IMPLEMENTATION OF PRE-APPLICATION ASSISTANCE
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1 Purpose and Background

1.1 Purpose
ACIL Allen Consulting was engaged in October 2014 to review the Australian Pesticide and Veterinary Medicines Authority’s (APVMA’s) implementation of new Pre Application Assistance (PAA) arrangements introduced in July 2014.

The purpose of the review was to recommend improvements to help ensure that the arrangements met their original intention.

This document sets out a summary of the main findings and recommendations.

1.2 Background
Under new arrangements introduced on 1 July 2014, a potential applicant may apply to the APVMA for regulatory advice prior to the submission of an application to register or amend a pesticide or veterinary medicine product.

Charges are applied for this service at rates as set out in the Agricultural and Veterinary Chemicals Code (AgVet Code) and related Instruments.

The new PAA scheme replaced relatively informal arrangements that had operated prior to July 2014 for which there were no direct charges and operates alongside other advice and guidance that the APVMA provides through its web-site, explanatory material and the general enquiries line.

At the same time, the APVMA has retained a free of charge enquiries line and a formal process for providing technical assessments to assist applicants in making later applications for registration, licences or permits.
2 Performance and stakeholder experience

2.1 Performance
The APVMA has processed around 90 applications for PAAs since 1 July.

Of the PAA applications processed by the APVMA up to the end of December 2014, 46 applications have been completed and 23 were still in progress. Of the completed applications, almost 60 per cent were outside the timeframe set by the APVMA.

Thirty two of the applications were cancelled, 25 of them within the APVMA’s timeframe target.

About a quarter of the applications initially processed as PAA have been reclassified as enquiries, with monies refunded to the applicant.

A number of applications for PAA have been referred to technical assessment under Item 25 of the AgVet Code as the APVMA considered that the technical issues were beyond the scope of the PAA scheme.

To date, the APVMA has collected initial fees of $32,200 and follow-up fees of $3214. Refunds for cancelled applications total $8750.

2.2 Stakeholder experience
Stakeholder views on the implementation of the PAA arrangements were sought through a review of feedback provided to the APVMA, interviews with peak bodies and an on-line survey made available to all interested parties on the APVMA website. By mid-October 2014, 21 survey responses had been provided to the survey, though not at all respondents had actually submitted an application for PAA.

Of the 18 respondents to the survey who had made an application for PAA, none indicated that they were satisfied with the administrative requirements, timeliness, cost, and quality of the response. Four of the 18 indicated that the timeliness of responses was just OK or better while 14 were dissatisfied or extremely dissatisfied. Half the respondents were dissatisfied or extremely dissatisfied by the administrative requirements.

Two of the 18 respondents who had used the service indicated that they were satisfied or extremely satisfied with the clarity, certainty and confidence obtained through the process. Twelve of the respondents indicated that they were dissatisfied or extremely dissatisfied.

Concerns of those who have used the service relate to

- uncertainty about the role, scope and purpose of the PAA arrangements;
- difficulties in obtaining access to the APVMA decision-makers in order to clarify regulatory pathways for new or unusual products;
- complexity of the administrative processes involved in submitting an application for PAA, including the charging regime;
- the APVMA’s performance against its timeframe targets and the length of time taken to provide advice; and
- the quality of advice, in terms of the clarity, consistency and relevance of responses.

Stakeholders understand the need to formalise the arrangements that existed prior to 1 July 2014, and in particular to provide more transparency, consistency and predictability in how the APVMA provides pre application advice and assistance.

However, there is a view amongst stakeholders that the new arrangements provide a lower level of service than was available before 1 July 2014, particularly in relation to the opportunity to engage on technical matters and more complex issues not specifically addressed in existing guidelines.

Stakeholders believe that the way in which the APVMA has implemented PAA has reduced the quality of interaction with the APVMA at the pre application stage.
3 Scope and purpose

3.1 The scope of PAA

External stakeholders have suggested that the APVMA has defined the scope of PAA too narrowly, with the result that PAA only meets some of the pre-application information needs of applicants.

The APVMA website indicates that PAA is intended to provide information for applicants on how they might meet the application requirements or address the statutory criteria for subsequent applications for registration, licences or permits.

However, applicants have indicated that in practice the APVMA is treating PAA as a source of information on administrative requirements and the location of existing guideline or other reference material. They have cited examples of PAA applications being rejected and monies refunded when the application has sought specific technical advice or has raised issues that require interpretation or judgement of guidelines.

