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Regulatory Burdens – Manufacturing and Distributive Trades
Productivity Commission
GPO Box 148
CANBERRA CITY ACT 2601

Dear Sir/Madam

Annual Review of Regulatory Burdens on Business – Manufacturing and Distributive Trades

The Animal Health Alliance (Australia) Ltd 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 Review of Regulatory Burdens on Manufacturing and Distributive Trades.

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.

In **Attachment B** we have detailed eight specific examples of existing regulatory practices that our industry views as either duplicative, excessive, overly costly or unclear in rationale for existence. These practices are negatively impacting on the manufacture and supply of Alliance member's products in Australia. For each example given we have collated our comments under four headings namely:

1. What is the issue?
2. Why it is an issue?
3. What is the cost to industry?
4. What is the proposed solution?

In these examples abbreviated **reference** is made to four regulators. These abbreviations and what they stand for are:

APVMA - Australian Pesticides and Veterinary Medicines Authority
TGA - Therapeutic Goods Administration
AQIS - Australian Quarantine and Inspection Service
OGTR – Office of Gene Technology Regulator

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

ATTACHMENT A

ALLIANCE MEMBER COMPANIES

MEMBER	ADDRESS
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 NSW 1670
Virbac (Australia) Pty Limited	Locked Bag 6000 MILPERRA DC NSW 2214

ATTACHMENT B

ISSUES IN RELATION TO REGULATORY BURDEN ON MANUFACTURING OF PRODUCTS RELEVENT TO THE ANIMAL HEALTH INDUSTRY

EXAMPLE 1

What is the issue?
The effectiveness and efficiency of AQIS as a regulator of Australian veterinary chemical products is questioned by industry.

Why it is an issue?
The veterinary chemical industry cannot obtain definitive time-frame commitments from AQIS to process permit applications and renewal applications, even though the regulator works on a "fee for service" basis. Industry confidence in AQIS complying with its own guidelines/standards when assessing industry product applications is lacking. Industry confidence that AQIS will even make a decision on any particular product application is lacking. Time-lines for assessment in excess of 3 years have been seen by industry. Uncertainty also exists in time-lines for renewal of existing applications.

What is the cost to industry?
Under the current system applicants have no idea of how long the assessment will take. This makes planning for the registration process very difficult. Costs are difficult to estimate as they include lost market share and delayed time to market, especially for seasonal products. In the case of a product with sales potential of $1 million per year, one years delay to market results in at least $1 million lost sales. Costs over the past 5 years to industry are estimated to be in the range of $20 - $50 million. In addition, there are industry increased resources needed to deal with the AQIS issues. Costs to the agricultural industry in not having vaccines available to treat various diseases are highly significant. There is also an animal welfare component – considerable suffering could be prevented by providing vaccines which prevent disease to Australian livestock within reasonable time-frames.

What is the proposed solution?
AQIS to implement similar time-frame commitments as the APVMA (statutory timelines). AQIS to agree a service charter with industry. The applicant can then have reasonable expectation of when the assessment will be complete and plan accordingly. In addition the sharing of information across the board between regulators should result in efficiency gains. Increased scientific resources in Biosecurity Australia (BA) and AQIS, focusing on risk management style reviews rather than what often appears to be a “nil risk” approach, would also instill more industry confidence. A more consultative process is required before policy changes are made that affect renewal applications where nothing has changed from previous approvals granted.

EXAMPLE 2

What is the issue?
Regulatory activities of three regulators (AQIS, TGA and APVMA) in relation to import permits being issued are not aligned where relevant, particularly for dealings with antimicrobial products. i.e.

1. APVMA – consents to import unregistered products/actives
2. AQIS – biological import permits
3. TGA – antibiotic products

Why it is an issue?
Duplication of effort on the part of regulatory personnel, particularly with AQIS and TGA. Doubling up on paperwork and files containing much of the same information etc. Duplication results in unnecessary use of resources. The process systems of each regulator do not appear to be aligned.

What is the cost to industry?
Direct company costs to industry include money, time and human resources in dealing with duplicate requests. Indirect company costs include the AQIS fees for processing permits. No fees are involved for TGA permits.

