Draft Report of the Independent Review of the Agvet Chemicals Regulatory System

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Independent Review Panel

AVA COMMENTS ON DRAFT RECOMMENDATIONS

RECOMMENDATION	KEY WORDS	AVA RESPONSE NOTES
Chapter 1 INTRODUCTION (pages 1-22)		
1. Recommendation The Panel recommends the following vision be adopted as the object of the legislation for the future pesticides and veterinary medicines regulatory system. The Panel recommends the following vision be adopted as the object of the legislation for the future pesticides and veterinary medicines regulatory system. 'A trusted and nationally consistent regulatory system for pesticides and veterinary medicines that enhances and protects the health of humans, animals, plants, and ecosystems while ~~improving~~ allowing access to safe and effective products and uses.'"	Vision	Agree. Animal health and welfare has always been an important concern for all veterinarians. As the Panel identified in its vision, protecting animal health into the future should be a key focus of the future regulatory system.
2. Recommendation	**Objectives**	Generally agree but with following comments
The Panel recommends that the future pesticides and veterinary medicines regulatory system is underpinned by the following 4 equally weighted objectives:		Why equally weighted? Only 1 of 4 objectives is directly applicable to non-production animal species.
• ~~safeguard~~ enhance animal health and welfare		Relying on chemicals to safeguard animal health & welfare ignores all the other health/welfare contributors – access to food/water, human behaviour, etc. etc.

		An objective that is missing, is to promote the judicious use of chemicals – "as much as is necessary, as little as possible", for a variety of reasons Another missing objective is "environmental protection"
• support primary industries		
• protect Australia's trade		
• contribute to biosecurity preparedness.		
3. Recommendation	Regulatory principles	Agree
The Panel recommends that the following principles should govern the design and implementation of the new regulatory system:		
• The regulatory system should be based on risk, not on hazard alone.		
• Processes and decisions should be objective, independent and science based.		
• Regulatory decisions should be transparent, and decision-makers should be responsive to all stakeholders, including the community, users, and the regulated industry.		
• Risk management measures should be reviewed as new information becomes available.		
• The system should be efficient and outcomes-focused by making use of streamlined and fit for purpose regulation.		
• The system should achieve a single nationally consistent model with shared responsibility for controlling the manufacture, import, export, supply, use, and disposal for regulated products.		
• The system should be adaptive to new technologies, practices, and knowledge.		
• The regulatory system should support a resilient supply chain.		Resilient primary produce supply chains (paddock to plate) rely on much more than the agvet chemical regulatory system. If the supply chain of agvet chemicals (raw materials to end user) is

		meant, some wordsmithing is necessary, e.g. “The regulatory system should allow suitably qualified access to essential agvet chemicals.”
Chapter 2 ESTABLISHING A TRULY NATIONAL REGULATORY SYSTEM (pages 23-50)		
4. Recommendation	Harmonisation	Agree. AVA concurs with the Panel’s finding that attempts to harmonise control-of-use through the existing Inter Governmental Agreement have been largely unsuccessful.
The Panel recommends that the Australian Government work with states and territories, in the first instance, to implement a single national applied law approach to control-of-use regulation. This would be hosted by the Commonwealth and operate on the basis of full Commonwealth constitutional reach.		
5. Recommendation	Harmonisation	Agree
The Panel recommends that the need for, and the scope, role and form of a new IGA are considered as part of this review’s implementation. The Panel recommends that the existing IGA be extended until this time, recognising that there are some matters, such as those relating to funding, that are unlikely to be resolved in the interim period.		
6. Recommendation	Harmonisation	Agree
The Panel recommends that should there be a need for an IGA in future, it should reflect the lessons learnt from the shortcomings of the current IGA including that it:		
• provides that where consensus on a common approach cannot be reached, a majority (e.g., two-thirds) agreement by jurisdictions will prevail		
• requires any jurisdiction that departs from the IGA approach to provide a public reason for such departure		
• mandates minimum resource levels for regulating control-of-use, to effectively meet assurance and compliance obligations (perhaps as a proportion of each jurisdiction’s domestic production value)		
• requires regular input by each jurisdiction for the purpose of public reporting against performance indicators for the entire regulatory system, supported by clear targets or goals		
• requires regular publication (or input to the Commissioner’s reporting) of performance against these indicators and targets or goals.		