This may be of assistance to first-time applicants, but it does little to assist applicants seeking advice on APVMA’s interpretation of guidelines or those seeking to develop regulatory plans for new or more complex products.

Potential applicants have a range of pre application requirements. These include:

- General enquiries
- Interpretation of guidelines
- Advice on matters not covered by existing guidelines
- Technical advice and guidance on trial protocols and other matters likely to be required in a full assessment
- Technical assessments.

The APVMA provides pre-application advice on all of these issues, through a range of different products and services, including PAA. However, the APVMA could provide clearer advice for industry on how best to seek different forms of advice and assistance. The website lacks detail on the scope and purpose of PAA and there are no worked examples to illustrate the kinds of issues on which PAA might prove useful or how industry might best engage with the APVMA through the pre-application process.

This may reflect some uncertainty within the APVMA itself about the role and scope of PAA and how it fits within the suite of other forms of pre-application advice and assistance that it offers. Some staff consider that advice on technical matters such as data requirements is outside scope and routinely reject applications for PAA that raise data issues. Others consider that technical advice is within scope and have sought to engage with industry on these matters.

The general lack of clarity in the purpose and scope of the PAA scheme has led to some confusion for applicants, unnecessary costs and delays in the processing of PAA applications and inconsistent handling of similar applications by different areas of the APVMA.
4 Handling of PAA applications

4.1 Internal management of PAAs

The APVMA’s internal arrangements for handling PAAs are not well coordinated and there is no clear business owner.

PAAs have been handled primarily from within the APVMA’s Case Management and Administration Unit (CMAU) and evaluation areas, with input from Legal and Compliance, internal assessment areas and external agencies as required.

This could operate efficiently if there were a clear and common understanding of roles and responsibilities, and there is no documenting of the roles and responsibilities of the various work areas involved in the processing of PAA applications, or their obligations to one another.

Initial processing and interpretation of PAA applications is undertaken in CMAU and the application referred to a relevant officer for advice on the approach to the request, handling strategy and initial estimate of cost and returned to CMAU for advice to the client.

If the quotation is not accepted within the five days, the application is cancelled. If accepted within five days by the applicant, confirmation of charges is sought from the relevant action area, an invoice is despatched to the applicant and the application returned to the relevant officer for action.

Advice is then prepared and provided to CMAU for compilation and dispatch to the applicant.

Until recently, it has been difficult to locate clear authority or ownership for PAA as a service or for the case management of individual applications across organisational boundaries. New organisational structures implemented on 1 October 2014 may provide more clarity in this respect. However, they do not locate a responsibility for PAA below the Executive Director (ED) level.

4.2 Engagement with applicants

Stakeholders have reported that the PAA process has placed a barrier between applicants and the APVMA.

Pre-implementation training for industry on the new PAA arrangements was limited to several information sessions and there was little involvement of industry in the design of the new arrangements. Website information is of a general nature and lacks examples of cases where pre-application assistance should prove useful or advice on how to engage most effectively with the APVMA at the pre applications stage.

At present almost all contact with PAA applicants is through electronic applications and email responses. In some cases the APVMA has insisted on email contact even where the applicant has specifically asked for a (cost recovered) face to face meeting.
While email provides a clear record trail, and allows the APVMA to manage process flows, it does not provide the best means to explore uncertainties or to communicate on complex issues about the best regulatory pathway for a new product.

The website indicates that the APVMA may provide PAA through a written response, a face to face meeting or a teleconference, and the costing guidelines clearly envisage the need for meetings at the pre application stage. However, in some instances there has been reluctance by the APVMA to engage with applicants or to try to understand what they are seeking from the PAA process.

On some occasions, senior the APVMA managers have responded to dissatisfaction from PAA applicants by offering informal meetings outside the PAA process. This reflects a genuine desire to respond to applicants, but undermines the PAA process and increases the risk of inconsistent treatment and advice to different applicants in similar circumstances.

There is no regular process for following up on the responses provided to applicants for PAA.

### 4.3 Management controls

The APVMA’s management controls for the operation of PAA need to be strengthened.

While there is some management oversight of individual PAAs, there is no overall coordination or management of PAA applications across the APVMA as a whole. Responsibility for the quality of PAA responses has been diffused across a number of staff at various levels in different sections.

