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Introduction

1.1 The registration of agricultural chemicals and veterinary medicines (collectively known as agvet chemicals) in Australia is managed by the Australian Pesticides and Veterinary Medicines Authority (APVMA). The APVMA is a statutory authority, established under the *Agricultural and Veterinary Chemicals (Administration) Act 1992*.

1.2 On 1 July 2014, the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* (the 2014 reforms) came into effect; in 2016 the Australian National Audit Office (ANAO) began a performance audit of the APVMA's implementation of those reforms. The ANAO's audit report was tabled in July 2017 as Auditor-General's Report No. 56 (2016-17), *Pesticide and Veterinary Medicine Regulatory Reform*.

1.3 In December 2017, the Committee resolved to conduct an inquiry based on the ANAO report under Standing Order 215 (c). The purpose of the Committee's inquiry was to establish the extent to which the APVMA has implemented the recommendations made by the Auditor-General.

1.4 The inquiry was advertised on the Committee's website and the Committee sought submissions from relevant stakeholders. A list of submissions received is at Appendix A. The Committee also held a public hearing in Canberra on 1 March 2018; the list of witnesses is at Appendix B.

ANAO report findings and recommendations

1.5 The ANAO found that the APVMA's implementation of the 2014 reforms had been 'mixed': key reforms were implemented on schedule, but 'the full scope of the reform program is yet to be implemented more than four years since the legislative amendments were developed'. The ANAO further found an 'absence of a robust set of performance measures' which hindered the APVMA's capacity to accurately assess the extent to which reform objectives had been met.[1]

1.6 The 2014 reforms were expected to increase the efficiency of APVMA processes and correspondingly reduce the regulatory burden on industry. However, the ANAO found that, given the absence of adequate performance measures, little evidence exists of these aims being met. The performance information the APVMA could provide the ANAO indicates that these increased efficiencies and reduced burdens had not eventuated:

> The limited performance information retained by the APVMA indicates that it has not achieved greater efficiencies in the delivery of its regulatory activities and, overall, the regulatory burden on industry has not been reduced since the reforms were implemented.[2]

1.7 The ANAO report made four recommendations, all of which were agreed to by the APVMA. These recommendations are presented in the table below.

1 Australian National Audit Office, Report No. 56 (2016-17), *Pesticide and Veterinary Medicine Regulatory Reform*, p. 7.

2 Australian National Audit Office, Report No. 56 (2016-17), *Pesticide and Veterinary Medicine Regulatory Reform*, p. 8.

Table 1: ANAO recommendations

Recommendation 1	The Australian Pesticides and Veterinary Medicines Authority should implement an internal quality framework to provide an appropriate level of assurance that its assessments are undertaken in a consistent manner and made in accordance with agvet chemical legislation.
Recommendation 2	The Australian Pesticides and Veterinary Medicines Authority should establish and monitor an appropriate set of measures and targets to assess the extent to which it is improving the effectiveness and efficiency of its regulatory activities through its ongoing reform agenda.
Recommendation 3	The Australian Pesticides and Veterinary Medicines Authority should improve its governance of the implementation of major reforms, including the maintenance of an oversight body with clearly defined responsibilities and robust project monitoring arrangements.
Recommendation 4	The Australian Pesticides and Veterinary Medicines Authority should implement a structured and systematic approach to identifying and responding to emerging business risks.

Source *Australian National Audit Office, Report No. 56 of 2016-17: Pesticide and Veterinary Medicine Regulatory Reform, p. 10.*

1.8 Noting that the APVMA agreed with all four recommendations, the Committee's inquiry focused on the steps the APVMA had taken in the six months since the audit report was tabled.

Post-reform reviews

1.9 While the APVMA's implementation of the 2014 reforms is the focus of this inquiry, the Committee also recognises that reforms of the APVMA are ongoing.

1.10 In 2015, the Government released the *Agricultural Competitiveness White Paper*. The following year, the Productivity Commission published its report on regulatory burdens on agriculture in Australia. This section

outlines the major findings of each as they relate to the regulation of agvet products and the role of the APVMA.

Agricultural Competitiveness White Paper

1.11 The White Paper notes the scale of the agvet products industry in Australia, with farm businesses spending more than $1.4 billion on chemicals in the financial year 2013-14. For that reason, the White Paper notes:

> It is important that the approval systems for chemicals are as efficient as possible, but maintain safeguards necessary to protect human health and to prevent damage to users, plants and animals, and the environment.[3]

1.12 The White Paper outlined the consequences of the regulatory burden posed by the agvet chemical regulation system, including that it 'slows access to newer and better products and increases chemical cost'. This, in turn, puts Australian producers at a competitive disadvantage to overseas producers.[4]

1.13 After noting the 2014 reforms, the White Paper discusses further action the Government will take to reduce this burden on Australian agricultural producers, outlining that the 'new approach for the APVMA to streamline access to products and better manage the risks these products can pose, while ensuring human health protection'.[5]

1.14 This approach will take a number of forms, including:

- limiting the pre-market assessments of low- and medium- risk products to focus on those with a higher risk profile;
- recognition of assessments from 'accredited third party suppliers and trusted chemical regulators'; and
- focussing assessment of products available 'in trusted overseas countries' on risks or conditions that are different in Australia (including 'different human health requirements, agricultural practices or environmental assets').[6]

1.15 The White Paper suggests that these changes will 'reduce delays for users and remove disincentives for registering chemicals with more uses in the

3 Commonwealth of Australia, 2015, *Agricultural Competitiveness White Paper*, p. 37.

4 *Agricultural Competitiveness White Paper*, pp 37 - 38.

5 *Agricultural Competitiveness White Paper*, p. 38.

