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8 October 2007

Chemicals and Plastics Regulation Study
Productivity Commission
LB2 Collins Street East
MELBOURNE VIC 8003

Email: chemicalsandplastics@pc.gov.au

Productivity Commission Study into Chemicals and Plastics Regulation

The Animal Health Alliance (Australia) Ltd [the Alliance] is the voice of the animal health industry in Australia. It represents registrants, manufacturers and formulators of animal health products. The association's member companies represent in excess of 85 per cent of all animal health product sales in Australia (ex factory gate). The Alliance manages both national and state issues with the objective of ensuring its members can operate within a viable regulatory environment. The Alliance also contributes to sustainable industry risk reduction practices that provide business opportunities to members and add value to the broader Australian community. A list of member companies and their addresses is given in **Attachment A**. The Alliance welcomes the opportunity to input to this Study into Chemicals and Plastics Regulation.

The content of this submission document is the same as that supplied by the Alliance to the Annual Review of Regulatory Burdens on Business: *Primary Sector*. In the Primary Sector Review Draft Research Report (August 2007) the issue of "delays, inconsistencies and complexity in agricultural and veterinary chemicals regulation" was identified (page XXX11) and the Draft Response 3.27 identified the recently commenced Commission Study into Chemicals and Plastics Regulation as the appropriate mechanism to deal with this issue. As such, the Alliance supplies this submission to the Commission to address the issues paper for its Study into Chemicals and Plastic Regulation.

Our member's products are a key production input and cost to Australian farmers in producing food, fibre and hides. These animal health products enable farmers to effectively produce cost competitive commodities that can compete on international markets.

Animal health products require approval from the Australian regulator – the Australian Pesticides and Veterinary Medicines Authority (APVMA) - before they can be supplied to Australian farmers. For biological type animal health products, such as veterinary vaccines that are imported into Australia, another regulator – the Australian Quarantine and Inspection Service (AQIS) - must also be satisfied on certain regulatory requirements in addition to those of APVMA.

The Alliance supports Australia having world class regulators that make science based decisions. We support both APVMA and AQIS aspiring to achieve and maintain this goal. Recently however, our industry has identified inefficiencies and inconsistencies with our key regulators in their dealings with our member's products (see **Attachment B** for details). In addition, the recent outcomes of the ANAO audit of APVMA (see **Attachment C**) have confirmed most of the shortfalls industry has identified. This has been further clarified by a recent industry (International Federation of Animal Health – IFAH) initiated international benchmarking survey where APVMA, and to a lesser extent AQIS, were compared for efficiency against like regulators in other OECD countries (see **Attachment D**). This IFAH benchmark survey has identified three

key areas of concern with the existing regulatory platform/process for animal health products in Australia. These are:

1. Regulatory framework increases time, cost & risk for bringing new products to market; prevents market access for advanced product technologies; increases scale of defensive R&D; erodes level of potential returns from existing products. This has occurred over the last 5-8 years.

2. Regulatory factors influenced decisions by companies to introduce fewer breakthrough products; to reduce product availability; to focus on older technologies; & to avoid certain product technologies.

3. Qualitative evidence from companies suggests 3 causes of deterioration in regulatory framework for animal health products: (1.) weakness in process used to manage trade risks; (2.) reduction in social acceptance of risks posed by animal health products leading to greater risk aversion & (3.) inadequacies of regulatory quality with APVMA and the network of risk assessors it manages.

The Alliance member companies aim to supply Australian farmers with the latest world class technology in relation to animal health products which are value for money and contribute to the international competitiveness of Australian primary production. Issues detailed in this submission, with respect to certain unnecessary regulatory burdens, have been identified as increasing the cost of animal health product supply and delaying their availability to farmers. Our industry is eager to see these identified impediments to regulatory efficiency analysed and rectified. The Alliance is committed to working with all relevant parties to achieve this outcome.

The Alliance is available to clarify any issues detailed in this submission.

Regards

Dr Peter Holdsworth
Chief Executive Officer
Animal Health Alliance (Australia) Ltd

ATTACHMENTS

ATTACHMENT A

ALLIANCE MEMBER COMPANIES

MEMBER	ADDRESS
Ancare Australia Pty Ltd	25/105A Vanessa Street KINGSGROVE NSW 2208
Bayer Australia	PO Box 903 PYMBLE NSW 2073
Boehringer Ingelheim Pty Ltd	PO Box 1969 Macquarie Centre NORTH RYDE NSW 2113
Elanco Animal Health	Level 5 Avaya House 123 Epping Road MACQUARIE PARK NSW 2113
Fort Dodge Australia Pty Ltd	PO Box 6024 BAULKHAM HILLS BC NSW 2153
Intervet Australia Pty Ltd	PO Box 2800 BENDIGO MC VIC 3554
Merial Australia Pty Ltd	Locked Bag 5023 PARRAMATTA NSW 2150
Novartis Animal Health Australasia Pty Ltd	PO Box 2003 NORTH RYDE NSW 1670
OzBioPharm	c/-24 Parkhurst Drive KNOXFIELD VIC 3180
Pfizer Animal Health	PO Box 57 WEST RYDE NSW 2114
Schering-Plough Animal Health	Locked Bag 2234 NORTH RYDE BC NSW 1670
Virbac (Australia) Pty Limited	Locked Bag 1000 PEAKHURST DC NSW 2210

ATTACHMENT B

INEFFICIENCIES AND INCONSISTENCIES WITH OUR KEY REGULATORS IN THEIR DEALINGS WITH OUR MEMBER'S PRODUCTS

DUPLICATE REGULATIONS

There is a duplication of requirements between APVMA and AQIS (AQIS assessing for endemic pathogens, APVMA basing decisions on the exotic status of disease).