Clearance and sign-off arrangements for PAAs have not been clearly set out and in practice have been weak or non-existent. Many responses to applicants have been provided to applicants without executive clearance.

While the separate areas involved in handling PAAs have developed tracking systems for the PAAs under their control, there is no overall process for reporting and monitoring on the progress of PAAs against timeframe or other targets.

There have been no arrangements in place for regular, consolidated reports on timeframes or performance.

### 4.4 Processes and workflows

The work flows intended to support the handling of applications for PAAs are inefficient, overly complex and unnecessarily time consuming.

CMAU developed a formal Work Instruction setting out the steps involved in processing applications for PAA within that unit. However, there was no authoritative description of the overall business process for handling PAA applications or a complete set of documents for the end to end process as a whole or internal timeframes that must be met.

The current process involves multiple handling of content between the case manager and relevant officers in technical areas with little or no supervision of the quality of the response by Section Heads (senior managers).

The APVMA has undertaken to acknowledge receipt of PAAs within 10 days and provide a written response or organise a meeting within 28 days. However, apart from requests that relevant areas
provide initial case plans and quotes within eight days of receipt and respond to the acceptance of quotes within three days, the APVMA has not established internal quality targets or timeframe KPIs that would ensure delivery of responses within these targets.

As PAAs are processed outside the APVMA portal, applicants are not able to monitor progress of their applications.

4.5 Consistency and quality of advice

The APVMA could do more to ensure a higher quality of advice on PAA applications.

At present, there is no systematic process for reviewing the accuracy, consistency or relevance of responses to PAA applications.

As already noted, there is no consolidated Work Instruction for the handling of applications for PAA.

Until recently, there was no requirement to obtain executive clearance of the handling strategy for PAAs or sign off for the content of the response.

There is no consolidated set of responses to PAAs and, as the handling of PAA applications is decentralised and managed through a number of separate systems, there is only a limited capacity to organise responses according to categories such as applicant, subject matter, or response.

As a result of these gaps in the support for PAA, clear variations in practice have emerged between different processing teams.

There are currently no quality standards and no agreed, transparent basis for determining the quality of responses.

Applicant feedback could be used as one measure of quality but to date this review represents the only effort to obtain feedback from applicants on their level of satisfaction with the APVMA’s handling of their applications.

The APVMA has not provided a review mechanism for applicants not satisfied with its responses, leaving applicants at the end of the process with nowhere to go if they do not feel that their questions have been appropriately answered.
5 Charging arrangements

5.1 Charging arrangements

The charging regime for PAAs is not fit for purpose for industry or the regulator.

It imposes unnecessary costs on applicants and the APVMA, slows the processing of applications and discourages the early exchange of information that would otherwise assist in improving the quality of applications for registration, licences and permits.

While the principle of charging for PAA and the level of the fees to be applied is set out in the AgVet Code, and therefore beyond the direct control of the APVMA, the APVMA’s implementation of the charging arrangements contributed to the cost and complexity of managing PAA.

The process and methodology for calculating charges is complex and involves multiple transactions between different parts of the APVMA and the applicant for relatively small sums of money. The practice of offering up-front quotes for PAAs that require more than two hours work (beyond $350) adds to the complexity and delays responses. Given the very small sums of money collected, it would be more efficient to offer flat fees or a tiered level of charges for different kinds of application. The charging system could follow similar principles to the modular arrangements for other applications.

The APVMA should seek to have the current charging arrangements revised and in the meantime work to streamline and simplify its administration of the charges for PAA applications.
6 A way forward

PAA applications represent a relatively small proportion of the APVMA’s overall resource effort, but they provide a highly visible point of engagement with industry and are a critical part of the reforms of pesticide and chemical regulation introduced on 1 July 2014 to improve the quality of applications and provide industry with greater predictability.

A better system for providing PAA can and should be developed.

Some of the problems that have arisen are not entirely within the control of the APVMA and will take some time to put right. The charging regime for example is set out in the AgVet Code and related Instruments. Development of a common understanding of the purpose and scope of the arrangements - and how best to make an application for PAA - will require efforts by industry as well as by the APVMA. The APVMA should however commence a process with government and industry stakeholders for addressing these problems as soon as possible.

Other problems with PAA are within the control of the APVMA and should be urgently addressed.

These include issues with the way in which the APVMA has engaged with industry on the operational design of the new arrangements, the internal controls and management of the processes and the APVMA’s communication with applicants.

