By the time this newsletter has been received and some of you may after reading this article wonder aloud about the state of mind that penned it, we will only have about a week to go before the end of another year. What has happened amongst the AVI in 2010 since the Pan Pacific conference in Brisbane this year I hear you ask! Following on from the Turkish belly dancing exhibition from several committee members at the conference dinner a new committee was duly formed. Everyone on the committee has contributed very effectively this year and I thank everyone for their contributions during this year and as a result from my perspective 2010 has been another successful year for the AVI. During the year the committee has worked on a number of topics across a range of areas:

i) We have worked with the AVA on new budgeting processes designed to help facilitate a return to budget surplus for the AVA. As a consequence of the fees review, the SIG fees were raised from $45 to $55 for 2011.

ii) The AVI held a number of very successful social functions during the year (thanks to Kasia for her great choices of venues). We hope everyone has enjoyed the opportunities to catch up with colleagues and friends during 2010.

iii) Maureen has done an outstanding job on the conference organising committee again and the programme for 2011 conference in Adelaide should cover for all manner of tastes.

iv) AVI has maintained representation on the new APVMA industry group along with the AVA and Finola has taken on this role for the committee – thanks Finola for the energy you bring to the responses!

v) The committee has responded to a number of submissions to AVA policy changes and more recently to a submission relating to better regulation of chemicals.

While as President I find the politics within the AVI not as exciting as the NSW labour party, we have, despite the lack of intrigue, assembled a keen band of colleagues who have worked very well through the last part of 2010 on behalf of us all. I need to thank Neil and Sally for their continued contributions to the AVI, to Pete for stepping very effectively into the treasurer role that Keren had managed for quite some time and to Vanessa for her great secretarial work this year.

From my perspective 2010 has been another year where the rate of change amongst the workplace has increased yet again and with the industry changes that have occurred and will be occurring over the next few months I know some of you will be facing the coming festive season wondering just what will happen in 2011 to your current position. Whatever the outcome, I hope any change experienced as a consequence of industry mergers ends as positively as possible. I am certainly looking forward to a time to recharge this year and I trust everyone has an opportunity to enjoy this time of the year with friends and family. I wish everyone a very happy, safe and rewarding (on Xmas day – for me new socks?) festive season and look forward to working with everyone again in 2011.

Best wishes

El presidente
AVI Committee Members 2010-2011

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AVI Program at Adelaide AVA Conference 2011

The AVA Annual Conference will be at the Adelaide Convention Centre in 2011, from May 15th to 20th. The theme of the 2011 conference is evidence-based medicine, and this will be reflected in the content of the daily plenary sessions, as well as in the programs of each of the eight concurrent streams.

The Industry program begins on Monday afternoon with a shared session with Welfare on the roles of veterinarians on animal ethics committees, followed by an update on antimicrobial resistance in conjunction with Public Health.

Industry alone sessions from AVPMA speakers begin the day on Tuesday, before the focus moves to results of the MRSA survey conducted by Darren Trott, and sessions with the Equine stream on developments on the Hendra vaccine and stem cell research.

“Cutting Edge Pharmacology” lectures feature on Wednesday up until lunch. These were very successful at the Pan Pac Conference in 2010, and this year will be delivered in part by academics from the school of pharmacology at the University of Adelaide medical faculty. Sessions in the Sheep stream on internal parasite control and OJD vaccination round off this diverse and interesting industry program.

As usual, there will be an AVI dinner at the conference, and many opportunities for social interaction with all of your veterinary colleagues. For details, see the conference registration brochure, out soon.

Maureen Revington  Scientific Organising Committee  AVA Annual Conference

KEREN COX-WITTON RESIGNS FROM COMMITTEE

It was at our August committee meeting that Keren announced her resignation from the committee and Honorary Treasurer. It wasn't a surprise, as we knew she was contemplating a career change.

Keren was elected to the AVI Committee in 2005 and became Treasurer in 2006, and continued in this role until her resignation.

She was an active committee member, and an excellent treasurer, capably dealing with the frustrations of the AVA financial system.

Keren contributed in many other ways as well, and was the driving force behind the very successful AVI biostatistics course held in 2009.

With Keren's knowledge of the regulatory system, she also represented AVI on the APVMA industry liaison committee.

With the sale of Fort Dodge, Keren decided to leave "industry" and is now pursuing her passion for wildlife at Taronga Zoo.

Keren, many thanks for your contribution to AVI, and best wishes for the future!