What is the proposed solution?
APVMA, AQIS and TGA liaise and streamline their processes so that:

1. they all accept data in the same format from industry
2. one set of data submitted can be accessed by all.

EXAMPLE 3

What is the issue?
APVMA does not recognize/accept overseas Good Manufacturing Practice (GMP) certificates issued by other recognized OECD country authorities as evidence to satisfy APVMA on the quality of product manufacture/release from overseas manufacturing facilities in relation to APVMA registered veterinary chemical products. All the relevant information APVMA requires is on the GMP certificate issued by other OECD counties but it is not in the specific EU-MRA (Mutual Recognition Agreement) format that APVMA will accept.

Also, it is necessary to maintain a document database of each issued EU-MRA formatted GMP certificate, as these are valid for 3 years only from the date of last inspection of the relevant facility. Renewal of these certificates must be followed up prior to expiry due to possible random issue of letters from APVMA requiring evidence of current GMP to be presented for registered products within 10 working days of the request.

Why is it an issue?
The cost and resources required to Australian veterinary chemical product registrants in negotiating with overseas subsidiaries and/or government agencies to convert an overseas issued GMP certificate to EU-MRA format acceptable to APVMA.

What is the cost to industry?
On average, a veterinary chemical product registrant needs to allocate 5 working days of a semi-skilled employee to deal with this issue each time it occurs. The employee cost is $100.00 per hour for 8 hours per day for 5 days which equates to $4,000 per event.

What is the proposed solution?
APVMA amend its processes/requirements so to accept as proof of GMP compliance the GMP certificates issued by recognized authorities in OECD countries in relation to manufacturing facilities of APVMA registered products.

EXAMPLE 4

What is the issue?
Two Australian regulators (APVMA and TGA) require information on the Australian importation and exportation of veterinary chemical active ingredients used in product production. APVMA requires the information for all veterinary chemical active ingredients while TGA only require it for antimicrobial actives/products. Both regulators require the information in different formats and require reporting at different times of the year.

Why it is an issue?
The cost to Australian veterinary chemical product registrants in generating the required data twice and in two different formats at two different times of the year.

What is the cost to industry?
On average, a veterinary chemical product registrant needs to allocate 5 working days of a semi-skilled employee to deal with this issue each time it occurs. The employee cost is $100.00 per hour for 8 hours per day for 5 days which equates to $4,000 per data generation activity.

What is the proposed solution?
APVMA and TGA liaise and streamline their processes so that:

1. they both request relevant data at the same date in any one year
2. they both accept data in the same format from industry
3. one set of data submitted to APVMA can be accessed by the TGA to source the antimicrobial data component.

EXAMPLE 5

What is the issue?
Similar auditing activities are undertaken by two Australian regulators (APVMA and AQIS) in relation to veterinary chemical product manufacturing facilities but there appears to be no attempt to harmonize these audit activities so to occur through one audit event.

Why it is an issue?
There is a duplication of certain auditing activities between the two regulators. In addition, the quality of the existing AQIS audits and the expertise of the AQIS auditors used is of concern to industry resulting in a lack of confidence in the process.

What is the cost to industry?
Veterinary chemical product registrants have to pay the cost of AQIS auditors to audit product manufacturing facilities that have already been audited by APVMA. For industry there is a cost involved in:

1. the APVMA's auditor's travel, living allowance and audit fee
2. the AQIS auditor's travel, living allowance and audit fee
3. organizing facilities for duplicate audits
4. audit administrative processes
5. downtime as a result of reduced manufacture activity during the audit.

AQIS – Cost varies between $4,000 to $10,000 depending on who does the audit; AQIS biologicals unit staff from Australia or Australian Government Veterinary Counsellor in the country of concern.

What is the proposed solution?
A study to identify overlap between the requirements between AQIS / APVMA /OGTR requirements, with the aim to propose ways in which systems can be streamlined and duplication of effort eliminated or significantly reduced. The exercise should involve not only GMP and other plant inspections but also documentation and other requirements that overlap between agencies.