APVMA - UNNECESSARILY BURDENSOME REQUIREMENTS

- APVMA's requirement for local efficacy studies for all products intended for use in food producing animals (even when the disease, the genetics of the animals and the environmental conditions have been shown to be no different to those overseas, APVMA will not accept efficacy data generated overseas). This regulatory position results in:

    1. increased registration costs
    2. increased timelines
    3. increased use of animals in studies resulting in unnecessary welfare issues
    4. increased burden on companies wishing to bring new products to the market
    5. issues with State ethics committees who do not always find studies to be necessary
    6. it becoming less attractive for companies to register new products in Australia

- APVMA's requirement that studies are conducted in several different States or locations, even if there is no scientific reason for this (e.g. for poultry housed in temperature and humidity controlled housing). APVMA are moving towards requesting studies in multiple States, with minimal scientific rational provided other than "environmental extremes". The impact of this regulatory position is the same as the 6 points listed above.

- APVMA's position that products designed to treat or prevent diseases which are exotic to Australia should not be registered. Often multinational companies produce multivalent vaccines. For example, four out of five of the antigens in a vaccine may be relevant to Australia, one of the five may not. Importation of the vaccine may be found by AQIS not to pose a threat to Australia (e.g. killed antigens). APVMA will not allow registration of the vaccine because of the exotic antigen - the company cannot justify producing a vaccine excluding the antigen just for the Australian market and so no product is registered or made available in Australia.

- APVMA's management of trade risk

    1. Since APVMA took over management of trade risk, requirements have increased dramatically. A straight forward scientific review is now undertaken in place of a more appropriate risk management strategy, which would ensure the protection of trade without placing unreasonable constraints upon applicants.

- APVMA's extended application forms and requirement to approve final printer proof labels has considerable increased the regulatory burden placed upon companies.

- Good Manufacturing Practice certification requirements: APVMA is increasingly prescriptive about the format certification should take, while not recognising that this aspect is virtually beyond the control of the manufacturer and applicant.

AQIS - HIGHLY PRESCRIPTIVE POLICIES WITH LOW EXPERTISE LEVEL IN THE BIOLOGICALS PROGRAM

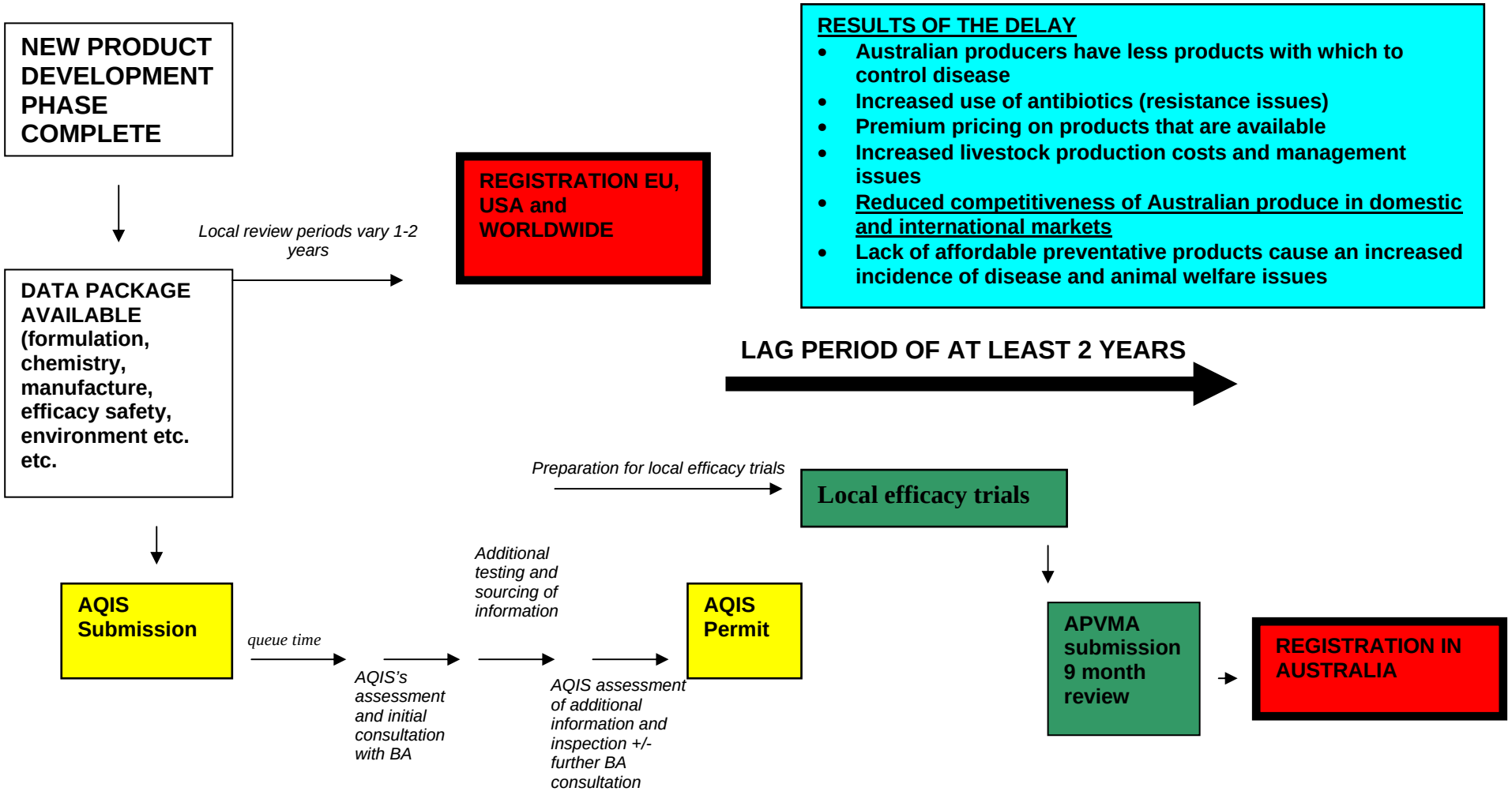
- AQIS has no staff with the appropriate post graduate expertise in microbiology or experience in vaccine manufacture to be able to make decisions when applications do not directly meet their policy documentation. AQIS routinely make requests to Biosecurity Australia (BA) for advice, due to lack of in-house expertise. BA is not appropriately staffed for such work, has no determined timelines and cannot cost-recover. The end result is very long timelines due to staff levels and hand over of evaluation between these two sections.