7. Recommendation	Commissioner	Agree. Currently, the regulatory scheme appears to have no identifiable leader and responsibility for the many elements is fragmented and decentralised. Whilst the APVMA is a technical, science-based agency it lacks policy expertise and maintaining the APVMA as a structurally separate, independent national regulatory agency should be founded on a strong scientific evidence base. In this respect the APVMA should accept input from subject matter veterinary medicine and vaccination experts external to the APVMA for registering veterinary medicines when internal scientific expertise is inadequate. The APVMA does not appear to have the appropriate risk appetite to deliver some regulatory areas based on stakeholder feedback and the Panel's engagement with the APVMA which demonstrated the agency's lack of willingness to meaningfully entertain the possibility of innovation or reform, as well as a reluctance to make greater use of the lower regulatory effort tools already available in legislation. Specific examples were outlined within the report where the Panel heard repeatedly of 'buck passing' between agencies which left stakeholders confused as to who

		could assist with their issue or inquiry. The Panel emphasised that the Commissioner will not be just another 'layer of bureaucracy' and would also have the authority to convene Expert Advisory Panels. The panels would consist of experts in the fields of public health, regulatory theory and implementation, and others as appropriate to consider contemporary issues of public concern and provide independent advice on those matters. The AVA strongly supports the establishment of a Standing Expert Veterinary Advisory Panel external to the APVMA to assist the new Commissioner and the APVMA – See Annex 12 Expert Advisory Panel
The Panel recommends the establishment of a statutory office holder in the Department of Agriculture, Water and the Environment to be known as the Commissioner for Pesticides and Veterinary medicines Stewardship.		
8. Recommendation	Commissioner	Agree.
The Panel recommends that the Commissioner will have responsibility for control-of-use functions including associated licensing activities.		
9. Recommendation	Commissioner	Agree.
The Panel recommends that the Commissioner advise Government on the performance of the regulatory system as a whole, based on public reporting of whole-of-system performance measures.		
10. Recommendation	Commissioner	Agree.
The Panel recommends that the Commissioner have responsibility for convening and hosting a number of forums including a Stakeholder Forum, Operational Forum and Expert Advisory Panels.		

11. Recommendation	Commissioner	Agree.
The Panel recommends that the Commissioner administer relevant grant programs and refer matters to operational areas for further accountable action as necessary.		
12. Recommendation	Commissioner	Agree.
The Panel recommends the Commissioner report publicly on the progress of the reforms in its first year, and as part of regular biennial reporting on the state of the regulation system as a whole.		
13. Recommendation	APVMA board	Agree.
The Panel recommends the establishment of a 5-member, skills-based board (including the CEO of the APVMA as an ex officio member) for the APVMA to strengthen the Authority's governance arrangements, provide the necessary oversight to support the regulator in managing operational, financial and performance matters, and drive the reform agenda.		
14. Recommendation	Forums and expert advisory panel	Agree.
The Panel proposes the establishment of 2 formal and one ad hoc consultation mechanisms by the Commissioner to consider, and offer advice to Ministers and the Commissioner as appropriate on, the impacts and other consequences of policies, laws and other initiatives that affect, or are affected by, the use of pesticide and veterinary medicine products. These mechanisms are:		
• a Stakeholder Forum		
• an Operational Forum		
• an Expert Advisory Panel (as needed).		
15. Recommendation	Forums and expert advisory panel	Agree.
The Panel recommends the Stakeholder and Operational forums have terms of reference consistent with those set out in Annex 10 and Annex 11.		
16. Recommendation	Performance measures	Agree.
The Panel recommends that the Commissioner establish a set of comprehensive performance measures that cover the entire regulatory system. The Commissioner should be responsible for producing a biennial report of whole-of-system		If access to veterinary medicines is part of the vision, this should be an important performance measure,