This will however require further attention from the APVMA leadership team and an assessment of whether additional resources are required together with improved systems and training available for staff involved in the delivery of this service.
Appendix A  Findings

Overview

- PAA was an important component of the recent package of reforms to the regulation of pesticides and veterinary medicines and is one of the services expected of a world class regulator.

- The APVMA and industry can both benefit from an effective process for providing pre-application assistance that provides greater certainty for applicants and improves the quality of applications.

- However, the APVMA’s implementation of PAA arrangements has not delivered the service and benefits as intended by the reforms to the AgVet Code.

- The APVMA has failed to meet the reasonable expectations of industry in terms of the coverage and content of responses, timeliness and consistency and relevance of advice.

Design and conception

- The purpose of the new arrangements was not as clear as it could have been.

- The APVMA has defined PAA too narrowly, with the result that PAA only meets some of the pre-application information needs of applicants.

- There has been no definitive statement by the APVMA of what the new PAA arrangements were intended to achieve, or the kinds of queries that PAA was intended to cover.

- There is a lack of clarity about how PAA fits in the spectrum of pre-application enquiries.

Internal handling of PAAs

- The APVMA’s internal handling of applications has not delivered timely, consistent or efficient outcomes.

- The handling of PAA applications has been fragmented and decentralised.

- Until recently, it has been difficult to locate clear authority or ownership for PAA as a service or for the case management of individual applications across organisational boundaries.

- There is no consolidated statement of the roles and responsibilities of the various work areas involved in the processing of PAA applications.

- Case management has been reasonably effective within individual work areas but has not been effective when applications have passed across organisational boundaries.

Engagement with applicants

- Engagement with stakeholders on the operational design of the PAA and training on how the new arrangements would operate was limited.
At present almost all contact with PAA applicants is through electronic applications and email responses. In some cases the APVMA has insisted on email contact even where the applicant has specifically asked for a (cost recovered) face to face.

There has been little attempt by the APVMA to engage with stakeholders to try to understand their underlying uncertainties or what they are seeking from the PAA process.

There is no regular process for following up on the responses provided to applicants for PAA.

Management controls

While there is some management oversight of individual PAAs, there is no overall coordination or management of PAA applications across the APVMA as a whole.

Clearance and sign-off arrangements for PAAs have not been clearly set out.

Responses to PAA applications were prepared and provided to applicants without an executive clearance process in place.

While the separate areas involved in handling PAAs have developed tracking systems for the PAAs under their control, there is no overall process for reporting and monitoring on the progress of PAAs against timeframe or other targets.

There has been no arrangement for regular, consolidated reports on timeframe or other performance information.

Processes and workflows

There is no authoritative description of the overall business process or complete set of end to end process documents for the process as a whole.

The workflows intended to support the handling of applications for PAAs are inefficient, overly complex and unnecessarily time consuming.

The current process involves multiple handling of content between the case manager and relevant officers in technical areas with little or no added value.

The APVMA has not established internal quality targets or timeframe KPIs that would ensure delivery of responses within its published timeframe targets.

As PAAs are processed outside the APVMA portal, applicants are not able to monitor progress of their applications.

Consistency and quality of advice

There is no systematic process for reviewing the accuracy, consistency or relevance of responses to PAA applications.

Until recently, there was no requirement to obtain executive clearance of the handling strategy for PAAs or sign off for the content of the response.
Variations in practice have emerged between different processing teams.

There is no consolidated set of responses to PAAs and only a limited capacity to organise or search responses for comparative purposes.

There are at present no quality standards and no agreed basis for determining the quality of responses.

The APVMA does not routinely seek feedback from clients on their satisfaction with the processing of their applications or the advice provided.

There is no review mechanism for applicants not satisfied with its responses, leaving applicants at the end of the process with nowhere to go if they do not feel that their questions have been appropriately answered.

Charging

The charging regime is burdensome and inefficient.

While the charges are based on hourly rates they are difficult and time consuming to administer. The charging regime adds unnecessary processing costs for applicants and the APVMA and slows the processing of applications.

The design of the charging regime discourages the early exchange of information that would assist in improving the quality of applications for registration, licences and permits.