- The policies for importation of live and inactivated veterinary vaccines are highly prescriptive. Over 50% of the viruses and bacteria included in these policies for specific evaluation by AQIS as potential contaminants of vaccines are widely endemic in Australia, so are arguably not an AQIS concern. There is no scientific rational in the policies for their inclusion. Potentially, therefore, these policies create a non-technical barrier to trade and therefore contravene the Sanitary and Phytosanitary Agreement of the WTO, to which Australia is a signatory.

Attached (page 7) is a schematic that captures a timeline comparison of Australian regulators that deals with animal products compared to like OECD country regulators.

Australian Regulation Timelines compared Worldwide

Development Phase	Year 1	Year 2	Year 3	Year 4	Year 5



ATTACHMENT C

OUTCOMES OF THE ANAO AUDIT OF APVMA

KEY FINDINGS & RECOMMENDATIONS EXTRACTED FROM ANAO REPORT ON APVMA
Full report - http://www.anao.gov.au/uploads/documents/2006-07_Audit%20Report_14.pdf

Key findings

Governance arrangements (Chapter 2)

10. The APVMA has met legislative requirements for developing its Corporate and Operational Plans, and seeks input from stakeholders in developing these plans. Legislative requirements, corporate objectives and risk management strategies are aligned in the APVMA's current planning documents. The APVMA monitors its performance against the objectives set out in the Corporate and Operational Plans.

11. In 2003, the Department of Agriculture, Fisheries and Forestry (DAFF) and the Department of Health and Ageing (DoHA) developed an outsourcing framework for the APVMA. The framework was designed to address recommendations in the previous ANAO report and in a National Competition Policy Review to introduce more contestability into the provision of scientific advice to the APVMA. Under the governance arrangements for the National Registration Scheme, policy affecting the operations of the APVMA is set by either being formally approved by the Primary Industries Ministerial Council, or through a Ministerial direction. The framework was not established under these arrangements. Also, it was not apparent from the available documentation that the framework has been formally endorsed by the APVMA Board.

12. To underpin the integrity of its decision making processes, and to provide confidence to stakeholders, the APVMA needs to better manage the risk of actual or perceived conflict of interest. The APVMA's arrangements for managing potential conflict of interest for some external service providers have, until recently, been inadequate. Aspects of the current arrangements also require strengthening. This includes requesting conflict of interest declarations from providers before work commences, and developing appropriate procedures to cover members of consultative committees.

Timeliness of the registration process (Chapter 3)

13. In processing applications to register pesticides and veterinary medicines, the APVMA is required to meet statutory timeframes for conducting preliminary assessments and finalising formal evaluations. The ANAO found that the APVMA does not have adequate systems and processes to provide assurance that the time recorded to measure its performance is reliable, and reflects actual performance.

14. The APVMA did not meet its legislative obligation of finalising all applications within statutory timeframes in the period examined by the ANAO (2001–02 to 2005–06). The overall time taken by the APVMA to make registration decisions, which includes applicant time in addressing deficiencies with applications, has increased over this period. Schemes designed to reduce the level of regulatory intervention for lower risk products have not been effective. No products have yet been registered under these schemes.

15. Although the APVMA has put in place a range of measures to assist applicants in registering products, there is still a high number of deficiencies (errors or omissions) in applications. The APVMA does not have systematic processes for analysing the type and cause of these deficiencies.

Managing external scientific advice (Chapter 4)

16. The APVMA obtains expert advice to assist it in evaluating applications to register pesticides and veterinary medicines, and to support other regulatory functions. This advice is provided mainly by the Office of Chemical Safety (OCS), the Department of the Environment and Heritage (DEH), State government departments and private consultants.