performance and make this report publicly available. The biennial reports would review progress in implementing the reforms decided by the Government in light of the Panel's current report. Reporting should commence 2 years from commencement of implementation of the proposed system reforms to allow a reasonable transition period for measuring impact.		e.g. the number of Minor Use Minor Species (MUMS) label claims registered
Performance measures, as a minimum, should address:		
• health impact		
– establishing formal human, animal, and environmental health risk indicators		
– number and nature of adverse experience reports and pharmacovigilance findings, and time taken to respond to adverse experience reports and any consequential actions.		
• industry impact		
– supply, use and disposal of pesticides and veterinary medicines.		
• community impact		
– social attitudes		
– community outreach and engagement.		
• regulator performance		
– number and type of regulatory decisions by the APVMA and Commissioner		
– number and type of audits and compliance activities, including information and education campaigns.		
• responsiveness to community concerns raised.		
17. Recommendation	Health risk indicators	Agree.
The Panel recommends that the Commissioner establish health risk indicators for Australia, similar to those used in the European Union, and publish outcomes in its reporting of performance measures.		Need to ensure the indicators are appropriate for Australia.
18. Recommendation	APVMA timeframes	Agree.
The Panel recommends the retention of statutory timeframes for the APVMA to complete its pre-market assessments as a vital input measure to the regulatory system and recommends that statutory timeframes should be expanded to a		Should be a performance measure

range of other decisions, such as licensing and responsiveness to the Stakeholder Forum, in the future regulatory system to improve transparency and accountability.		
Chapter 3 PROTECTING THE HEALTH AND SAFETY OF PEOPLE, ANIMALS, AND THE ENVIRONMENT (pages 51-77)		

19. Recommendation	Surveillance system	Agree. High standards in animal welfare and the humane treatment of animals are essential for maintaining the social licence for sport e.g. horse and greyhound racing, livestock production and domestic and international trade in animals and animal products. Safe and effective veterinary medicines should be available to treat diseases. In addition, the AVA and the community expect good animal welfare in the management of vertebrate pest animals including horses which should be part of any contemporary regulatory system of protecting the health and safety of people, animals, and the environment. Reporting of the use of veterinary medicines has many benefits, however, product registrants can only report sales data and quantities of active constituent used in manufacture of veterinary medicines, not how the product was ultimately used. A system of clinical record review and audit to determine actual use that was anonymised and non-threatening could provide valuable ongoing real time information. Absence of data about system performance will become increasingly unacceptable to both industry and the community in future. Conversely, the availability of convincing data on safe and

		effective performance would provide strong support for the social licence to continue to use veterinary medicines in Australia.
The Panel recommends that the Commissioner be assigned responsibility to build a surveillance system fit for the needs of a 30-year future. The system should:		
• Collate and analyse information from multiple data sources which may include annual pesticides and veterinary medicines sales and volume data, industry quality assurance programs, users records, literature searches, changes in market expectations, decisions by overseas regulators, and intelligence or reports from professional bodies and academic institutions.		
• Incorporate residue detections from monitoring of domestic produce, environmental monitoring data and adverse experience reports to support a more comprehensive surveillance system.		
20. Recommendation	Information access	Agree.
The Panel recommends that the Commissioner develop arrangements to curate all such sources of information to enhance data accessibility and usefulness for research, policy formulation, public transparency, international reporting obligations, and system response purposes.		
21. Recommendation		Agree.
The Panel recommends the Commissioner consider how to best utilise and capitalise on current record keeping requirements for use of pesticides and veterinary medicines in Australia.		
22. Recommendation	Produce monitoring	Agree.
The Panel recommends a Government-led national domestic produce monitoring program be established.		
23. Recommendation	NRS extension	Agree.
The Panel recommends that the domestic scheme should build on and extend the current National Residue Survey infrastructure, which would leverage existing processes for sample collections, laboratory analysis and result reporting, as well as staff expertise.		