6 *Agricultural Competitiveness White Paper*, p. 38.

Australia market' and will 'result in a reduced regulatory cost to business of around $68 million annually'.[7]

Productivity Commission: Regulation of Australian Agriculture report

1.16 Following the White Paper, the Treasurer, the Hon Scott Morrison MP, requested that the Productivity Commission inquire into 'the regulatory burden imposed on Australian farm businesses'.[8]

1.17 The Productivity Commission's report noted that, despite multiple reviews and reforms of agvet product regulation, 'concerns remain', including:

- unnecessarily lengthy, complex and duplicative registration procedures; and
- inter-jurisdictional inconsistencies, particularly in control-of-use regimes, which can make it costly and confusing to comply with regulatory requirements.[9]

1.18 The report suggested that the APVMA could 'increase its use of international assessments and decisions for products already registered by trusted comparable regulators overseas'.[10]

1.19 The issue of excessively long registration process was also covered in the Productivity Commission's report, which noted that 'costly and time-consuming registration processes can mean that some chemicals are only available in Australia several years after they are available overseas (or they may not become available at all)'.[11]

1.20 The Productivity Commission report noted that the APVMA had outlined several reforms that could be undertaken without the need for new or amended legislation. These were:

- better profiling of applications and the risks involved, and establishing faster pathways to register products or make variations, including through online self-assessment, notifiable variations and compliance with standards;
- increasing the use of assessments conducted by comparable regulators both domestically and internationally;

7 *Agricultural Competitiveness White Paper*, p. 38.

8 Productivity Commission, Inquiry Report No. 79, *Regulation of Australian Agriculture*, 15 November 2016, p. iv.

9 Productivity Commission, *Regulation of Australian Agriculture*, p. 291.

10 Productivity Commission, *Regulation of Australian Agriculture*, p. 291.

11 Productivity Commission, *Regulation of Australian Agriculture*, p. 297.

- aligning technical guidelines and guidance material to those agreed internationally through recognised forums such as the OECD, the International Cooperation on Harmonisation of Technical Requirements for Veterinary Medicinal Products and the Codex Alimentarius;
- seeking efficiencies in process through more contestable provision of assessment services; and
- streamlining internal business processes to speed up the assessment of applications.[12]

Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017

1.21 At the time of writing (April 2018), the *Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017* is before the Senate. This bill makes a range of technical amendments to the operations of the APVMA, as outlined in the Explanatory Memorandum:

- reduces the regulatory burden on industry by simplifying reporting requirements for annual returns;
- reduces the administrative burden on the APVMA and industry by increasing the flexibility of the APVMA to manage errors in an application at the preliminary assessment stage;
- reduces the regulatory burden by enabling the APVMA to grant part of a variation application under section 27 of the Schedule to the Code Act (the Agvet Code);
- enables a person to apply to vary the relevant particulars or conditions of a label approval that is suspended, to the extent that the variation relates to the grounds for suspension;
- establishes civil pecuniary penalties for contraventions of provisions relating to providing false or misleading information in the Agvet Code and the Administration Act;
- amends the notification requirements in section 8E of the Agvet Code so that the APVMA and [Food Standards Australia New Zealand] will have the flexibility to agree on appropriate timeframes for notifications;
- amends the definition of expiry date in the Agvet Code to mean the date after which a chemical product 'must not' be used; and
- makes minor and technical amendments to the Administration Act and the Agvet Code, including the repeal of redundant provisions.[13]

12 Quoted in Productivity Commission, *Regulation of Australian Agriculture*, p. 295.

13 *Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017*, Explanatory Memorandum, p. 1.

1.22 The then-Minister for Agriculture and Water Resources, the Hon Barnaby Joyce MP, described the bill as addressing 'simple, non-controversial changes that could be done now that improve the efficiency of the regulator and increase the speed to which farmers can get access to safe effective chemicals' and as the forerunner to a 'detailed review of the whole legislative framework'.[14]

Evidence received

1.23 The Committee received evidence from a number of stakeholders in the agvet and broader agricultural sector. Many of them expressed concern about the inefficiencies of APVMA's approval processes, before and after the 2014 reforms were implemented. This section outlines that evidence, including suggestions made to improve APVMA's processes, along with evidence received from the APVMA.

Importance of the APVMA to Australia's agricultural sector

1.24 Submitters generally noted the importance of the APVMA to Australia's agricultural sector, noting that the efficient and effective regulation of agvet products is vital.

1.25 For example, Animal Medicines Australia, the peak body representing animal health companies in Australia, highlighted the importance of the APVMA's role and contrasted this importance with the frustrations of industry:

> The effective and efficient regulation of agricultural and veterinary chemicals is essential to protect the health and welfare of our livestock, horses and companion animals in Australia. The APVMA is a critically important chemical regulator for Australia that supports a $60billion agricultural industry and $12billion pet industry.
>
> […]
>
> The APVMA operates on a cost-recovery basis which, in the current situation, means that industry is paying for an inefficient, unpredictable and untimely regulator. If the government provides an efficient, transparent and predictable regulatory system, then

14 Hon Barnaby Joyce MP, Minister for Agriculture and Water Resources, Second Reading Speech, *Hansard*, 25 October 2017, p. 11 889.