17. The APVMA has established adequate formal arrangements with external service providers, with the exception of some State government departments.

18. OCS and the DEH have generally met the assessment timeframes set by the APVMA. However, almost half of all efficacy and safety assessments finalised in 2004–05 by State government departments or private consultants exceeded the timeframe specified by the APVMA. The ANAO considers the APVMA's arrangements for managing the timeliness of safety and efficacy assessments could be improved by systematically monitoring reviewer's performance, and analysing the causes of delays, to identify opportunities for improvement.

19. Since 2001–02, the APVMA has committed in its Service Level Agreements with OCS and DEH to paying a minimum of 80 per cent of the annual budget for estimated services agreed with each agency. This is regardless of whether services of an equivalent value are provided during the financial year. The current arrangement of providing guaranteed minimum funding to OCS and DEH for provision of scientific advice is different from the APVMA's arrangements for engaging other services providers, and stems from its reliance on these agencies for advice. In this context, the APVMA has recently sought to identify other sources of advice, but only for some of the services provided by OCS. No action has been taken to identify alternative providers for the advice currently provided by DEH. It would be timely for the APVMA to assess whether a more contestable approach to the provision of scientific advice would be beneficial and lead to greater efficiencies in the allocation of resources, and thus benefit fee and levy payers.

Monitoring product quality (Chapter 5)

20. All veterinary medicines must be manufactured to quality standards, and the APVMA has two schemes to confirm that manufacturers comply with these standards — the Manufacturers' Licensing Scheme, and the Overseas Good Manufacturing Practice Scheme.

Manufacturers' Licensing Scheme

21. A licence is issued to manufacturers by the APVMA under Part 8 of the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code). Under the current licence conditions, the APVMA has not established appropriate access arrangements for staff to undertake regulatory activities. In practice, the APVMA relies on the licence holder granting access when and if requested. The APVMA uses third party auditors to assess manufacturers' initial and ongoing compliance with quality standards. However, third party auditors have only been authorised to conduct audits prior to a licence being issued to a domestic manufacturer of veterinary medicines. In practice, third party auditors also undertake audits after the licence has been issued, and appropriate authorisations should be in place.

22. The APVMA relies on the results of the compliance audits to determine whether licenced manufacturers of veterinary medicines are meeting quality standards. The ANAO found that audits were regularly undertaken after the due date and key documents, such as the audit report, were either overdue or had not been provided to the APVMA. Without these reports, the APVMA has limited assurance that veterinary medicine manufacturers are complying with the Australian Code of Good Manufacturing Practice for Veterinary Chemical Products.

23. The APVMA was unable to provide documentation (including the audit report) for the audits undertaken by the Therapeutic Goods Administration (TGA) on its behalf. This is contrary to the arrangements in the Memorandum of Understanding between the APVMA and the TGA.

Overseas Good Manufacturing Practice Scheme

24. Prior to October 2005, the APVMA did not have systems to confirm that overseas manufacturers of veterinary medicines complied with manufacturing requirements following registration. Conditions of product registration are now in place that require the registrant to hold appropriate certifications of compliance for all relevant overseas based manufacturers. The APVMA undertook an initial assessment of evidence of overseas manufacturer compliance in October 2005, and found that its data set was incomplete because registrants did not identify all overseas manufacturers to be used when completing the product application; and/or had not advised the APVMA of changes to the manufacturers they use, after the product was registered.

Quality of pesticides

25. In September 2005, the APVMA established a program to assess the quality of active ingredients used in the manufacture of pesticides. Records must be held by registrants to prove the quality of the active ingredients used. In February 2006, the APVMA commenced checking these records. The checks found that more than 90 per cent of the records were missing, incomplete or contained errors. Without reliable records, the APVMA can not gain assurance on the quality of pesticides available for sale in Australia.

Reviewing registration decisions

26. Under the Agvet Code*5*, the APVMA determines whether chemicals approved or registered in previous years meet contemporary standards of safety and efficacy, and do not pose unacceptable risks to people, animals, crops, the environment or to trade. The APVMA established the Chemical Review Program (CR Program) in October 1994 to identify and review chemicals of concern. The APVMA has reasonable arrangements in place to identify chemicals that require review and to prioritise the reviews according to the risks they represent. However, the time taken to progress through the list of chemicals to be reviewed is slow despite efforts being made to improve the timeliness of reviews. Of particular concern is that the risks associated with chemicals remain. Up to date information on the review program has not been made available to the general public, including users of the affected products.

Cost recovery arrangements (Chapter 6)

27. The APVMA has taken practical measure to collect the required amount of levy and annual fee revenue. Although there is some misstatement by companies of sales on which the APVMA's levy payments are calculated, the amounts are relatively minor, and the APVMA has taken steps to address these.

28. The APVMA has established processes to identify the costs of its regulatory activities, to inform the setting of appropriate charges. The cost recovery model is due to be reviewed in 2007–08, as part of a broader review occurring within the Agriculture, Fisheries and Forestry portfolio. This review is timely given some major legislative and organisational changes to the APVMA since its current costing model was last revised in 2003.