24. Recommendation	Produce monitoring	Agree.
The Panel recommends the Commissioner finalise the design of the domestic produce monitoring program with multi-year sampling priorities determined in consultation with the National Residues Survey, primary producers, manufacturers, state and territory governments, and the community.		
25. Recommendation	Environment monitoring	
The Panel recommends that water, waterway sediment and soil samples be monitored to detect the levels of pesticides in the environment. The testing program should be scalable and targeted, based on risk. Implementation should be graduated to reflect available resources and ensure cost effectiveness.		Agree. This section (R25-R29) refers to pesticides in the environment and not directly to veterinary medicines. However, because of their importance these recommendations are supported. It is recommended that surveillance of AMR is also included in environmental monitoring.
26. Recommendation	Environment monitoring	Agree.
The Panel recommends that an Environmental Monitoring Plan be developed through consultation to identify areas of priority for monitoring.		Shouldn't the plan come first – ie R26 should be swapped with R25
27. Recommendation	Environment monitoring	Agree.
The Panel recommends the Commissioner use a risk-based methodology to determine the collection locations for environmental monitoring based on regulatory need and recommendations through consultation with the Stakeholder Forum and taking account of the 13 major water catchments and key agricultural zones (for soils) across Australia. Further, the Panel recommends the collection and testing of samples be done on a seasonal basis to take account of differing cropping, weather patterns and pesticide patterns.		

28. Recommendation	Pesticide MRLs water	Agree.
The Panel recommends the current guidance for levels of pesticides in potable and non-potable water ultimately be given the same status as MRLs and enforced by relevant water and environmental agencies.		
29. Recommendation	Environment monitoring	Agree.
The Panel recommends that environmental monitoring of waterways, sediment and soil be funded by the government. Residue soil testing should be incorporated into any soil monitoring program established under the National Soil Strategy.		
30. Recommendation	ADRs	Agree. The majority of AERs received by the APVMA relate to animal health concerns arising from the use of veterinary medicines. Pharmacovigilance systems which utilise adverse experience reports to collate, monitor, respond to and identify trends are important and reporting on veterinary medicines is well advanced compared to pesticides, which is at best lacking. The APVMA's compliance activities need to have continued access to AERs and the Commissioner and the APVMA will need to closely collaborate on AERs.
The Panel recommends that the machinery for streamlining processes for adverse experience reporting be provided in legislation for holders of approvals, registrations, exemptions, and licences. These holders will be obligated to notify the Commissioner when they become aware of an unintended effect, safety related issue, lack of efficacy, quality or contamination concern (either product related or through unintended exposure to humans, animals or the environment), or other adverse events associated with a pesticide or veterinary medicine product.		
31. Recommendation	ADRs	Agree.
The Panel recommends the Commissioner collates adverse experience reports to establish a system wide 'pharmacovigilance' approach, expanding on the approach adopted internationally for veterinary medicines.		

32. Recommendation	ADRs	
The Panel recommends that data presented through adverse experience reports is analysed to identify issues and trends arising from these reports and, in concert with the information available to the Commissioner through expanded monitoring and other intelligence sources, inform the broader surveillance system and priority setting.		Agree.
33. Recommendation	Product-use information sharing	Agree.
The Panel recommends sound information sharing practices be established between the APVMA and the Commissioner to allow APVMA access and the opportunity to respond to those matters relating to the registration and exemption of products, or the supply of those products.		
34. Recommendation	ADRs	Agree.
The Panel recommends the Commissioner establish an interface that provides users and the public with contemporary details of validated adverse experience reports. The Panel also recommends the interface support the streamlining of submission of adverse experience reports.		
35. Recommendation	ADRs	Agree. Data gathered through system surveillance would support evidence-based advice and better inform the regulatory system. It will also identify information gaps to inform scientific research and build national capacity with experts in veterinary medicines. The recommendations are therefore supported. Consideration should be given to establishing an AER Advisory Panel to harness the wealth of appropriate skills present in the veterinary profession.
The Panel recommends that trends identified through system surveillance data be reported publicly in the Commissioner's biennial report.		