> our industry will gladly support and comply with the requirements of that system.[15]

1.26 The Pastoralists and Graziers Association of WA, an industry organisation representing primary producers, argued that the APVMA's inefficiency has flow-on costs for the industry:

> The overall lack of efficiency costs the agvet chemical industry.
>
> As chemical registrants will pass this cost down the chemical supply chain, distributors and retailers will need to increase their prices by more than the actual increase in price to maintain an adequate margin for the product. It is unlikely any of these sectors can absorb this extra cost, and inevitably this cost will be passed back to the producer.[16]

1.27 CropLife Australia also noted that the costs of inefficient regulation of agvet products are borne across the sector, including at the individual farm level:

> The cost burden of the APVMA falls on the regulated entities – the developers, manufacturers and registrants of innovative crop protection products – through a cost recovery process. Delays and inefficiencies end up adding unnecessary costs to crucial agricultural input products, which is a cost that ends up on the farm gate. The importance of this regulator maintaining its technical competencies whilst significantly improving efficiencies is crucial to the plant science industry and the nation's farming sector.[17]

1.28 The rural advocacy and service organisation WA Farmers made a similar point, noting that the delays in implementing the 2014 reforms had frustrated the sector, including:

> … pharmaceutical and chemical companies who invest millions of dollars developing new products for market, or applying for licenses to bring new products into Australia, which meet the safety and environmental standards.[18]

1.29 The Veterinary Manufacturers and Distributors Association (VMDA), a peak body representing the animal health industry, argued that 'by any measure, the introduction of the changes and the subsequent performance of the APVMA has been poor'.[19]

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15 Animal Medicines Australia, *Submission 2*, p. 3.

16 Pastoralists and Graziers Association of Western Australia, *Submission 4*, p. 4.

17 CropLife Australia, *Submission 5*, p. 2.

18 WA Farmers, *Submission 6*, p. 2.

19 Veterinary Manufacturers and Distributors Association, *Submission 3*, p. 1.

Positive outcomes

1.30 While the Committee did not receive much evidence expressing satisfaction with the APVMA's implementation of the 2014 reforms, some initiatives did attract positive remarks.

1.31 Animal Medicines Australia pointed to the capacity to lodge applications online as a 'useful reform', and also – despite some inconsistencies – was pleased by the pre-application assistance process.[20]

1.32 The submission from WA Farmers made the same point, noting that the pre-application process and improved recognition of international data had resulted in 'small improvements' in APVMA's processes.[21]

Inconsistencies

1.33 The ANAO's first recommendation was that the APVMA should 'implement an internal quality framework to provide an appropriate level of assurance that its assessments are undertaken in a consistent manner and made in accordance with agvet chemical legislation'.[22]

1.34 A major theme highlighted by witnesses relates to this point, noting what they considered to be inconsistencies in the ways product registrations were handled.

1.35 Animal Medicines Australia, for instance, argued that a culture of inconsistent decision making has resulted in a confused system:

> A history of ad hoc and individual decision making, in addition to the substantial loss of staff and corporate knowledge, have meant that the consistency and predictability of APVMA decisions has been severely compromised. Countless quick fixes and patches to APVMA operations have accumulated over time, such that the workflow processes and infrastructure have become increasingly complex, haphazard, inefficient and ineffective.[23]

1.36 While finding the increased consideration given to international assessments a positive step, Animal Medicines Australia nonetheless noted that some members had found:

> … that the consideration of international data/assessments is inconsistent across different sections, assessors and case managers at APVMA. Inconsistencies in the treatment of international

20 Animal Medicines Australia, *Submission 2*, pp 1 – 2.

21 WA Farmers, *Submission 6*, p. 2.

22 Australian National Audit Office, Report No. 56 (2016-17), *Pesticide and Veterinary Medicine Regulatory Reform*, p. 10.

23 Animal Medicines Australia, *Submission 2*, p. 2.

> data/assessments has thus reduced the improvements in performance that could have been gained from this measure.[24]

1.37 This argument was also made by WA Farmers:

> However the recognition of international data submitted is inconsistent across different sections, assessors and case managers at APVMA.[25]

1.38 More broadly, WA Farmers argued that the APVMA's 'historical practice of ad hoc decision making' continues, with the result that the APVMA produces 'haphazard, inefficient and inconsistent outcomes'.[26]

1.39 Similarly, the VMDA argued that the APVMA's inconsistent approach has caused it to be seen as a gatekeeper, rather than as a facilitator:

> 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.[27]

1.40 At the Committee's hearing, Mr Adams, Executive Director of the VMDA, expanded on the industry's concerns with inconsistency:

> The regulatory burden has increased on industry, not decreased, mainly due to confusing and variable decision-making and a lack of transparency on the part of the APVMA, in terms of how it arrives at some of those decisions, and certainly a lack of certainty as to outcomes for registration applications. Obviously there is always an amount of uncertainty, based on the fact that somebody is scientifically assessing the application. But, in general terms, most of our applicants know what they need to provide, and they get variable results and differing answers on the same questions.[28]

Efficient processing of applications

1.41 Aside from the issue of inconsistencies, a further finding of the ANAO report echoed by industry stakeholders was that the APVMA has performed poorly against its legislated timeframes for the registration of agvet products. More broadly, the evidence received by the Committee suggests that the APVMA does not efficiently process registration applications, in a host of ways. It was also noted that, in addition to the

24 Animal Medicines Australia, *Submission 2*, p. 2.

25 WA Farmers, *Submission 6*, p. 2.

26 WA Farmers, *Submission 6*, p. 2.

27 Veterinary Manufacturers and Distributors Association, *Submission 3*, p. 2.

28 Mr Jim Adams, Veterinary Manufacturers and Distributors Association, *Committee Hansard*, 1 March 2018, p. 19.

financial implications, delays in the registration of products may lead to circumstances where new, and needed, products are unavailable when they might be most useful. The VMDA provided a practical illustration of this, noting a Ceva Animal Health product where a delay in approving a product (already available in the European Union) had animal welfare implications: 'the only option in Australia at this time is a human medicine equivalent tablet that cannot be accurately divided for dosing'. VMDA estimated that the delay in registering this medicine 'is costing the company at least $20 000 for each month that it remains unavailable'.[29]