29. The APVMA has generally taken appropriate measures to manage the under or over recovery of revenue. This includes proposing reductions to levy rates when excess revenue has accumulated, and setting funds aside (in a Risk Reserve) to offset an unexpected fall in revenue.

Overall audit conclusion

30. The APVMA plays a vital role in the regulation of pesticides and veterinary medicines. Since the ANAO's previous audit in 1997–98, and particularly in recent years, the APVMA has introduced various initiatives to improve the effectiveness of its operations. However, key programs to monitor the quality of pesticides and veterinary medicines, such as the Manufacturers' Licensing Scheme and the Chemical Review Program, could be better administered. Greater emphasis needs to be given to compliance programs and to completing chemical reviews in order for the APVMA to provide assurance that manufacturers of pesticides and veterinary medicines are meeting the required standards, and that products approved for sale in Australia are safe and effective. The APVMA is also not meeting its obligation to finalise all applications within statutory timeframes. This increases the cost of regulation, for both the APVMA and applicants, and impacts on users' access to pesticides and veterinary medicines.

31. The ANAO considers that, to deliver its regulatory functions more effectively, the APVMA needs to address some key issues relating to the broader management of the National Registration Scheme. These include reviewing the current arrangements for sourcing expert scientific advice to inform its registration decisions, and the role of State and Territory government agencies in conducting compliance monitoring activities on its behalf. In addition, the APVMA should examine options for establishing more effective arrangements for regulating pesticides and veterinary medicines deemed to be lower risk. Such arrangements should allow the APVMA to utilise its resources better, potentially resulting in improved timeframe performance for determining applications.

32. The ANAO has made six recommendations aimed at improving the APVMA's regulation of pesticides and veterinary medicines.

APVMA response

33. The APVMA welcomes the ANAO report and accepts the six recommendations of the report. The recommendations will assist our efforts to continue to strengthen performance as an efficient and effective regulator. Actions to implement the recommendations are underway.

34. With respect to Recommendation 1, the APVMA will strengthen existing arrangements for managing potential conflicts of interest in the identified areas. The APVMA will implement Recommendations 2 and 3 by building on current initiatives to manage and report on timeliness of processing registration applications and by more systematic analysis and communication to the chemical industry of types of deficiencies in their applications. Current arrangements for procuring external scientific advice will be reviewed to implement Recommendation 4. The operation of the APVMA's Manufacturers' Licensing

Scheme will be strengthened through implementation of Recommendation 5. With respect to Recommendation 6, the APVMA will assess current approaches to chemical review and disseminate more comprehensive information on reviews to stakeholders.

Recommendations

Recommendation No. 1 Para 2.26

The ANAO recommends that the APVMA strengthen arrangements for managing potential conflict of interest by:

a. requesting external service providers to provide positive assurance on the absence of a conflict of interest, prior to undertaking any work ;and
b. documenting appropriate procedures for members of consultative committees, consistent with legislative requirements.

APVMA response: *Agreed.*

Recommendation No. 2 Para 3.8

To improve arrangements for monitoring and reporting on statutory timeframes for processing applications to register pesticides and veterinary medicines, the ANAO recommends that the APVMA:

a. systematically monitor timeframes for conducting preliminary assessments;
b. report timeframe performance for applications that are refused or deemed to be withdrawn; and
c. establish processes to verify the accuracy of time entries.

APVMA response: *Agreed.*

Recommendation No. 3 Para 3.32

The ANAO recommends that the APVMA improve its registration processes by systematically analysing the type and cause of errors or omissions in applications, to better target its initiatives to improve the quality of applications.

APVMA response: *Agreed.*

Recommendation No. 4 Para 4.30

The ANAO recommends that the APVMA review its current arrangements for obtaining scientific advice from Australian government agencies to assess whether a more contestable approach would be beneficial and lead to greater efficiencies in the allocation of resources.

APVMA response: *Agreed.*

Recommendation No. 5 Para 5.19

To improve the Manufacturers' Licensing Scheme Compliance framework, the ANAO recommends that the APVMA:

a. include appropriate access provisions for relevant APVMA staff and third party auditors in licence conditions and Deeds of Authorisation; and
b. develop and implement processes for third party auditors to undertake audits by the required date and institute follow up mechanisms if the relevant audit report is not received within stated timeframes.

APVMA response: *Agreed.*

Recommendation No. 6 Para 5.43

To improve the effectiveness of the Chemical Review Program, the ANAO recommends that the APVMA:

a. assess whether the current approach and time taken to complete reviews adequately addresses the risks presented by the chemicals not yet under review; and
b. communicate the status of reviews currently underway, emerging issues and updates on planned activities.

APVMA response: *Agreed.*

ATTACHMENT D

IFAH INTERNATIONAL BENCHMARKING SURVEY RESULTS

BENCHMARKING THE COMPETITIVENESS OF THE AUSTRALIAN ANIMAL HEALTH INDUSTRY

A REPORT BY BUSINESS DECISIONS LIMITED
MARCH 2007

Full report - http://www.animalhealthalliance.org.au/default.asp?V_DOC_ID=1696

THE EXECUTIVE SUMMARY

THE STUDY

In Australia, the animal health industry is regulated primarily by the Federal government through the Australian Pesticides and Veterinary Medicines Agency (APVMA), an independent Australian Government statutory authority within the portfolio of the Australian Government Minister for Agriculture, Fisheries, and Forestry. It was established to implement the National Registration Scheme (NRS), a partnership between Australia and its states. This replaced earlier, state-level schemes for assessment and approval of animal health products. NRS created a single Australian market in animal health products. This, combined with the emphasis on rapid science-based risk assessment by APVMA, created substantial benefits for companies, making market access easier and speeding up innovation. Companies recognise the value of these reforms.

