Australian Government
Australian Pesticides and Veterinary Medicines Authority

June 2008

PROGRESS ON IMPLEMENTATION OF RECOMMENDATIONS AND ADDRESSING SUGGESTIONS of the ANAO PERFORMANCE AUDIT 2006

'Regulation of Pesticides and Veterinary Medicines'

RECOMMENDATION 1 – CONFLICTS OF INTEREST		

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;
(b) documenting appropriate procedures for members of consultative committees, consistent with legislative requirements.
	Implementation Actions:
	• Ensure efficacy Service Level Agreements (SLA's) (and reviewers manuals) contain conflict of interest (COI) provisions
	• Ensure all contracts and SLA's contain COI declaration requirements
	• Develop COI instructions for committee members
	  • Develop pro-forma
	  • Advise members and implement
	  • Included in Quality Management System
	  • Audit against requirements
		Progress:
		Efficacy SLA's and reviewers manuals contain COI provisions.
		
		Contracts and SLAs contain COI declaration requirements.
		
		COI implications introduced at RLC, ILC, ITC, MLS-ILC[1] and members advised.
		
		Draft pro-forma and guideline on compliance with COI requirements developed. Introduced/discussed at ITC 25 (June 08). Following revision will be introduced/implemented at committee meetings in 07/08 financial year.

[1] Registration Liaison Committee, Industry Liaison Committee, Industry Technical Committee, Manufacturers Licensing Scheme Industry Liaison Committee

➔ (suggestion) …the ANAO considers that the APVMA should assess whether there are alternative approaches to gaining assurance that its performance standards are met by those providers that have not signed formal agreements.	**Actions:** • Introduce formal 'quality' performance assessments for service providers • Progress SLAs with all States • Ensure all work either through SLA or contract	**Progress:** More detailed quality performance assessments has been incorporated into sign off on all work orders (efficacy, public health, environment) NSW SLA has been signed Tas SLA has been signed WA SLA has been signed Qld SLA has been signed SA SLA has been signed
➔ (suggestion) …the ANAO considers the APVMA's arrangements for managing the timeliness of safety and efficacy assessments could be improved by regularly monitoring reviewer's performance, and analysing the causes of delays, to identify improvement opportunities	**Actions:** • Start formally measuring efficacy performance and take appropriate action	**Progress:** Pilot audit of efficacy 'delays' conducted late 2006. Measures of efficacy performance in place Dec 2006. Quality performance assessments (see above) will assist in identifying gaps and delays. APVMA also currently exploring opportunities for certain application types to allow registrants to separately seek review of efficacy data by approved reviewers prior to making application to the APVMA. This has potential to translate to lower APVMA assessment timeframes and application fees. Consultation on an operational notice occurred in November 2007 – APVMA is considering comments and consulting with UK and NZ regulators that have similar systems in operation. *Also linked to Recommendation 3*

RECOMMENDATION 2 – REGISTRATION TIMEFRAMES		
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.**	**Implementation Actions:** • Introduce reporting of preliminary assessment (screening) timeframes • Include refused and withdrawn applications in timeframe statistics • Ensure routine audits are conducted to verify accuracy of time entries (clock movements)	**Progress:** Preliminary assessment timeframes are measured manually; Electronic means of capturing preliminary assessment in final stages of development – expected to be available for quarter 2 reporting (December 2008) published on the APVMA website. Refused and withdrawn applications now included in timeframe statistics. Pilot audit of Clock Manual conducted late 2006. Planned audits twice p.a.
➔ (suggestion) To provide more consistency and certainty in its application of legislative provisions, the APVMA should: • review the appropriateness of its policies and procedures for refusing or deeming applications to be withdrawn; • align operational practices with any changes to policies or procedures; and • formally communicate any changes to applicants, to manage expectations and facilitate compliance	**Actions:** • Finalise current review of appropriateness of refusing/withdrawing • Discuss with industry via liaison committees • Formally publish and communicate policies with applicants	**Progress:** Review finalised. Changes to key registration process (KP25) identified including better explanation of when to refuse or withdraw applications. Has been discussed with industry in general terms and key process changes presented to ILC in April 07. A revised operational policy has been prepared for inclusion in the next revision of the Manual of Requirements and Guidelines (MORAG). In addition the APVMA has created an instrument under the Agvet Codes to deal with additional information submitted by applicants voluntarily during the course of an application. The instrument provides additional time for the APVMA to consider the information.