Timeliness of assessment

1.42 The ANAO audit report highlighted that 'Timeliness of assessment decision-making is a primary performance metric for the APVMA and of particular interest to industry stakeholders' and noted that the 2014 reforms included new statutory timeframes for assessment decision-making as well as a new method of calculating those timeframes. Under those conditions, the ANAO found that the APVMA had finalised application assessments on time in 79 per cent of cases in 2014-15 and 68 per cent in 2015-16. [30]

1.43 Beyond that, the ANAO found that:

> Overall, data trends on the timeliness of assessments suggest an initial improvement in performance compared with the pre-reform period. This has been followed by fluctuations in the level of assessments completed on time and a recent decline, in the context of fewer applications to be assessed and an increasing backlog of overdue assessments.[31]

1.44 The APVMA has historically demonstrated what the Chief Executive Officer, Dr Chris Parker, has described as 'volatility' in its performance measurement of completing assessments within the legislated timeframes.[32]

1.45 In his response to the Joint Committee of Public Accounts and Audit, Dr Parker noted recent improvements in the APVMA's performance, while still noting that it fell short of the goal:

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29 Veterinary Manufacturers and Distributors Association, *Submission 3*, p. 3.

30 Australian National Audit Office, Report No. 56 (2016-17), *Pesticide and Veterinary Medicine Regulatory Reform*, p. 37.

31 Australian National Audit Office, Report No. 56 (2016-17), *Pesticide and Veterinary Medicine Regulatory Reform*, p. 39.

32 Dr Chris Parker, Australian Pesticides and Veterinary Medicines Authority, *Committee Hansard*, 1 March 2018, p. 3.

> Our timeframe performance increased one percentage point in 2016-17, with 69 per cent of applications finalised within the statutory timeframes as opposed to the 68 per cent achieved in 2015-16. In the December 2017 quarter, timeframe performance for product, active and permit applications increased to 74 per cent, up from 58 per cent in the previous quarter. There is volatility throughout the APVMA's quarterly performance reports, the APVMA has never reached 100 per cent on time performance.[33]

1.46 In his evidence to the Committee, Dr Parker acknowledged that the APVMA's assessment performance dropped sharply after September 2016, picking up only in the last quarter of 2017, and accepted that the announced relocation of the Authority was at least in part a cause of that volatility.[34]

1.47 The VMDA, however, suggested that apparent recent improvements do not reflect the reality of the registration process for new products:

> 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.[35]

33 Australian Pesticides and Veterinary Medicines Authority, *Exhibit 1*, p. 1.

34 Dr Parker, APVMA, *Committee Hansard*, 1 March 2018, pp 4 – 5.

35 Veterinary Manufacturers and Distributors Association, *Submission 3*, p. 2.

1.48 In its submission to the Productivity Commission review, the National Farmers' Federation (NFF) argued that the APVMA's poor performance on this measure has acted as a disincentive for agvet producers considering registering products in Australia:

> The Australian Pesticides and Veterinary Medicines Authority (APVMA) has a consistent track record of failing to meet set approval timeframes, and the uncertainty and expense of the approvals process acts as a deterrent to global chemical companies when assessing markets for new products.[36]

1.49 CropLife Australia noted that improved performance on this measure would have important flow-on effects for agvet businesses in Australia:

> Improving consistency and predictability of regulatory decision timeframes will have an extraordinarily positive impact on the business decisions made by CropLife members and their global parent companies, leading to a significant increase in the number of new and innovative products being introduced to the Australian market. As a result, Australian farmers will gain access to vital tools to control pests, weeds and diseases, some of which are already available in other international jurisdictions, increasing Australia's international competitiveness and having a considerable positive effect on the agricultural sector, and therefore the Australian economy.[37]

1.50 Jurox Pty Ltd, a veterinary pharmaceutical company, gave the Committee an illustration of the consequences for them of the APVMA's slow processing of an application to register a generic version of a heart drug for dogs:

> It was submitted to the regulator on 1 November 2016 and should have come out in September 2017. We have had no communication until we met up with the Head of the APVMA (Acting Head at that time) in November 2017… We had not been given the courtesy of access to their efficacy and safety assessment report at that stage. We only received that in November 2017 after a request to have access. Unfortunately it has still not been approved by the APVMA. Today one of our new competitors, the English company Dechra, announced that they are launching a first to market generic and we think this is unacceptable.[38]

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36 National Farmers' Federation, *Submission 61 to Productivity Commission review of Regulation of Agriculture*, p. 13.

37 CropLife Australia, *Exhibit 3*, p. 4.

38 Jurox Pty Ltd, *Submission 1*, pp 2 – 3.

1.51 In his evidence to the Committee, Dr Parker explained that the processing of registration applications happens within the context of the APVMA's status of being largely funded by cost-recovery mechanisms and that the APVMA efficiency rate is, to some extent, dependent on how much applicants are willing to pay:

> What I'm really looking forward to next year is being able to talk with industry and government about what our fees and charges are and whether industry is even prepared to pay for 100 per cent approval. It may be an unsustainable level; I don't know. If we can get as high as we go, and if industry's prepared to pay for that—because we are 100 per cent cost recovery in that area—then maybe we would look to increase the size of the organisation. But at the moment I can only work with the guidelines I have in regard to fees and charges and the [Average Staffing Level] numbers that sit in my cap, if you like. I think that bringing staff on a non-ongoing basis to manage a workload may be one of the strategies that you can do, but ultimately industry has to pay for that. The organisation has run at a $3.5 million operational loss for the last three years. That's unsustainable.[39]