Following on from the major policy reforms of the 1990s, there have been further changes in the regulatory framework, its implementation, and its decision-making processes. It is feared that these may have created problems for competitiveness by placing restrictions on new technologies; increasing test requirements for new and existing products; and by creating unpredictability.

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

Our principal sources of evidence are two major quantitative surveys with companies, one carried out in Australia and the other in the USA. The sample achieved in Australia represents around 85% of total sales in the industry. The sample achieved in the USA represents around 80% of sales in the US market. More than 50 in-depth interviews were also undertaken with companies of different sizes and types in Australia and the USA.

THE INDUSTRY

Animal health companies supply Australian 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.

Moreover, Australia, one of the world's leading exporters of meat, livestock, and fibre, 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 efficiency, as well as the safety and quality of food.

Despite its importance for Australia and Australians, 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.

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

THE FINDINGS

The Importance of Good Regulation

- Because of the nature of the technologies used by the industry, its products and operations are regulated extensively. Companies accept the need for regulation and see it as a necessary pre-condition for competitiveness. Public policy delivers major benefits for animal health companies in Australia. Government action protects intellectual property; creates intangible assets (through pre-market licensing); sets high quality thresholds for market participation; and, strengthens consumer confidence.

- Companies recognise the particular strengths of the Australian approach to regulation. In contrast to earlier systems, it provides rapid, predictable access to the entire Australian market for products based on older, non-controversial technologies. Most companies believe it is predominantly based on high quality science, clearly defined processes, and well-established rules. It is, moreover, seen by companies to be generally open and accessible.

- A high quality, well-respected regulatory system, combined with a world class science base and attractive market conditions, has helped make Australia an attractive location for investment by multi-national animal health companies. For certain types of products, Australia is part of the global R&D network of multi-national companies and an attractive market in which to exploit global intellectual property.

Competitiveness, Innovation and Regulations

- Innovation continues to be the principal long-term driver of competitiveness of the Australian animal health industry, according to evidence from our surveys. And, animal health companies continue to bring important new products to the Australian market. In contrast, short-term competitiveness is driven by the need to exploit existing products fully.

- Within companies, innovation is a process. Success depends on being able to meet a series of critical success factors. In attempting to meet these requirements, companies may encounter two major groups of obstacles: internal obstacles within companies or obstacles in the external business environment.

- Companies identify that the external business environment creates the most significant obstacles to innovation in the Australian Animal Health Industry. Specifically, companies in the Australian Animal Health Industry identify the following obstacles to innovation: the small size of market segments (92%); and, the Australian Regulatory Framework (58% of companies). In contrast, the US regulatory framework is, in the opinion of companies based in the USA, the single biggest obstacle to innovation.

- This is an unusual finding from our research. In all other regions covered by the research programme[1], companies identified the local regulatory framework as the biggest obstacle to innovation. Australia does not follow this pattern. Qualitative evidence suggests that this reflects recognition of benefits created by regulatory reforms in the 1990s and the impact of the small size of the Australian market on the economics of new product development.

- Companies recognise, however, that the regulatory framework, although it forms part of the external business environment for individual companies, is a 'controllable' obstacle, In general, there is little that the Australian government can do to address the small size of market segments. In contrast, the regulatory framework, and its impact on companies, is the direct result of public policy decisions. Taking this into account, it is therefore a major obstacle to innovation.

- Companies believe that the Australian regulatory framework creates problems for them because it increases development time (75% of companies); increases the costs of development (67%); creates significant uncertainty (67%); and, re-directs resources into defensive R&D (58%). This is

[1] The overall benchmarking programme undertaken by Business Decisions Limited in 2006 covered Australia, Canada, Europe, Japan, and the USA.

important because all of these problems impact significantly upon factors that are critical to the success of the innovation process. Our surveys provide quantitative measures of these impacts.

- In the five year period between 2001 and 2006, companies in Australia believe that regulatory factors **increased the average length of time** needed to develop a major new product for food producing animals by over a year and by a similar amount for companion animal products. As a proportion of the total time needed to develop new products ("cycle time") this is a faster rate of growth than occurred in the USA in the same period for similar products.

- Moreover, regulatory factors have caused the **average cost** of developing a major new product for the Livestock sector to increase by around 35% 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 around 25% in real terms over the last five years. Costs grew by similar amounts in the USA.

- **Defensive R&D** absorbs at least 25-30% of total R&D budgets in Australia. This is mandatory expenditure needed to keep existing products on the market. It diverts scarce resources away from innovation and triggers reductions in the availability of products. Evidence from our surveys suggests that the level of Defensive R&D has risen significantly since 2001. By comparison, companies in the USA currently spend 15%, a slight decrease since 1996.

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 Australia shows that exploiting existing products is influenced by market-based factors and regulatory-based factors. Companies in the USA, in contrast, identify the regulatory framework for licence renewals as the biggest single obstacle to exploiting existing products more profitably.