Neil Cooper
<table>
<thead>
<tr>
<th>Time</th>
<th>MONDAY</th>
<th>TUESDAY</th>
<th>WEDNESDAY</th>
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<tbody>
<tr>
<td>8-8.50</td>
<td>Amendments to Ag and Vet Chemical code and new legislation (APVMA speaker)</td>
<td>Cutting edge pharmacology 1. Drug interactions and adverse reactions to herbal remedies used in veterinary practice (I Musgrave) 2. Potential novel treatments for atrial fibrillation (D Saint TBC)</td>
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<td>9-9.50</td>
<td>APVMA bioequivalence guidelines and what this means for study design (APVMA speaker)</td>
<td>Cutting edge pharmacology 1. Pharmacogenomics (A. Somogyi) 2. Nutrigenomics (K Hahn)</td>
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<td>10.30-11.20</td>
<td>Morning Tea</td>
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<td>11.30-12.20</td>
<td>Plenary</td>
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<td>12.30-1.30</td>
<td>Lunch</td>
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<td>1.30-2.20</td>
<td>Results of the MRSA survey (D Trott)</td>
<td>Update on AAWS (P Thornber)</td>
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<td>2.30-3.20</td>
<td>FeV and FIV update (P Irwin)</td>
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<td>3.30-4.00</td>
<td>Afternoon Tea</td>
<td>Afternoon Tea</td>
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<tr>
<td>4-4.50</td>
<td>1. Vets on animal ethics committees (J. Dandy) 2. Australian code of practice (M Bate)</td>
<td>Update on Hendra virus vaccine (D. Middleton)</td>
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<td>5-5.50</td>
<td>Antimicrobial resistance: current and needed surveillance and regulation in food and livestock (D. Jordan; D Trott)</td>
<td>Cutting edge pharmacology (equine twist). 1. The pharmacological modulation of stem cells (S. Bailey) 2. Update on equine performance enhancing drugs (W Vale TBC)</td>
<td>Peer-reviewed papers</td>
</tr>
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</table>

**AVI PROGRAMME FOR THE ADELAIDE CONFERENCE**

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AVI Christmas Dinner

The AVI Annual Christmas Dinner for 2010 was held on the 25th of November at Essen, a lively German restaurant in Ultimo, NSW. Over 30 AVI members attended the much anticipated evening.

Delicious wines and German beers were well accompanied by the traditional Bavarian fare, which included platters of German sausages, sauerkraut, bread dumplings, schnitzels and salmon fillets in puff pastry. The desserts also did not disappoint with crème brulée and Blackforest cake to end the feast. What better way to kick off the festive season!

The AVI social events offer a fun and relaxed atmosphere for our members to catch up with old friends and meet new ones in an informal setting. In our ever growing and ever changing industry, it is always a pleasure to meet like-minded vets working in diverse and interesting roles within the industry sector, including government, education, consulting, research and marketing.

Keep an eye out for upcoming AVI social function in 2011!

Kasia Hamilton
AVI Social Secretary
APVMA Reform - response to DAFF proposal.

Finola McConaghy has been working with Bruce Twentyman from AVA on a combined response to the recent proposal from the Minister for Agriculture, Fisheries and Forestry, Senator Joe Ludwig for reform of the regulation of ag-vet chemicals. This is an important document and the Minister has made a recent press release stating: The Minister Assisting on Deregulation, Senator Nick Sherry, said inefficiencies in the current regulatory system have led to a backlog in the chemical review program and may have discouraged companies from developing new and safer chemicals or bringing them to Australia. "This is the first step to delivering the Government’s election commitment to better protect human health and the environment through efficient regulation of agvet chemicals," Minister Sherry said. Funding for the reform proposals, totalling $8.75 million over four years, was announced in the Mid Year Economic and Fiscal Outlook statement. Stakeholders are being urged to have their say on the proposed reforms before 20 December 2010 but consultation will remain open until late January 2010 (sic). Presumably the Minister is listening to Industry concerns and attempting to improve the system There is potential for our voice to be heard so if you have not commented please check out our draft, which follows and send a comment to finola.mcconagy@naturevet.com.au

The Australian Veterinary Association
Industry Special Interest Group
Submission to the Better Regulation of Agricultural and Veterinary Chemicals
Policy Discussion Paper
December 2010

Address: Agvet Chemicals – Early Harvest and APVMA Reforms Team
Agricultural Productivity Division
Department of Agriculture, Fisheries and Forestry
Email: agvetreform@daff.gov.au
Dear Members of the Early Harvest and Reforms Team,

Introduction

The Australian Veterinary Association (AVA) is the national organisation representing veterinarians in Australia. Its 6300 members come from all fields within the veterinary profession. Clinical practitioners work with companion animals, horses, farm animals, including cattle and sheep, and wildlife. Government veterinarians work with our animal health, public health and quarantine systems while other members work in industry for pharmaceutical and other commercial enterprises. We have members who work in research and teaching in a range of scientific disciplines. Veterinary students are also members of the Association.

We commend the Minister for proposing to amend the current system to promote better regulation of Ag-Vet chemicals.