1.52 Dr Parker argued that, based on his discussions with industry, timeliness is more important than the cost of the application process:

> It is the time frames that cost them money in the long term. They put all their manufacturing and all their labelling and all that sort of thing that all has to be done over quite a period of time. If we miss a time frame, then that has a cost to them. There is also a cost associated with of course not being able to bring the product to market in the time lines they thought they did.[40]

Use of international evidence

1.53 As noted above, the 2014 reforms allowed the APVMA to consider international evidence, although only in limited ways. The Productivity Commission report outlined the ways the APVMA currently uses international evidence:

- decisions — the APVMA does not accept the decisions per se of international regulators. However, it accepts data, assessments and standards that contribute to a particular international decision;
- data — the APVMA accepts data generated according to a number of international guidelines, as long as they are relevant to the specific

39 Dr Parker, APVMA, *Committee Hansard*, 1 March 2018, p. 4.

40 Dr Parker, APVMA, *Committee Hansard*, 1 March 2018, p. 7.

application for registration. Accepted data include those generated according to the OECD test guidelines, the Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO) guidelines, and the International Cooperation on Harmonisation of Technical Requirements for Veterinary Medicinal Products guidelines;

- assessments — the APVMA accepts specific assessments if the data supporting them are made available. Accepted assessments include:
  - ⇒ hazard assessments conducted by EU member states, Canada and New Zealand;
  - ⇒ risk assessments conducted by the FAO and WHO;
  - ⇒ risk assessments for products where the exposure assessment is comparable to one conducted by another regulator; and
- standards — the APVMA routinely uses international standards, including FAO standards and specifications, and international methodologies for exposure assessment.[41]

1.54 Witnesses to this inquiry suggested that expanded use of international evidence and assessments would assist the APVMA to more efficiently assess product registration applications.

1.55 CropLife Australia recommended that, under the right conditions, increased use of overseas assessments would create efficiencies in the APVMA registration process:

> Utilisation of overseas decisions in limited situations only (protected cropping, household, home garden and in certain situations, label extensions) to avoid the re-assessment of data and assessments to revalidate the same conclusions while ensuring equivalency in exposure and environmental risks.[42]

1.56 Mr Adams of the VMDA made a similar point at the Committee's hearing, arguing that while not all products can have overseas assessments automatically applied in Australia, elements of the process could be made more efficient by greater use of those that can be used:

> A product has been registered overseas, somebody wants to register a similar product here and they've got to start all over again as if the APVMA have never heard of aspirin before in their lives. It's a legislative imperative in that case.[43]

41 Productivity Commission, *Regulation of Australian Agriculture*, p. 301.

42 CropLife Australia, *Exhibit 3*, p. 4.

43 Mr Jim Adams, Veterinary Manufacturers and Distributors Association, *Committee Hansard*, 1 March 2018, p. 27.

1.57 The NFF also argued for increased use of international data and assessments 'accepted by well-regarded overseas regulators' as a way of improving the system's efficiency while maintaining standards.[44]

1.58 AgForce Queensland suggested that an appropriate safeguard would be to require assessments from multiple overseas regulators and pointed to the benefits this would bring the sector:

> More broadly, the Government could enable registration of low-risk chemicals in Australia based on the registration status of the product from two trusted international regulators demonstrating robust registration and testing processes. This would streamline some pesticide registration processes and provide a greater range of access within our relatively small market.[45]

1.59 Voice of Horticulture, an organisation representing horticultural growers and enterprises, also argued that the relatively small size of Australia's market when compared to the expense and difficulty of registering products has meant that overseas producers have access to products unavailable in Australia.[46]

1.60 The Australian Veterinary Association similarly supported the move to recognise assessments from 'trusted foreign regulators'.[47]

1.61 Asked by the Committee what changes to the APVMA's assessment processes have been made since the ANAO audit, Dr Parker outlined two main areas: improvements in the pre-application process and increased use of international data.[48]

1.62 Of the pre-application assessment, discussed by some witnesses as being a step in the right direction but still limited in scope, Dr Parker explained that there will now be a greater reference to technical assessments at this stage, rather than a purely administrative process:

> … if you have some technical people in the pre-application assessment, they can say, 'That's probably not good enough. You need to go away and get a bit more information before you put the application in to us. If you have that information, we should be

44 National Farmers' Federation, *Submission 61 to Productivity Commission review of Regulation of Agriculture*, p. 13.

45 National Farmers' Federation, *Submission 17 to Productivity Commission review of Regulation of Agriculture*, pp 7 – 8.

46 Voice of Horticulture, *Submission 42 to Productivity Commission review of Regulation of Agriculture*, p. [13].

47 The Australian Veterinary Association, *Submission 26 to Productivity Commission review of Regulation of Agriculture*, p. 2.

48 Dr Parker, APVMA, *Committee Hansard*, 1 March 2018, p. 7.

> able to do it a little more quickly for you.' That's probably the key for me, particularly with a new chemical.[49]

1.63 In terms of international data, Dr Parker noted that the APVMA had previously been 'a little bit risk averse' in its use of international assessments. However, the APVMA will increasingly use international assessments where they are applicable rather than redoing each step of the application assessment process:

> As you know, there are a whole lot of regulators all around the world, with a number from quite sophisticated bureaucracies. In the past, I think we've been a little bit risk averse in the manner in which we use international assessments, so I've instructed the staff that, unless there is an obvious difference and we've been provided with the data—and they're two quite major caveats at the moment—there would be no reason why there wouldn't be a number of modules. We break up these applications into modules: chemistry, toxicology and efficacy—that sort of thing. But my view and the view that my senior managers are now working with their staff on is that a cow is a cow is a cow. If you've got a treatment for Ostertagia, brown stomach worm, in America, and we've got a treatment here […] then you'd be sitting there saying, 'Why would we redo an efficacy assessment? Why would we do a tox assessment again?' There might be an environmental component, because we do have different environments to the US, for instance, and there could possibly be a trade component as well, which they don't care about. I don't see any need—and this is what we're starting to do now—to do those bits of assessment when we know that that's it.[50]

Limited use of electronic systems

1.64 A further inefficiency in the APVMA's process is its limited use of electronic systems for receiving and processing product registration applications. One of the key components of the 2014 reforms was increasing the APVMA's capacity to receive applications online. The ANAO audit noted that this reform was 'largely complete' as of 1 July 2014.[51]

1.65 However, as the audit found:

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49 Dr Parker, APVMA, *Committee Hansard*, 1 March 2018, p. 7.