- Our surveys show that regulations, the most important and 'controllable' obstacle facing companies, create four major problems for the exploitation of existing products. They divert financial resources away from the development of new, innovative products (50% of companies); create significant uncertainty (42%); increase the cost of production (42%); and create disproportionate costs for maintaining/extending marketing authorisations (42%).

Regulatory Decision-making and Competitiveness

- In Australia 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.

- 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.

- Companies have a high degree of confidence in the use of high quality science to assess new and existing products in Australia. They lack confidence, however, in the use of risk assessment and the consistent application of guidelines for new products. For existing products, companies believe that, in most cases, the overall processes for applying new tests and for reviewing the dossiers of existing products are unpredictable.

- Evidence from our surveys suggests that companies perceive that the overall quality of the scientific risk assessment processes in Australia are, in general, high and equal to the level of similar processes in the USA. An exception to this is the quality of scientific assessment of efficacy. This is poor, when compared to standards in the USA.

Strategic Decisions and Regulations

- Major strategic decisions taken by animal health companies in Australia and in 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 between 2001 and 2006. In the last five years, 60% of animal health companies in Australia **reduced the number of breakthrough products launched**. Regulations had an impact in more than two-thirds of cases.

- Our surveys show that companies have shifted some investment away from Australia in recent years. However, this has been confined predominantly to investment in production facilities. Regulations have played a role in only some of these decisions. In contrast, there has been **little switching of R&D investment away from Australia**.

- Many companies in Australia have **reduced their product range** in recent years. Nearly three quarters of all companies have reduced their overall product range and 55% have cut back their coverage of species or indications over the last five years. Some (30%) have also reduced the geographic coverage of their product range. Regulations have had an impact on the vast majority of these decisions.

- Our survey shows that when companies make choices between different technologies, regulations have an impact. Nearly two-thirds of animal health companies (60%) in Australia have made a **strategic decision to focus on older or existing technologies, rather than innovative technologies**. In the majority of cases (67%), regulations have played a part in this decision. Nearly three quarters of companies are also avoiding certain product technologies (70%), and regulations played a role in all cases.

THE CONCLUSIONS

The Australian Animal Health Industry is a relatively small high-tech sector, but it makes a disproportionately large socio-economic contribution to Australia and its citizens. However, the Animal Health Industry needs be competitive, if this process is to continue. Although regulatory reforms made more than ten years ago have made Australia an attractive location for investment by some multi-national animal health industries, our surveys show that the Australian Regulatory Framework is one of the most important obstacles to improving the competitiveness of the animal health industry.

Regulations create significant problems for competitiveness if they have a negative impact on the critical success factors that determine the ability of companies to innovate successfully and to exploit existing products fully. Evidence from our surveys shows how the Australian Regulatory Framework increases the time, cost, and risk of bringing new products into the Australian market; prevents market access for advanced product technologies; increases the scale of Defensive R&D; and erodes the level of potential returns from existing products.

These problems have occurred primarily over the last five to eight years and have had an important negative impact on strategic decision-making by animal health companies operating in Australia. Regulatory factors have influenced decisions by companies to introduce fewer breakthrough products, to reduce product availability, to focus on older technologies, and to avoid certain product technologies.

But Australia continues to be an attractive location for investment by multi-national animal health companies, in part because of its regulatory framework. This situation, however, reflects steady changes in investment decisions taken over the last ten to fifteen years and may not yet reflect fully the negative changes in the regulatory framework that have occurred since 2001. Moreover, the attractiveness of Australia to the global animal health industry may already be restricted to products based on older, less controversial technologies, because of regulatory factors.

Qualitative evidence from companies suggests that there are three causes of this deterioration in the Australian Regulatory Framework for animal health products: weaknesses in the processes used to manage trade risks; a reduction in the social acceptance of risks posed by animal health products, leading to greater

"risk aversion"; and "inadequacies of regulatory quality"[2] within APVMA (the Australian risk assessment and management agency for animal health products), and the network of risk assessors it manages.

Policy-makers in Australia now face a difficult choice. They are approaching a cross roads and must choose between allowing the more recent, negative trends in regulatory decision-making to continue unchecked or implementing a process of reform designed to reverse the recent deterioration.

Without change, there is a reasonable risk of a distortion of capital allocation decisions within an important industry, as a result of regulatory factors. This may, unless corrected, pose important threats to Australia and its citizens. Over time, the trend, identified in our studies, towards fewer products and a lower level of less technologically-advanced innovation may continue, posing challenges for agricultural competitiveness, animal welfare, food safety, and the effective protection of humans from animal diseases. At the same time, high value-added business investment may be switched away from Australia and towards more open, predictable and proportionate but equally high quality regulatory environments.

Action is needed to improve the way in which trade risk decisions are taken so as to make them more predictable, transparent, and consistent. Alongside these changes, policy-makers need to evaluate the costs and benefits of embedding risk aversion and social concerns into the regulatory decision-making processes for animal health products. Ideally, such issues should be dealt with through primary legislation, and subject to wide-ranging debate and full impact assessment, rather than by technical changes in implementation processes. Finally, problems of regulatory quality need to be resolved. This may necessitate finding additional resources for APVMA, establishing new management processes, and more effectively utilizing and managing the use of external experts.