While the main features of the charging regime were set out in legislation and are beyond the control of the Regulator, the operational implementation of the arrangements by the APVMA was not fit for purpose and disproportionate to the cost of calculating and collecting the money.
Appendix B   Recommendations

Clarity of purpose

- Clarify the purpose of pre application assistance.
- Clarify how PAA fits within the APVMA’s suite of services providing pre application advice and support.
- Clarify the extent to which technical advice may be provided within the PAA arrangements.
- Provide worked examples to assist staff understand how different requests for assistance would be handled.

Change strategies

- Plan and implement basic administrative improvements as quickly as possible e.g. revise work instruction, and implement executive checking of all responses.
- Engage with key industry and government stakeholders on the reasons for seeking to change the PAA arrangements so soon after implementation.
- Seek industry support in the design of a new suite of pre application assistance products and services.
- Seek industry and Ministerial support for a less burdensome charging regime for PAA.
- Seek industry support for co-design of more appropriate PAA arrangements.

Design

- Broaden the scope of PAA to allow technical advice, including protocol assessments.
- Identify the different kinds of pre-application assistance required by industry stakeholders, including:
  - General enquiries
  - Interpretation of guidelines
  - Advice and guidance, including on technical matters
  - Data waivers
  - Protocol assessments
  - Technical assessments
- Develop appropriate products and services to meet these different needs and provide appropriate systems and processes to support them.
- Over time, integrate all forms of pre-application advice and guidance into a common fit for purpose process with integrated CRMS/ internal IT systems.
Internal handling of PAA applications

- Provide a single process owner for all forms of pre application assistance with accountability for PAA performance and outcomes.
- Develop a consolidated statement of the roles and responsibilities of the various work areas involved in the processing of PAA applications.
- Clarify the role of case managers in the handling of PAA, including the ability to specialise with registration areas for senior case management team leaders, to allow them to better develop their technical capacity and understanding of the issues raised on PAA applications.

Engagement with applicants

- Provide additional explanatory material and training so that industry has a better understanding of cases where pre-application assistance should prove useful and how to engage with the APVMA through the pre-application process.
- Provide more flexibility for staff around communication with PAA applicants. Where necessary, staff should contact applicants by telephone or email to understand what they are seeking from the process and to clarify the nature of their application.
- Include an option within PAA for applicants to request meetings to allow for discussion of regulatory and development plans for new products.
- Including guidance on data requirements for non-standard and discussion of more complex matters that are not covered by existing guideline material.
- Actively follow up with applicants after a response has been provided to ensure that the advice has addressed their questions.

Management controls and accountability

- Incorporate executive clearance in the process for the handling of PAA applications and sign-off of advice and allocate the responsibility within formal Work Instructions.
- Develop internal and external service standards for processing enquiries, PAA and other requests for advice.
- Develop a common reporting and monitoring system for all PAA applications against timeframe and other targets.
- Design and develop a reporting process which can provide regular, consolidated reports on timeframe and other performance.

Processes and workflows

- Develop an authoritative description of the overall business process and incorporate in Work Instructions. A suggested process is provided in Figure 1 below.
Figure 1 – Suggested work process for PAA applications

- Provide earlier involvement of technical areas in filtering PAAs and the planning of cases
- Allocate responsibility for the quality of responses to Section Heads in the evaluation areas. Hold managers and staff accountable for the internal timeframes and quality of responses to PAA applications.
- Redesign forms to provide more transparent sign-offs and reduce the need for double handling of information.
- Manage and document meetings within the evaluation and assessment areas.
- Incorporate internal timeframes KPIs that would ensure delivery of responses within published timeframe targets in Work Instructions.
- Ensure that PAAs are processed through the APVMA portal, to provide a common platform for managing applications and enable applicants to monitor progress of their applications.

Consistency and quality of advice

- Ensure that responses to applications are approved at an executive level
- Redesign forms so there is greater accountability for the advice provided and less chance of information being inadvertently omitted or changed in the compilation of a consolidated response.
- Develop a consolidated and searchable internal database for PAA applications and responses.
- Develop a mechanism for applicants to seek review or redress where the response to an application for PAA has not dealt with their request.
Provide an applicant satisfaction form with each response to a request for PAA.

Charging

Seek to have the current charging arrangements removed or revised to make them less burdensome and more efficient, including eliminating or simplifying the process required for the provision of quotations.

Consider a charging system based on similar principles to the modular arrangements currently applied for other applications.

In the meantime, implement simpler and more streamlined administrative arrangements for the administration and application of the charges.