36. Recommendation	ADRs	Agree.
The Panel recommends that the residue monitoring results of domestic produce and environmental water and adverse experience reports should be publicly available ASAP , providing the community with assurance that pesticides and veterinary medicines are being used safely, or in cases of exceedances, that response action is being taken.		The currently published NRS annual reports are often a year or more late – this time lapse should not be more than 3 months.
37. Recommendation	ADRs	Agree.
The Panel recommends that the results of these programs should be collated and published in an informative and educational manner. The data must be de-identified and privacy concerns must be addressed prior to publishing, consistent with the Australian Privacy Principles.		
38. Recommendation	Chemical reviews	Agree.
The Panel recommends improving the transparency and responsiveness of the chemical review process. This will be achieved by establishing a formal trigger (such as a relevant international decision in specific circumstances) for a chemical review to the APVMA.		
39. Recommendation	Chemical reviews	Agree.
The Panel recommends that the trigger should not result in repeated near identical reviews within a 3-year period.		
40. Recommendation	Chemical reviews	Agree.
The Panel recommends that, if in its judgement the APVMA does not consider that the trigger is relevant to Australian circumstances, it may determine not to undertake a review. The APVMA would be required to publish a statement of reasons for its decision, disclosing any information relied on to inform its decision.		
41. Recommendation	Chemical reviews	Agree.
The Panel recommends the APVMA continue to be able to initiate a review if it is concerned that the risks of a product are not being suitably managed.		
42. Recommendation	Chemical reviews	Agree.
The Panel recommends the Commissioner have responsibility for referring substances to the APVMA for review where issues have been identified through its system-wide surveillance program.		

43. Recommendation	Chemical reviews	Agree.
The Panel recommends that the chemical review process rely on established suspension, cancellation, and variation administrative processes. This approach will streamline regulation and rely on processes established for other administrative actions by the APVMA.		
44. Recommendation	Humaneness score	
The Panel recommends that a humaneness score for vertebrate pest control products, based on the model developed and used by the NSW DPI Vertebrate Pest Research Unit, and adopted by the Australian Animal Welfare Strategy, be presented on the label so that users can make an informed decision regarding the humaneness of a vertebrate pest control product.		Agree. This humaneness score should be developed in consultation with the Australian Veterinary Association.
Chapter 4 ENSURING RESPONSIBLE USE (pages 78-114)		
45. Recommendation	General product obligations	Agree. Placing the notion of a shared responsibility on all users will require considerably more educational effort to be applied by the Commissioner and APVMA. Notwithstanding, Implementation of standards may be variable. For these reasons the recommendations 45-47 is supported only on the condition that further significant education is provided.
The Panel recommends (concurrent with the recommendations for achieving nationally consistent control-of-use) that general product obligations should apply to dealings with pesticides and veterinary medicines to formalise and acknowledge responsibilities of all users across the life cycle of a product from design to disposal.		
46. Recommendation	General product obligations	Agree.
The Panel recommends the general product obligations build on existing processes already operating in industry, including codes of practice, WHS risk management plans, spray diaries, animal treatment records, and industry QA and		How about reviewing, simplifying and consolidating the existing processes – improving their

stewardship schemes and be consistent with existing management practices to minimise regulatory burden with meeting these obligations.		efficiency, and reducing the regulatory burden?
47. Recommendation	General product obligations	Agree.
The Panel recommends the general product obligations be performance based, preventative, tailored, integrated and consistent, and apply to the life cycle of pesticides and veterinary medicines products. The expectations that apply to general product obligations shall be limited to what is reasonably practicable for the particular obligation holder to avoid harms to health, safety and trade, and actions to demonstrate compliance through suitable analysis, systems and record keeping (Annex 7 provides suggested example obligations).		