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[2] A term used by the OECD, "regulatory quality" refers to the efficiency, predictability, proportionality, transparency, and accountability of processes used by governments (and their agencies) to implement primary legislation.

IFAH Benchmark survey summary

- Survey participants cover more than 85% of animal health products sales by $ value on market in Australia.
- Survey results compared Australian with US regulatory environment – closest to Australian in structure and process.
- APVMA overall seen as quality regulator – science based decision maker, world class, open, transparent.
- Innovation is the primary driver for new product development in Australia – long term focus of business
- External obstacles to innovation 1. market size (92% companies); 2. regulation (58%) (US 1. regulation)
- Regulatory system increase development time (75% companies); increase development costs (67%); redirect resources into defensive R&D (58%).
- For 2001-06, companies believe regulatory factors increased average time period to develop major new food producing animal products/ companion animal products by over 1 year (faster increase than in US)
- Average cost to develop major new livestock product increased 35% in real terms over last 5 years. Pet product increased approx' 25%. (Similar in US).
- Defensive R&D absorbs approx' 25-30% of R&D budgets. Significant increase since 2001. (US approx' 15% - slightly down since 1996).
- Exploiting existing products is most important driver of short-term competitiveness. This enhances returns to investors, provides cash for re-investment in new products & sustains sales & marketing infrastructure needed to launch new products.
- Market factors are primary influencers in exploiting new products – regulation is second. (US is regulation)
- 4 major problems created by regulation in exploiting existing products: 1. diverts financial resources away from developing new innovative products (50% companies); 2. creates uncertainty (42%); 3. increases cost of production (42%); 4. creates disproportionate costs for maintaining/extending market authorisation (42%).
- Australian companies lack confidence in risk assessment used by regulator and in consistent application of guidelines for new products. For existing products, application of new tests & for reviewing dossiers of existing products – existing processes unpredictable. For all processes, use of science is of high quality (equal to US) except for efficacy (poor compared to USA).
- 60% of companies in last 5 years reduced no' of breakthrough new products launched with regulation impacting on more than two thirds of these.
- Investment in production facilities has shifted away from Australia in recent years. Little switching of investment in R&D away from Australia.
- Approx' 75% companies reduced product range; 55% cut back on species claim/indications in last 5 years. 30% decreased geographic coverage. Regulation a major impact here.
- 60% companies made strategic decision to focus on older or existing technologies rather than innovative technologies. Regulation impacts 67% on this decision. 70% companies avoiding certain technologies and regulation a major factor here.
- Australia attractive for R&D investment on existing product technology – new product here first e.g. sheep & then use data package for overseas authorisation. Not new innovative products though.
- Regulatory framework increases time, cost & risk for bringing new products to market; prevents market access for advanced product technologies; increases scale of defensive R&D; erodes level of potential returns from existing products. This has occurred over the last 5-8 years.
- Regulatory factors influenced decisions by companies to introduce fewer breakthrough products; to reduce product availability; to focus on older technologies; & to avoid certain product technologies.
- Qualitative evidence from companies suggests three causes of deterioration in regulatory framework for animal health products:
    1. weakness in process used to manage trade risks;
    2. reduction in social acceptance of risks posed by animal health products leading to greater risk aversion &
    3. inadequacies of regulatory quality with APVMA and the network of risk assessors it manages.

ALLIANCE ANNOUNCEMENT OF IFAH BENCHMARKING SURVEY

26 April 2007

IFAH Benchmarking Survey

The Animal Health Alliance in conjunction with the International Federation of Animal Health commissioned Business Decision Ltd to survey and benchmark the regulatory environment facing the Australian animal health industry and to compare it with the regulatory environment facing animal health companies in USA. Similar benchmarking was conducted for the regulatory environments in the European Union, Japan and Canada.

The benchmarking is principally based on evidence obtained from two major quantitative surveys with companies, one in Australia and the other in USA. The survey sample achieved in Australia represents around 85% of total product sales in the industry. The sample achieved in the USA represents around 80% of product sales in the US market.

The Australian Pesticides and Veterinary Medicines Authority (APVMA) - the principal regulator of animal health products – was found overall to be a quality regulator making science based decisions to a world class standard in an open and transparent manner. Overall the APVMA was evaluated as marginally behind USA in the comparison, and well ahead of other OECD country regulators.

The survey also found that industry saw the regulatory framework in Australia as much less of an obstacle to innovation in the animal health industry than in other countries. However, three key areas were clearly identified where improvements in the Australian regulatory environment within which the APVMA operates need to be made to meet international benchmark standards. These were:

1. the regulatory processes to manage trade risks;
2. the negative social acceptance of risks posed by animal health products leading to greater risk aversion; and
3. aspects of the regulatory assessments involving APVMA and its network of risk assessors it manages.

The Animal Health Alliance is working with the APVMA to analyse the identified areas for improvement and develop processes to rectify these. A global animal health conference is scheduled for 15-16 November 2007 in London UK, to compare the benchmark results in the USA, Australia, the European Union, Japan, and Canada. The complete Australia/USA benchmark survey can be viewed at www.animalhealthalliance.org.au. Details of the global animal health conference are available on the same web site.