50 Dr Parker, APVMA, *Committee Hansard*, 1 March 2018, p. 7.

51 Australian National Audit Office, Report No. 56 (2016-17), *Pesticide and Veterinary Medicine Regulatory Reform*, p. 24.

> … there were extensive weaknesses in the APVMA's management of the project. Specifically, core IT project management practices such as technical and user acceptance testing was not undertaken prior to releasing new applications into production. In addition, key project documentation was either not prepared or was incomplete.[52]

1.66 Animal Medicines Australia noted that, while some parts of the application process have been moved to electronic systems, others have not, creating inefficiencies. They gave the illustration of pharmacovigilance data, which the APVMA system requires to be entered manually:

> In other regulatory jurisdictions, pharmacovigilance reports are submitted electronically via a validated database. This also means that electronic dossiers built for another jurisdiction (such as the EU) must be reworked prior to submission to APVMA.[53]

1.67 Animal Medicines Australia also noted that some data from the supply chain is submitted electronically while others are on paper forms which must then be added to the APVMA database manually.[54]

1.68 At the Committee's hearing, Dr Parker of the APVMA acknowledged that the Authority 'has had a history of underinvesting in IT'.[55]

Over-regulation of some products

1.69 While the reduction of the administrative burden on industry was an aim of the 2014 reforms, witnesses also highlighted that the APVMA registration process is inflexible in terms of what products it applies to, placing a substantial regulatory burden on low-risk products.

1.70 Animal Medicines Australia noted this issue, arguing for streamlined approval processes for products that should be considered low-risk:

> … the current risk assessment framework and high pre-market authorisation requirements impose a substantial regulatory burden on industry that is often disproportionate to the risks that the products pose. For products that are well known, do not enter the food chain, pose low risks to users and where those risks are already well characterised, there should be a streamlined regulatory assessment to bring such products to the market. Such

52 Australian National Audit Office, Report No. 56 (2016-17), *Pesticide and Veterinary Medicine Regulatory Reform*, p. 26.

53 Animal Medicines Australia, *Submission 2*, p. 2.

54 Animal Medicines Australia, *Submission 2*, p. 2.

55 Dr Parker, APVMA, *Committee Hansard*, 1 March 2018, p. 12.

> products may include flea collars, companion animal shampoos, or vitamin and mineral supplements.[56]

1.71 The Pastoralists and Graziers Association of Western Australia noted the 2015 *Agricultural Competitiveness White Paper*, which highlighted that existing agvet regulation 'imposes a heavy regulatory burden on industry that is often disproportionate to the risks that products pose'.[57]

1.72 WA Farmers drew attention to this point, noting that the APVMA's current risk assessment framework and 'high pre-market authorisation requirements… impose substantial regulatory burden on industry, which is disproportionate to the risks that the products pose'.[58]

1.73 Mrs Metcalf of the VMDA provided a practical example, in describing the risk-averse culture of the APVMA:

> I think that it's telling that, for example, within the APVMA, if you want to register, let's say, a dog shampoo, you have to provide the same amount of data, and it undergoes the same amount of scrutiny, as for a brand-new anaesthetic […]
>
> You're having to provide all this data for a dog shampoo, as you would for an anaesthetic. Any sensible person, in my opinion, would say, 'Well, obviously a dog shampoo is much lower risk than an anaesthetic' […]
>
> Interestingly, in a lot of other jurisdictions, they don't require it.[59]

1.74 The Department of Agriculture and Water Resources (DAWR) acknowledged the issue in its 2015 White Paper, noting that reform of APVMA processes was required to minimise unnecessary burdens:

> Australian agricultural and veterinary (agvet) chemical regulation imposes a large regulatory burden. It is often disproportionate to the risks these products pose. This slows access to newer and better products and increases chemical cost. Australian producers often cannot access the chemicals they need to improve their competitiveness and manage resistance. Overseas producers can gain an advantage in accessing new chemicals well before their Australian counterparts.[60]

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56 Animal Medicines Australia, *Submission 2*, p. 2.

57 Pastoralists and Graziers Association of Western Australia, *Submission 4*, p. 2.

58 WA Farmers, *Submission 6*, p. 2.

59 Mrs Lee Metcalf, Veterinary Manufacturers and Distributors Association, *Committee Hansard*, 1 March 2018, p. 19.

60 *Agricultural Competitiveness White Paper*, pp 37 - 38.