We are disappointed with the very short time frame for comment, as realistically many companies close down over Christmas and this is a very busy time of the year. As this consultation process is very important we request that in future you provide more time for consultation and preferably not over the Christmas holiday period.

Observations

We note that the aims of the reforms relate only to protection of humans and the environment, as this proposal covers veterinary chemicals we propose that the ‘promotion of positive animal health outcomes’ is added to the reform objectives.

1. Implementing complete risk frameworks for agvet chemicals assessment and review

The current process of collection of adverse experiences (AERPs) to agricultural and veterinary chemicals should be included in the risk framework for assessment and review. Veterinary chemicals which present a safety risk will result in an increased incidence of AERPs and evaluation of the AERPs collected will assist in assessing risk.

2. Improve the quality and efficiency of agvet chemical assessment and registration process

2.1. Lodging applications.

We support the possibility of pre-registration assistance to applicants, provided this was not compulsory. Could this assistance be provided as an add-on fee so that registrants who invest in staff training and present acceptable applications do not subsidise other applicants? Companies requiring assistance are likely to be small companies. Is there potential for funding from the Department of Small Business?

2.2. Assessing applications

The Policy refers to exclusion of efficacy and trade components for low risk products, this should be expanded to include a ‘low risk’ registration system where a series of chemicals are listed as safe and applications for registration for products which include only these chemicals, and make low level health claims only are simple and inexpensive to register. This system exists in the EU, the US and New Zealand where there are lists of low risk chemicals. Additionally the TGA has a system for ‘listed’ chemicals.

One member was concerned that reduced efficacy evaluation would result in the potential for product failure and the manufacturer could not be held responsible, which for products such as parasiticides would be unacceptable. Obviously any ‘low risk’ system is for ‘low level’ efficacy claims relating to maintenance of health.
2.3. Assessment timeframes

We support the proposal for reducing assessment timeframes and the option of an Accelerated Assessment Process. However this fee should be more reasonable such as double the fees, not five times the fees. Furthermore this should not disadvantage applications who cannot afford these fees as there is the potential that these applications could remain at the end of the queue while other applicants who pay more are advanced. This is not an equitable solution for a problem of under-resourcing and resultant delayed registration time frames.

3. Enhancing the agvet chemical review arrangements

Our industry has major concerns regarding the proposal for a new requirement for updating registrations to contemporary standards.

There are a very large number of veterinary chemicals which were registered under the state system, before the APVMA was established. The safe history of use of these veterinary chemicals, with low incidence of AERPs supports the safety of these chemicals. Both large and small pharmaceutical companies simply will not pay for new trials to support these registrations and there is significant potential for these chemicals to be deregistered. A key aspect of this reluctance from innovator companies will be the issue surrounding data protection of the data generated. If data generated becomes readily available to other companies this will reduce the likelihood even further of the data being generated. This will mean that neither veterinarians nor farmers will have access to these chemicals which are often reasonably priced, as they are relatively old chemicals. As this system is based on risk, an assessment of AERPs should be included in any proposed review. Possibly this review is aimed at Pesticides which have a much greater potential for risk to both humans and the environment than veterinary chemicals.

We urge the Minister to reconsider whether this is a requirement for veterinary chemicals. Were such a system to be implemented the ‘technical check’ proposed should focus on the registration details as well as the chemistry and manufacturing details to ensure there has been no ‘drift’ from the registration details on record at the APVMA. It is our understanding that the VMDA is proposing a Check list and we support this proposal.

It is worthy to note that in countries where a review and update policy of this type has been used, that is, Europe, there has been an overall loss of old but effective therapies, contributing to black-market trade in chemicals and a substantial increase in the cost of therapies as only the newest and best supported chemicals are left.

A further concern about this proposal is the perceived inability of the APVMA to manage the resource demands that the suggested approach will require. Currently the regulator does not have sufficient funds or staff to cope with the submissions already under review. Would the government provide additional resourcing into this area for this to be actioned without negatively impacting the timelines?

Or will these costs be passed through to industry and thence, end-users of the same chemicals which are put up for review. Industry would not oppose the review of chemicals deemed to be dangerous or an unreasonable risk to trade, but using Europe wholly as an example, many chemicals which ought have been deemed as safe, effective and low risk, have been eliminated from the market wholly because they came up for review and no-one was prepared to commit to the spend to defend them.

4. Using overseas assessments to their full extent

For many veterinary medicines designed to provide therapy for diseases that have a common pathogenesis between countries, it is appropriate to use overseas assessments, but for some classes of medication designed to treat certain diseases, including vaccines, overseas data is not always appropriate.
5. Establishing and independent science panel

Support in principle however should a science panel report on the APVMA’s progress with reducing the backlog? This is an administrative function. Would the panel also be assisting directly in reducing the backlog? It is mentioned that the science panel would replace the advisory board. The advisory board has a different mandate to a ‘science panel’.

