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House of Representatives
Standing Committee on Agriculture and Water Resources
PO Box 6021 Parliament House Canberra ACT 2600

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Auditor-General Report No. 56 (2016-2017)
Pesticide and Veterinary Medicine Reform

The VMDA is a peak body representing the animal health industry in Australia and comprises manufacturers, scientists, regulatory consultants and distributors. The VMDA is a member-driven organisation, and members are encouraged to contribute to the successful future of Australian animal health and our export efforts.

The VMDA believes that a robust and efficient regulator for agricultural chemicals and veterinary medicines (Agvet chemicals) is necessary for Australia to maintain and grow our farming sector, equestrian sports and pursuits and for the maintenance of the all-important domestic pet sector, and animal welfare. In addition this industry contributes a significant volume to Australia's export, and VMDA members who are in the main manufacturers with facilities in Australia, play a large part in this.

The stated aim of the APVMA to be a 'contemporary world class regulator' must be coupled with a genuine appetite to support Australia's export efforts and to adopt such policies and procedures as will enhance those efforts.

The ANAO Audit of the APVMA addressed Agvet chemical reforms introduced in 2014, and the performance of the regulator in implementing those reforms.

By any measure, the introduction of the changes and the subsequent performance of the APVMA has been poor. The statement by the previous CEO of the APVMA in her letter to ANAO on 3 May 2017, to the effect that the legislative reforms had been implemented 'with no significant disruption to industry being able to make applications', was simply not the case.

For the APVMA to function as an effective regulator it must be a pathway for safe and effective agvet products to reach the market in a timely manner, not just for the benefit of industry, but for the long-term advantages created by the availability of these animal health solutions for our community, both farming and domestic.

While the APVMA has many key people, including those at senior levels, who work diligently to try to provide effective registration and regulation of agvet chemicals, they work hampered by the structures and historical problems of the organisation, and under legislation which has been roundly criticised by the Federal Court.

The APVMA must be a facilitator, and not a gatekeeper. It is the job of the regulator to register suitable products, and not to seek ways of refusing products which, regrettably, is often the perception created by the inconsistent performance of the Authority.

In addition to the adverse findings of the ANAO Audit, the VMDA through the experiences of its members, has identified the following key elements of the Authority's performance which are of concern:

Statistics:

The reporting of quarterly statistics in recent times has indicated an apparent increase in the ability of the authority to meet legislative time frames, but the statistics as reported do not clearly represent the underlying true story.

A claim for 80% in-time performance for veterinary applications for instance, does not make clear that approximately 80% of applications received are of an administrative nature (label changes etc.) or are for changes to existing products that require little assessment, or in recent times applications for retrospective approval of active constituents that had been fully evaluated but not assigned an approval number. It follows therefore that virtually all of these would be approved within the relatively short statutory time frames allowed, thus making up the bulk of the 80% 'approved within time frames'.

The sad story is therefore that the other 20% of applications received are for actual new products that will be of benefit to industry and the community, and therefore virtually all of genuine product applications are not approved within the statutory time frames, and the 'major' product assessments (representing the more innovative and therefore potentially valuable new products) suffer most in these circumstances.

Time Frames:

Increased time frames were introduced with the reforms in 2014, when the APVMA said that increasing those periods would provide a more realistic time frame and allow it to meet its statutory obligations.

The opportunity to stop the clock was removed, and replaced with the option to extend the timeframe by 1/3 +1 month, with the reassurance that the APVMA would NOT necessarily take this much time.

The APVMA has not managed to stay to these timeframes for the more complex applications (Items 2, 10, 14). Even once extended, they are blown out with no good reason.

Example: Ceva Animal Health has an Item 2 application (new active, new product) that was submitted in December 2015. This was extended to 9 Jan 2018. As at this time, chemistry review for the active ingredient has not finished, although all other reviews are complete. The amended Gazettal date of 27 Feb 2018 has now passed, which means that the product cannot possibly be registered until May 2018 at the earliest.

a) this is 11 months longer than the original timeframe.
b) there are no issues with the application - all reviews are positive. Note that the product is already registered in EU, with the same data package.
c) this same application was submitted in NZ at the same time - it has been registered in NZ since September 2016.
d) this is an animal welfare issue - the only option in Australia at this time is a human medicine equivalent tablet that cannot be accurately divided for dosing.
e) this is costing the company at least $20000 for each month that it remains unavailable.

The Authority has noted that transition from pre-July 2014 to post-July 2014 was achieved without significant disruption to service delivery and involved an ongoing program of business improvement.

Not only do the above numbers and example indicate that this is not true, there were quite a few applications that were negatively affected by the changes with the legislation applied retrospectively to products already in the system, not because the application was deficient, but due to dilatory APVMA assessment. This meant that those applications were subjected to extended timeframes and the inability of registrants to submit new data, which would have been allowed if the assessment had been completed on time.

While overall 'time to completion' may not have changed significantly since the reforms of 2014, the legislative changes in respect of time frames made at that time, coupled with a DAWR prediction of smoother and faster 'running clock' application processes, have clearly resulted in the perception of poor performance. This is further exacerbated by a statistical reporting process that does not reflect the reality experienced by most applicants.

Pre-Application Assistance (PAA):

PAA was introduced in the reforms of 2014 as a way for applicants to gain 'advice' prior to submission so that applications would be of an appropriate quality. This has been promoted as providing 'transparency' and 'certainty' and in a recent external review commissioned by the APVMA was regarded by the reviewers as a significant tool to help eliminate 'poor quality' applications that are claimed to be the root cause of many of the current delays. However, even time frames agreed under this arrangement have not been kept.