RECOMMENDATION 3 – APPLICATION ANALYSIS		
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.	**Implementation Actions:** • Establish mechanisms for on-going monitoring of errors and omissions (deficiencies) • Identify groups of possible deficiencies for efficient recording (in progress) • Undertake recording / populate database • Conduct quarterly analysis and identify key problem areas • Based on results develop mechanisms/initiatives to address problem areas (better instruction, seminars, training etc)	**Progress:** Established mechanisms for the ongoing monitoring and recording of errors and data analysis. Recording pro-forma under development. Resources identified to offset workload impact of conducting recording.
RECOMMENDATION 4 – OBTAINING SCIENTIFIC ADVICE		
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.	**Implementation Actions:** • With the Office of Chemical Safety (OCS) and The Department of Environment, Water, Heritage and the Arts (DEWHA) identify areas of opportunity for greater flexibility in service provision. • Develop outsourcing frameworks for OCS and DEWHA • Review outsourcing frameworks in terms of efficiency of use of resources and report to the Primary Industries	**Progress**: Meetings held with OCS and DEWHA in 2007. Agreed plan for OCS – outsourcing framework agreed and outsourcing commenced in Feb 2008. Agreed plan for DEWHA – outsourcing framework under development.

	Ministerial Council (PIMC) • Consider proposing formal Ministerial Agreements regarding duties of Departments, for consideration by the Primary Industries Ministerial Council (PIMC) and Health and Environment Ministers	
➔ (suggestion) The ANAO considers that the APVMA should seek formal consideration of the (Health Assessment Services) Framework by the PIMC, including reviewing the nature of existing arrangements for obtaining external scientific advice.	**Actions:** • Paper to the Product Safety and Integrity Committee (PSIC) (to PIMC) re current framework and review of outsourcing framework (see above)	**Progress**: Agreed plan for OCS – outsourcing framework agreed and outsourcing commenced in Feb 2008 Agreed plan for DEWHA – outsourcing framework under development.
➔ (suggestion) …the ANAO considers improvements could be made by requiring agencies to meet specified timeframes in all cases where advice is provided. The APVMA could also request OCS and DEH to provide data on the actual time taken to complete assigned tasks… This would allow the APVMA to determine whether current timeframes are appropriate.	**Actions:** • Assess data on actual time taken • Strengthen requirements for agencies to meet timeframes	**Progress**: Note: Agencies do, in general, meet specific timeframes. Pilot project completed to measure actual times taken. Identified need to ensure process efficiency with OCS and DEWHA.

➔ (suggestion) The ANAO considers that in the short-term, the APVMA should review existing arrangements to improve agency timeframes. In the longer-term, further and more substantial reductions in timeframes……. may require the APVMA to identify and use additional providers.	**Actions:** • Document timeliness of agency processing of applications • Determine appropriate timeframes for pieces of work	**Progress**: Pilot project completed to measure actual times taken. Identified need to ensure process efficiency with OCS and DEWHA. Potential use of additional providers relates to use of outsourcing frameworks (see above) and the subsequent review of the frameworks in terms of efficiency of use of resources.
➔ (suggestion) Other measures the APVMA could take to improve its arrangements for assuring the quality of advice by external providers include: • maintaining a formal record of any issues identified through its quality checks of advice provided by OCS and DEH …	**Actions:** • Establish formal record of provider quality performance for assessments	**Progress**: Quality issues discussed with agencies at quarterly meetings. More detailed quality performance assessments incorporated into sign-off on all work orders and review of these will identify any systematic quality issues.
➔ (suggestion) The risks that arise under the current guaranteed funding arrangement would not arise under a more straightforward fee-for-service arrangement, where payments are made only where services are provided. Nevertheless it is appreciated that when negotiating a fee-for-service arrangement, consideration will have to be given, at least in the short-term, to the APVMA's ability to access alternative sources of scientific advice	**Actions:** • Pursue further reforms to fee for service arrangements in consultation with agencies	**Progress**: Meetings held with OCS and DEWHA in 2007. DEWHA SLA signed, with payment of 80% minimal annual budget removed, no annual budget agreed to, but understanding of 'predicted level of activity' for 07/08 financial year. OCS SLA signed, with payment of 80% minimal annual budget removed, no annual budget agreed to, but understanding of 'predicted level of activity' for 07/08 financial year. Rate of increase in fees payable (standard formula using CPI and WCI used in past) agreed to by DEWHA and OCS.