6. Enhancing the provision of expert advice

Support in principle however, is this the same as the independent science panel? It is not clear from the document if there is a proposal for a science panel as well as an expert adviser panel?

7. Improving legal interaction with the APVMA

Support in principle a legal-friendly delegate, charged with finding solutions from the existing Act, would be a more useful change, rather than using the Act as an explanation for the inability of the APVMA to make sensible interpretations.

8. Improving the APVMA’s compliance enforcement activity
   Review of compliance

Although we support a more graduated compliance regime, the compliance process should be reviewed as there appears to be increased compliance activity relating to companies that manufacture registered products, compared with companies who promote and supply unregistered products. The manufacture and promotion of unregistered products is more likely to result in risks to people and the environment, so should be a major focus of the compliance group. Further, failure to prosecute these people provides a competitive advantage to them and supports the assumption that others can get away with the same thing, thus undermining respect for the legislation.

The recent Imtrade situation however demonstrated that the ability of the APVMA to manage serious non-compliant practices does not provide confidence in the current structures.

Summary

We welcome the Government’s continuing work to increase the efficiency and effectiveness of the Australian Pesticides and Veterinary Medicines Authority. Cutting red tape in the regulation of pesticides and veterinary medicines must remain a high priority as well as ensuring appropriate health and safety standards for people and the environment.

We are pleased to support the Government in its commitment to improving the system that regulates pesticides and veterinary medicines and offer the observations above to assist in that process.

Dr Finola McConaghy BVSc, DipVetClinStud, PhD
Australian Veterinarians in Industry Representative
APVMA Industry Liaison Committee 46th meeting – 4 November 2010
Report on relevant veterinary issues discussed

APVMA Operational Plan was provided to all

Industry Input to APVMA Operational Planning

Each group was asked to provide input regarding their thoughts on the APVMA Operational plan.

Main comments:

APVMA should focus on timely delivery of applications
Sticking to time-lines
AHA commented that Australia was a very small market globally and the significant delays in registration which have been occurring present a disincentive for multinationals. For example the CEO of the company with one of the new anthelmintics said they would not be presenting a similar registration to Australia in the future because the requirement for a dossier on trade issues, which is unique to Australia, caused significant expense and delays. This would have a major impact on the availability of new chemicals.
VMDA advised they were disappointed with the lack of response from the APVMA relating to compounding. Happy that a KPI structure was being put in place

Discussion of Key Performance Indicators for ILC

Discussion of APVMA compliance review and recommendations

Discussion of APVMA 2007 Restructure Review

Post-Meeting Technical Issues Meeting, small number remained for this

Working Group updates;

Labelling Code: in abeyance, to be reactivated to contribute to labelling standard

Reduced Chemistry requirements; no current resources

Compounding Pharmacies:
APVMA advised need to add: representative from Professional Compounding Chemists Association, Australia Pharmacy Board, Dept Health from various states as they control prescribing rights (single rep), DPI state representatives (single rep possibly Lee Cook), representative from BOVA (some discussion about this but had no reason to deny membership and if they are involved in setting up any guidelines they will need to follow them)
Chair to convene working group to develop ToRs and report back to ILC

Working group to investigate the need for changes (if any) to current exemption of veterinary medicines prepared by veterinary surgeons or pharmacists in accordance with instructions of a veterinary surgeon.

The draft terms of reference are:

- Review the practices of extemporaneous compounding of veterinary medicines in Australia including
  - The outcomes of the review by the National Coordinating Committee for Therapeutic Goods
• The role of extemporaneous compounding in providing veterinary medicines of public value
• Compare the present legislative and manufacturing arrangements to other countries
• Review the advertising of compounded veterinary medicines
• Consider the practice of preparing more doses than that required by a particular instruction and holding for this later supply
• Preparing a report on the findings of the review and make recommendations that will preserve the bona fide need for compounding, while ensuring the quality, safety and efficacy of those preparations.

Compliance Legislative Reform; Not to be an industry driven working group, will be driven by Neville Matthew

Veterinary Immunobiologicals: No current discussion

Dear Members

The festive season is upon us and CPD has slipped down the priority list (just temporarily!) behind Xmas dinners and New Year’s parties! However, there is a very interesting event planned for February next year which might be worth putting in your diaries – follow the link below to learn more!

**ASID-ASA Summit on Antimicrobial Resistance. University of Sydney Law School - 7 & 8 February 2011** Registration complimentary. Please register at [www.antimicrobialsummit.com.au](http://www.antimicrobialsummit.com.au). For further information and to make suggestions contact the Antimicrobial Resistance Summit Secretariat on 02 8204 0770 or at info@antimicrobialsummit.com.au

Be sure to let us know if you have any CPD courses you would like to notify our members of!

**Best wishes for Christmas and the New Year!**

*Sally Colgan*
CPD Coordinator AVI