Relocation

1.75 Although the ANAO's audit did not focus on the APVMA's planned relocation from Canberra to Armidale, the topic was nonetheless of interest to the Committee and to industry stakeholders. The ANAO audit found that the APVMA 'should implement a robust risk management framework and oversight arrangements' regarding its relocation project, and highlighted staff retention, particularly of technical assessment staff, as the highest risk.[61]

1.76 The Pastoralists and Graziers Association of WA, for example, noted that the relocation had understandably impacted on the APVMA's efficiency:

> The PGA notes that the poor timeframe performance (despite a small improvement on the previous quarter) for registration of crop protection products reported in the 2017 September quarter cannot have been assisted by the forced and artificial relocation of the APVMA from Canberra to Armidale, and the earlier resignation of its CEO in April 2017.
>
> Such a turnover at the executive level in advance of a major relocation cannot have assisted business as usual, let alone change management.
>
> Given that the APVMA's own relocation strategy (APVMA in Armidale: Relocation Strategy) expects only about 10 - 15 per cent of current staff to move to Armidale, the relocation can only add to the difficulties being experienced by the APVMA.[62]

1.77 Noting the shortcomings of the 2014 reform process, WA Farmers were concerned that:

> Instead of focusing on developing the urgent and necessary reforms required to assist the APVMA during the move to Armidale, the Department has spent more than three years rectifying the failures of the 2014 reform package.[63]

1.78 Asked whether the APVMA's relocation to Armidale had made the implementation of the reform program more difficult, Dr Parker acknowledged that it 'presents challenges', but highlighted the Authority's risk management of the relocation process:

> … one of the key business risks for us is retention of staff and loss of staff. I would contend that, given the improvements we have

61 Australian National Audit Office, Report No. 56 (2016-17), *Pesticide and Veterinary Medicine Regulatory Reform*, pp 54 – 56.

62 Pastoralists and Graziers Association of Western Australia, *Submission 4*, p. 3.

63 WA Farmers, *Submission 6*, p. 2.

> managed in our performance, that is a measure that we are managing that risk effectively. It remains a challenge, as it will be right through until we move, but we have procedures and practices in place. We have recruitment plans in place and we have a full suite of support for existing staff that allows us to continue to do the job we need to do.[64]

1.79 Dr Parker noted that the APVMA was, at the time of the Committee's hearing, finalising a whole-of-staff survey to determine what proportion of the currently Canberra-based workforce was planning to relocate to Armidale. The results of that survey will give the APVMA more information on future recruiting needs, as well as providing a fuller picture of operational efficiency and other risks associated with the relocation.[65]

1.80 In addition to the focus on recruitment to assist with the relocation, the APVMA has established a committee to manage the risks associated with the relocation.[66]

1.81 Ms Amy Fox, Deputy CEO of APVMA, outlined some of the main risks the APVMA is managing as a consequence of its relocation, including:

- staff retention;
- inadequate capacity of the shared service providers or outsourcing arrangements;
- inability of the Authority to maintain and grow capability in the medium term; and
- adequacy of the Authority's IT capacity, including e-working arrangements.[67]

Governance arrangements

1.82 The Committee heard that the operations of the APVMA would be improved by better governance structures, including the establishment of a governance board.

1.83 The APVMA had a governance board until it was abolished following the Uhrig Review of the governance of statutory authorities in Australia in 2004.[68]

64 Dr Parker, APVMA, *Committee Hansard*, 1 March 2018, p. 9.

65 Dr Parker, APVMA, *Committee Hansard*, 1 March 2018, p. 16.

66 Dr Parker, APVMA, *Committee Hansard*, 1 March 2018, p. 9.

67 Ms Amy Fox, APVMA, *Committee Hansard*, 1 March 2018, pp 12 – 13.

68 Mr Ian Thompson, First Assistant Secretary, Sustainable Agriculture, Fisheries and Forestry Division, Department of Agriculture and Water Resources, *Committee Hansard*, 1 March 2018, p. 10.

1.84 The VMDA argued that a re-established governance board would lead to improvements in stakeholder consultation, links between the Minister for Agriculture and the APVMA and a further source of ideas and approaches:

> 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.[69]

1.85 Animal Medicines Australia, however, expressed scepticism about the usefulness of such a move:

> It is unlikely that the creation of a new governance structure at APVMA would be sufficient to deliver the substantial improvements needed. The addition of a Board seems likely to merely add another layer of governance and decision-making to the registration process, resulting in increases to timelines and associated costs for applicants, but deliver minimal benefits or service improvements for applicants, or result in improvements in animal health and welfare.[70]

1.86 Dr Parker outlined the governance changes the Authority was undertaking in response to the issues identified in the ANAO audit:

> The agency now has a Major Projects Board and a team to oversee implementation of business improvements, and we are establishing a dedicated program board to oversee our relocation. We reviewed our management of business risk, which resulted in a revised risk management framework and an updated risk profile that we revisit monthly. Our new framework and strengthened risk culture means that risks associated with our relocation to Armidale are being prioritised and managed effectively.[71]

1.87 More broadly, the APVMA governance structure includes an executive leadership team (the CEO, the two deputy CEOs and the SES-level heads of each section of the APVMA), an externally-chaired audit committee and

69 Veterinary Manufacturers and Distributors Association, *Submission 3*, p. 6.

70 Animal Medicines Australia, *Submission 2*, p. 3.

71 Dr Parker, APVMA, *Committee Hansard*, 1 March 2018, p. 2.

the Major Projects Board. The APVMA's Advisory Board was abolished in 2015.[72]

1.88 Representatives of DAWR noted to the Committee that the idea of re-establishing a board for the APVMA is being considered:

> The government is looking at the need for a governance board for the APVMA. The APVMA is one of the few regulatory bodies in the Commonwealth that doesn't have a governance board. Without a governance board, there is a significant responsibility on the chief executive officer and it means a whole lot of things point at one person without the diversity of views you might get by having a board. A board can also provide a mechanism for reporting, accountability and discussing the operational policy issues of the organisation.[73]

