's of the VDD's regulatory processes are becoming more unpredictable, leading to restrictions on the use of certain products that are not adequately justified on the basis of science and risk.
- Unpredictability is increased by political involvement in regulatory decision-making. This makes it more difficult for companies to develop new products and to exploit existing ones. Politicisation of the overall Canadian regulatory decision-making process, as a result of administrative discretion, has contributed to increases in the time and risk of developing new products.
- Evidence from our surveys suggests that companies perceive that the performance of Canadian risk assessment agencies is mixed. International respect for the work of the VDD is judged to be poor, especially when compared to standards set by agencies in the USA and Australia. In contrast, companies in Canada have a more positive view of the work of the VBS and the respect that other regulators have for it.

Strategic Decisions and Regulations

- Major strategic decisions taken by animal health companies in Canada, Australia, and the USA are directly affected by regulations. This is because of the impact of regulatory factors on the short and long-run drivers of competitiveness.
- Our surveys show that regulations have influenced the number of breakthrough products launched by animal health companies over the last five years. Between 2001 and 2006, 60% of animal health companies in Canada **reduced the number of breakthrough products launched**. Regulations had an impact in all of these cases. This problem is not confined to Canada. In the USA, 64% of animal health companies reduced the number of breakthrough products launched, and regulations had an impact in all cases, whilst in Australia 60% of animal health companies reduced the number of breakthrough products launched. Regulations had an impact in 67% of cases.
- The majority of animal health companies in Canada have located production investment outside their home region and in many cases regulation had an impact on the decision. Some multi-national companies in Canada have also **shifted investment in R&D out of Canada**. Two-thirds of companies have switched some of their R&D budgets outside Canada and in most cases regulations had an impact. There are also indications that investment in production facilities and R&D are also switching away from the USA, and that regulations are an important factor in these decisions. In contrast, there has been little switching of R&D investment away from Australia, although there has been some switching of production investment.
- Many companies in Canada have **reduced their product range** in recent years. Over 85% of all companies have reduced their overall product range and three-quarters have cut back their coverage of species or indications over the last five years. Some (33%) have also reduced the geographic coverage of their product range. Regulations have had an impact on all of these decisions. In Australia and the USA a similar pattern emerges, although the reductions have not been as great as in Canada.
- Our survey shows that when companies make choices between different technologies, regulations have an impact. Over three-quarters of animal health companies (77%) in

Canada have made a strategic decision to **focus on older or existing technologies, rather than innovative technologies**. In the vast majority of cases (92%), regulations have played a part in this decision. Over a half of all companies are also avoiding certain product technologies (56%), and regulations played a role in all cases. A similar pattern emerges in both the USA and Australia.

THE CONCLUSIONS

As a small, high-tech industry, the animal health sector uses advanced technologies to deliver a wide range of socio-economic benefits to Canada and Canadians. But a high-level of competitiveness is essential if this process is to continue. Our surveys show that the Canadian Regulatory Framework has become the biggest single obstacle to improving the competitiveness of the animal health industry.

For new products, this occurs because of the impact of extended regulatory approval times and the high level of sales of unregulated products on the economics of importing intellectual property into Canada. Approval delays dilute intellectual property protection, erode the value of markets, increase the capitalised cost of innovation, and create opportunities for suppliers of unregulated products. Markets for unapproved products dilute returns, and reduce opportunities for responsible, regulated competitors.

Effective exploitation of existing products is also negatively affected by regulatory factors in Canada.

These problems have had an important impact on strategic decision-making by animal health companies operating in Canada. Regulatory factors have influenced decisions by companies to introduce fewer breakthrough products, to locate investment in production and R&D outside Canada, to focus on older technologies, and to reduce the number of products available to customers.

There are, companies believe, three underlying causes of these problems. First, “regulatory quality” is poor at both the VDD and the VBS. Second, risk acceptance has declined within the VDD leading, in some cases, to risk aversion. Moreover, this has occurred without open, political debate amongst elected representatives. Finally, there is a large market for unapproved pharmaceutical products.

Our surveys and in-depth interviews provide clear evidence of significant weaknesses in Canada’s regulatory framework for animal health products. They have created barriers to innovation, contributed to a reduction in the availability of existing products, and triggered a partial shift away from advanced technologies and towards older, well-established methods.

There is, moreover, evidence that regulatory failure may have occurred. Widespread availability of unregulated products, many of which are of unproven safety, quality, and efficacy, exposes users and animals to higher than anticipated levels of risk, whilst, at the same time, failing to deliver socio-economic benefits. Extensive delays in the approval of new or improved products reduces innovation and, over time, reduces the availability to users of modern, safe, and effective animal health products.

Action is needed to resolve the problems at the VDD and VBS, and to reduce the size of the market for unregulated products. At VBS, there are some grounds for optimism. Companies have, according to qualitative evidence, a broadly positive view about the agency, recognising its openness and collaborative approach. Its difficulties are, moreover, predominantly caused by gaps in resources and expertise. Resolving these problems should be relatively straightforward, so long as policy-makers are willing to make available appropriate resources.

The problems facing the VDD are more complex, and have been present for a considerable period of time. Action is clearly needed to establish modern process management tools (such as guidelines and binding time lines), to improve expertise, and to increase resources. Alongside this, steps may need to be taken to bring the failings at the VDD to the attention of appropriate oversight institutions within the Government of Canada. Such a step may provide an opportunity to ensure that risk acceptance decisions are made solely by elected representatives and to facilitate the full establishment within the VDD of the Government of Canada's regulatory policies and management tools.

Finally, Canada's market for unregulated products needs to be closed. This may require changes in primary law, but is essential if the competitiveness of the animal health industry is to be restored and citizens are to be protected fully against risks to human health, animal welfare and the environment.

In response to these concerns, regulators in Canada have begun to take action, and a series of reform initiatives have been announced.

At the VDD, a number of important changes have been made. Internal restructuring has taken place, facilitating important changes in human resources. New Drug Submission Guidelines are to be implemented during 2007. These should improve the clarification of technical requirements. And, an internal tracking system has been established. This monitors the progress of submissions and could help ensure that, over time, performance standards are met.

Further changes are also planned by the VDD. VICH guidelines are to be adopted in a timely manner, and the backlog of submissions is to be eliminated by 31 March 2009. Alongside these commitments, the VDD intends to implement a stream-lined review process for companion animal products, recognising the distinctive risks posed by such products. Other potential changes being considered include the development of a rationale to determine whether or not Canadian-specific studies are justified, and greater collaboration with regulatory agencies outside Canada.

Reform measures have been announced at the VBS as well. Regulators have made a commitment to remove the backlog of submissions by the end of 2007, and the overall review process is to be streamlined. VBS is, for example, considering the possibility of introducing phased submission, so that dossiers being assessed in the USA can, at the same time, be reviewed in Canada.

As well as reforms within regulatory agencies, VDD and Health Canada are considering legislative changes that, if implemented, could significantly reduce the scale of the market for unapproved products in Canada.

This programme of reform represents a significant step forward, but it remains embryonic and, in parts, incomplete. The entire programme of proposals needs to be implemented; all commitments made by regulators must be met; and ideas must be turned into action. At the same time, additional reforms may be necessary within the VDD to combat risk averse attitudes and to improve the quality of scientific assessments.