APVMA is the most appropriate agency to be responsible for all certifications where activities are to be conducted in a GMP controlled environment. The three agencies should agree to accept information in the same format which could be captured in one core document – i.e. the APVMA Chemistry & Manufacture section.

Where overseas GMP certification is accepted by the APVMA this should also be accepted by AQIS.

EXAMPLE 6

What is the issue?
AQIS requires full import permits, including applications for renewal, every 2 years for importation of highly processed "products of fermentation" for use in veterinary chemical product manufacturing. These products e.g. ivermectin and the stearate chemicals are highly processed and pure and as such do not carry the risks associated with plant or animal materials. Multiple companies import these chemicals, usually from the same overseas manufacturing sources and a separate import permit application is required in every case. This has been a relatively recent imposition on industry and appears to have no scientific rationale.

Why it is an issue?
This relatively new regulatory imposition costs companies financial and human resources in generating the information to support the permit application, the costs for processing the permit application and lost time awaiting the permit being issued.

What is the cost to industry?
Direct costs to industry include money, time and human resources in dealing with a permit that was not required until recently. The approximate cost is 5 working days at $100 per hour, with a total equaling $4,000 per incident. In addition companies must pay AQIS fees for processing these permits.

What is the proposed solution?
Highly purified chemicals such as ivermectin should not require an import permit. Where there has been no change to the quarantine policy AQIS should justify any change to importation conditions or requirements.

Companies would be prepared to provide an annual declaration to AQIS for these products if necessary. Alternatively the process could revert to the previous system AQIS has in place and so abolish the permit unless the import material is coming from an unknown manufacturer or one with a suspicious history.

EXAMPLE 7

What is the issue?
AQIS requires holders of import permits to seek their review/renewal every 2 years. For veterinary vaccines, an updated full dossier is usually also required to support the application for renewal.

Why it is an issue?
The two yearly renewal process results in costs to industry with respect to requirements to provide updated vaccine dossiers, which requires liaison with overseas subsidiaries. Also, hold ups in entry of final products or production ingredients into Australia while the applications/dossiers for permits are being reviewed/renewed can occur. No new data is usually supplied by the permit holder in support of the two yearly review/renewal but the permit holder is required to await the permit being re-issued before they can legally continue importing the product/ingredient. As all applications are placed in a queue, there can be delays of some months before an application is evaluated. There appears to be no credible risk management processes used by AQIS in dealing with these permits being reissued.

What is the cost to industry?
The permit holder pays for:

1. preparation of the renewal application
2. AQIS to process permits being re-issued
3. holding product/ingredients on wharves while awaiting the relevant permit to be re-issued
4. hold ups in manufacturing with production inputs held up on wharves
5. the loss of product sales via this delay.

The total cost can amount to tens of thousands of dollars per company per year. There is also a significant cost to AQIS in resources.

What is the proposed solution?
Reassessment and renewal of permits should be required by AQIS when the level of risk of importing the material has changed. If there has been no change in the level of risk in importing the material, then a reassessment should not be necessary.

AQIS should put a system in place to identify when import permits should be reassessed based on the scientific need, rather than implementing an arbitrary 2 year renewal period.

Industry recognizes that it may take AQIS some time to put such a system in place. In the interim, we propose that AQIS extends the renewal period for vaccines to 5 years, except when there is scientific justification for the import permit to be reassessed within a shorter time period.

EXAMPLE 8

What is the issue?
The extended time-frames that APVMA use to process applications to over sticker approved product labels with amended product shelf life information is commercially unrealistic.

Why it is an issue?
It is an issue because the time-line to test retention product, obtain an extension of shelf life and over-sticker the product is not far off the 12 months shelf life extension that is approved. A company may as well do nothing and save their APVMA application fees, stability testing costs and write-off the product.

What is the cost to industry?
Stock valued at less than $50,000 would not be extended due to the regulatory difficulties. Across the industry millions of dollars would be lost in value of product lost sales and waste disposal cost of expired products.

What is the proposed solution?

The regulatory process should be reviewed with the aim to produce a quicker turn around (no more than one month) for minimal risk products. Expert scientific resources with industry experience are needed to assess such product applications.