1.89 Mr Thompson from DAWR further noted that:

> An issue that has been identified by the ANAO report and by recent reviews is: would a board, which has accountabilities, has a chair and members with a range of experience, help a CEO do things like maintain standards, accountability, consider risk appetite across adopting overseas approaches. Would a board give some of those policy issues that affect how things are done—would a board give more assurance to Dr Parker's recent announcements about how we'll do international assessments? Something like the approach that might be taken to pre-assessments, when signed off by a board, might give that more imprimatur and confidence that it's a well-considered process and a range of views have been taken into account. As I said, the government's giving consideration to a board; it hasn't reached a landing on it yet.[74]

1.90 Dr Parker also referred to two additional reviews he has commissioned: an independent review of the Authority's operational performance (commissioned in August 2017; report published in January 2018) and a process of assurance mapping (begun in December 2017) to ensure that the measures the APVMA has in place will adequately address business risks. Dr Parker noted that the APVMA had committed to implement all recommendations of the independent review and, of the assurance

72 Dr Parker, APVMA, *Committee Hansard*, 1 March 2018, p. 9.

73 Mr Thompson, DAWR, *Committee Hansard*, 1 March 2018, p. 10.

74 Mr Thompson, DAWR, *Committee Hansard*, 1 March 2018, p. 15.

mapping process, would 'take these recommendations forward and embed assurance processes that close any gaps in our risk management'.[75]

Funding

1.91 The APVMA is largely funded through a cost-recovery mechanism of charging applicants for the registration of a product. Witnesses to this inquiry, including the APVMA itself, suggested that the existing model will need to change if the APVMA is to effectively and efficiently met its legislative obligations into the future.

1.92 Animal Medicines Australia made this point, arguing that the industry regulator needs to be adequately funded:

> AMA believes that comprehensive investment in the regulator is urgently needed to bring its infrastructure, processes and guidelines in line with current global standards, and enable the regulator to meet its legislative obligations. The APVMA must be adequately supported and resourced to allow full implementation of the 2014 reforms (including the recommendations in the ANAO report), meet its legislated timeframes for assessments, and continue efforts to improve overall performance without imposing further disruptions to service delivery.[76]

1.93 WA Farmers also called for greater investment in the APVMA, given its critical role:

> WAFarmers believes sound investment in the APVMA is urgently required to bring its infrastructure, processes and guidelines in line with current global standards.[77]

1.94 As noted above, Dr Parker highlighted to the Committee during its hearing that, the APVMA has 'run at a $3.5 million operational loss [per year] for the last three years', and described that as 'unsustainable'.[78]

1.95 Further options for funding the APVMA's digital strategy are currently before government, as that strategy is reliant on additional funding.[79]

75 Dr Parker, APVMA, *Committee Hansard*, 1 March 2018, pp 2 – 3.

76 Animal Medicines Australia, *Submission 2*, p. 3.

77 WA Farmers, *Submission 6*, p. 3.

78 Dr Parker, APVMA, *Committee Hansard*, 1 March 2018, p. 4.

79 Dr Parker, APVMA, *Committee Hansard*, 1 March 2018, pp 12 – 13.

Committee comment and recommendations

1.96 The Committee notes the importance of Australia's agricultural chemicals and veterinary medicines industry to farmers, agvet producers and to the wider Australian public.

1.97 A well regulated industry requires a strong regulator. It is of paramount importance that agvet chemicals are adequately regulated to ensure that they are safe and effective. For that reason, the Committee is concerned by the evidence presented in the ANAO report and by submitters and witnesses to this inquiry that suggests that the APVMA has struggled to fully implement the 2014 legislative reforms on schedule.

1.98 While recognising that the APVMA has made progress since the ANAO audit, and in particular has established stronger governance practices than it held in the past, the Committee is pleased that DAWR is considering re-establishing a Board of Directors. The Committee believes that a board, with members appointed by the Minister, would improve governance of the APVMA by giving additional support and advice to the Chief Executive Officer and could improve links between the APVMA and the Minister.

1.99 The Committee believes, on the evidence it received, that there is a strong case for reconsidering the APVMA's funding model. Under the APVMA's current funding model, it does not appear to have the capacity to reach its statutorily required targets for registering agvet products.

1.100 Noting the intense interest in the APVMA's relocation to Armidale and its ongoing implementation of regulatory reforms, the Committee believes that it would be useful for the ANAO to undertake a follow-up audit to monitor the Authority's progress in responding to those changes. The Committee is also interested in the results of the APVMA's early 2018 survey of staff intentions regarding relocation options, and the effect those results have on the APVMA's management of the relocation project and its work more broadly.

Recommendation 1

The Committee recommends that the Auditor-General undertake a further audit of the Australian Pesticides and Veterinary Medicines Authority in 2019, to assess the APVMA's ongoing implementation of regulatory reforms and its management of the relocation program.

Recommendation 2

The Committee notes and supports the Department of Agriculture and Water Resources in considering, in consultation with industry, the establishment of a Board of Directors for the Australian Pesticides and Veterinary Medicines Authority. The Committee recommends that, if a Board is to be established, the Minister for Agriculture should be consulted in relation to the appointment of Members to provide additional oversight and further links between the Minister and the APVMA.

Recommendation 3

The Committee recommends that the Department of Agriculture and Water Resources actively consider different funding models for the Australian Pesticides and Veterinary Medicines Authority, to enable it to fulfil its responsibilities in a timely manner.

Recommendation 4

The Committee recommends that the Chief Executive Officer of the Australian Pesticides and Veterinary Medicines Authority provide to the Committee by the first quarter of the 2018-19 financial year the results of the staff survey undertaken in early 2018 and the APVMA's consequential action plan and updated risk assessment matrix relating to its relocation to Armidale.

Rick Wilson MP
Chair