In the statistics released by the APVMA for the December 2017 quarter, 12 of 39 PAA applications were finalized within time frame. Ceva Animal Health currently has two PAA applications outstanding - one by 3 months, and the other by 2 months. This is more than double the original time frame for relatively straightforward questions, and it is disappointing that even a relatively recent innovation such as this has suffered due to lack of resources.

Provision of additional data:

The legislative reforms provided that applicants could not provide additional data once an application had been accepted for assessment, **unless** the APVMA requested it. This was intended to stop applicants submitting poor applications and then 'drip-feeding' the regulator with additional data until it was satisfied that there was enough, rather than the applicant doing all of its work up front and providing a proper application.

On the face of it, this is a laudable aim, but it has in reality simply been a blocking point that allows inefficient assessors to request more information or issue a notice proposing to refuse a product (adding additional months to the time frame), when the issue could have often been resolved with a phone call or email requesting the missing or additional data, as was the case prior to July 2014.

The legislative outcome is also somewhat ambiguous, with DAWR claiming that the APVMA could request any data that it needed at any time, and the Authority claiming that it could not do so, or at least would choose not to do so as a matter of policy since the original aim of the legislation changes driven by DAWR was to avoid the 'back and forth' communications slowing down the process.

Examples of the problems caused by this aspect of the reforms include the adoption of new guidelines by the APVMA Chemistry section **after** an application has been submitted and then applying those to the application **but of course without being able to allow the submission of further data to satisfy the new guidelines.**

A further example similar to the above is the refusal/claimed inability to accept mid-study stability data to provide for maximum shelf life for the product while it is still being assessed. This puts Australia at a significant disadvantage (2-3 years behind) compared to for instance the EU where this is allowed (as it was previously allowed in Australia). Again, the legislative intent is at odds with practical reality.

Preliminary Assessment:

This is where the APVMA assesses the application from an administrative perspective only. That is, to ascertain whether it contains all of the necessary elements to be assessed. It does not include any element of technical assessment, which was the case prior to July 2014. As a consequence, some applications that are submitted under e.g. Item 7 where the formula has to be 'closely similar', are not identified as deficient until some time after submission when the formulation is checked and evaluated.

A return to the previous arrangement where a nominal amount of technical assessment could be carried out to identify simple deficiencies like this would avoid delays and extra work for both applicant and regulator.

Low regulatory approaches to registration:

The CEBRA project was intended to provide a 'tool' for self-assessment and a genuine path to 'low risk' product registrations.

However, the management of this project at the time created a 'gulf' between what was proposed and what was delivered, which was a matrix by which an applicant could ascertain whether or not his product required registration. In no way does it provide a pathway to clarify what is acceptable as 'low regulatory' and in fact there is only one very restrictive type of product that can achieve 'self assessment'.

The Guidelines Project currently under way with APVMA and industry participants will hopefully lead eventually to a transparent pathway that will allow applicants to determine which path they wish to take depending upon data available, claims to be made, etc.

Armidale relocation:

The VMDA was and remains, opposed in principle to the relocation, but accepts that we must now work to help with a smooth transition. This decision has had a significant effect on the availability of suitably qualified scientists for application assessments, and will continue to do so until the move is complete and the staffing and assessment arrangements are settled.

It must be pointed out however, that the APVMA's performance was unsatisfactory before the relocation was proposed. The issues mentioned in our submission were and remain, in need of being addressed irrespective of the location of the regulator.

APVMA structure:

Many of the issues highlighted in our submission stem, we believe, from the decision taken by the previous CEO to merge the Ag and Vet Programs and then split the Authority by function rather than product type.

Much is made in the independent review carried out for the APVMA by the Reason Group of the fact that ours is one of the few (only?) regulators in the world to regulate both ag and vet.

The VMDA believes that lack of experience of the products and the practical use of them, as well as the significant differences in the processes for the two product sectors (Vet has a Manufacturers Licensing Scheme with QC and QA measures to assure quality of product where Ag does not), results in assessment delays and queries that would not have applied when there were two separate programs.

The VMDA does not believe that 'process' overcomes structure and lack of specific expertise. Accordingly we recommend that the previous separate programs are reinstituted, with Program Directors and an Executive Manager of Registration overseeing and coordinating both programs.

Supervisory / Governance Board:

The VMDA recommends that a supervisory or governance board is established with direct links to the Minister and DAWR. While not a Management Board, it would have the opportunity to request information and make recommendations regarding the operations of the APVMA and its policies and procedures.

Significant representation from the major industry stakeholders would be essential, as well as other groups, and with an independent Chair. This would also provide for meaningful industry consultation and input.

Summary:

Much of the information provided by the ANAO Audit and the descriptions of current and future APVMA procedures and plans paint a picture of a potentially 'world class' regulator, however the present situation remains unsatisfactory and in need of reform.

As the next tranche of legislative reform is proposed and examined, DAWR and the APVMA must, in consultation with stakeholders, ensure that those reforms provide for practical outcomes that will be of benefit to all.

The stated aims of the APVMA 2015-2020 Corporate Plan:

- Deliver regulatory decisions that are timely, science-based and proportionate to the risks being managed.
- Reduce the burden on industry in complying with regulatory requirements.
- Build a client focused approach to service delivery committed to continuous improvement.
- Operate as a contemporary, high performing and efficient organisation.

These cannot be achieved without effective and workable legislation and sufficient resources applied by Government to get the APVMA back on track and providing the services for which is was created and which it is capable of delivering.

Jim Adams
Executive Director