RECOMMENDATION 5 – GOOD MANUFACTURING PRACTICE		
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.**	**Implementation Actions:** • Seek legal advice regarding provisions for authorising persons to conduct audits • Investigate appointing GMP staff as APVMA authorised personnel • Revise all Deeds of Authorisation and Manufacturing licenses • Establish timeframe performance statistics for audits • Revise processes for engaging manufacturers about audits • Consider and implement improved follow-up mechanisms for audits	**Progress**: Legal advice received. Appointing GMP staff as authorised personnel can occur. The APVMA has appointed 4 staff as authorised persons. Deeds to be revised, no need to alter Manufacturing Licences. Timeframe performance statistics established. Efficiency improvements for the management of audits being considered; resources engaged and operational policies/procedures under development for improved audit follow-up.
➔ (suggestion) Practical options available to the APVMA to help identify overseas-based veterinary medicine manufacturers missing from the APVMA's data set include: • promulgating the APVMA'S position on the Overseas GMP Scheme and its requirements through an Operational Notice; and • advising its relevant Committees, particularly the MLS Industry Liaison Committee, of the risks associated with overseas products and encourage	**Actions:** • Promote overseas GMP compliance through APVMA newsletter • Promote need to advise of changes to manufacturers	**Progress**: Compliance being promoted by schedule of desk audits. Considering further promotion activities as appropriate.

reporting of information about undetected overseas manufacturers.		
RECOMMENDATION 6 – CHEMICAL REVIEW		
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.**	**Implementation Actions:** • Develop plan to assess current approaches • Assess current prioritisation mechanisms • Measure time taken to complete APVMA reviews • Identify and analyse reasons for delays in finishing reviews • Benchmark time taken to conduct reviews in Australia with overseas regulators • Produce issues paper and conduct consultation • Identify and develop strategies for improving timeliness • Develop communications tools to improve public exposure to reviews and their progress.	**Progress**: Plan to assess current approaches developed. Consultant engaged to conduct analysis of current approaches. Consultation expected to occur in second half of 2008. Introduction of new approach to communications being used for new reviews (eg. neomycin and carbendazim).

Other Suggestions:		
COMPLIANCE		
➔ (suggestion) …as the APVMA is not undertaking formal compliance planning as required by the 1995 Agreement, it should inform the Primary Industries Ministerial Council of its current compliance programs, including its ongoing interactions with the States and Northern Territory; and seek revision of the 1995 Agreement to recognise more recent developments.	**Actions:** • Paper to PSIC (to PIMC) regarding history of compliance agreements, current arrangements, plans to improve SLAs, concept of MOUs with States on operational matters	**Progress**: Raised need to revise compliance SLAs at RLC March 2007. Approval in principle given at RLC March 2007 to concept of MOU – draft MOU provided to State coordinators for comment. This approach has been supported by PSIC. Originally intended to propose MOU to PSIC in 07/08 financial year. PSIC also has expressed a desire to revisit the mutual National Registration Scheme Ministerial Agreement and further progression of the MOU is interrelated with those activities.
➔ (suggestion) *(Ag QA scheme)* The ANAO considers that it would be also be useful for the APVMA to: • communicate its findings to stakeholders; • develop strategies to raise awareness of the need to comply with registration conditions; and • develop and impose sanctions for (repeat) non-compliance	**Actions:** • Consider whether additional strategies are required to ensure awareness and compliance • Pursue reform of 'compliance toolkit'	**Progress**: Plan to scope a review of the Ag QA scheme in 07/08 financial year, with the review to occur in the following year. Considering avenues for sanctions for repeat non-compliance on case-by-case basis, using monitoring information from 06/07 financial year. Investigating strategies to optimise the use of current compliance tools with a view to targeting areas for reform.

COST-RECOVERY ARRANGEMENTS		
➔ (suggestion)…given that the levy is now applied to sales of all products (rather than only those with sales over $100 000) it may be timely for the APVMA to review its criteria for targeting registrants for audit, and to implement specific measures to raise awareness among registrants who have not previously been required to declare sales data	**Actions:** • Review criteria for targeting registrants • Raise awareness amongst registrants who have not been previously required to declare sales data	**Progress**: Criteria reviewed for 07/08 financial year. Proposed concept of small business guide for new registrants.
➔ (suggestion) ...the ANAO considers that the APVMA could improve the transparency of its cost recovery arrangements by more widely articulating its policy for the management of equity, including the amount, and components of, its Risk Reserve. This may include providing further, and more detailed, information on its website, or in its Annual Report.	**Actions:** • Provide more detailed information on management of equity on website and in Annual Report	**Progress**: Management of equity already reported in Annual Report Explained at ILC in April 07.