48. Recommendation	licensing veterinary medicine activities	Agree. Recommendations 48-50 are generally supported. However, there are issues with recognition of registration of veterinarians in some jurisdictions. National Recognition of Veterinary Registration (NRVR) is in place in Victoria, South Australia, Tasmania, ACT and Queensland. Each of these jurisdictions recognises the registration of a veterinarian in any other state or territory of Australia with 'deemed registration'. Under NRVR veterinarians register in the state or territory in which they reside. Registration fees will be payable only in one state for states participating in NRVR. In practical terms a veterinarian with full registration who resides in NSW, e.g., will be deemed as registered should they wish to work in the ACT, Queensland, South Australia, Tasmania, Victoria. Although the Panel considers that recognition of veterinary registrations in jurisdictions is out of the remit of this review, the Panel is nonetheless entitled to make a recommendation that the Western Australian and Northern Territory Governments should be encouraged to participate in the National Recognition of Veterinary Registration scheme.

The Panel recommends a national licensing framework be developed by the Commissioner to operate under a single national law to regulate activities with pesticides and veterinary medicines. All licences for individual schemes created under the national licensing framework would, for the most part, be issued by the Commissioner, who would also have responsibility for compliance and enforcement activities associated with activities conducted under a licence. The exception would be good manufacturing practice licensing, which would continue to be administered by the APVMA.		
49. Recommendation	licensing veterinary medicine activities	Agree.
The Panel recommends that such licences, where relevant, incorporate mandatory licence conditions that allow for the recognition of industry quality assurance schemes.		
50. Recommendation	Special use licence	Agree.
The Panel recommends that existing licensing schemes (Commonwealth, state, and territory) are transitioned to the new national licensing scheme, except where it is inefficient, or a licensing approach is no longer considered the most appropriate basis for regulation under the revised regulatory system.		
The following are the Panel's proposals for initial licensing schemes under the new national licensing framework:		
• supply of internationally registered products		
• good manufacturing practice		
• supply or use of substances for research purposes		
• supply of hormonal growth promotants		
• dealings with Stockholm Convention substances		
• supply or use of restricted chemical products as defined under the Agvet Code (possibly including Schedule 7 Poisons Standard products)		
• aerial application of pesticides (pilots and contractors that employ pilots, drone operators)		
• ground applicators		
• commercial pest controllers (pest management technicians)		

• special use licence to use a product contrary to the withholding period, re-entry interval, export slaughter interval or spray buffer zone.		
51. Recommendation	Education training	Agree. Veterinarians are university and professionally trained, have their registration accredited by state and territory jurisdictional authority, so are registered for the responsible use of veterinary medicines. Refer also to veterinary profession overview and DVM degree and CPD obligations.
The Panel recommends that all operators who apply chemicals in a commercial setting (be it agricultural or domestic) complete accredited education, training, competencies or other relevant qualifications in chemical use and application techniques, including handling, storage, risk assessment and management, end of life cycle disposal and recycling, regardless of whether the activity is subject to licensing.		This could inadvertently lead to adverse animal welfare outcomes if veterinary medicines were not under the control of a veterinarian.
52. Recommendation	Training standards	Agree
The Panel recommends that the Commissioner completes the work of HACCUT to establish training standards for restricted chemical products and Schedule 7 poisons, and builds on it to develop a comprehensive set of publicly available national training and competency standards for dealing with pesticides and veterinary medicines.		
53. Recommendation	Competency standards	Agree
The Panel recommends that competency standards be established for roles introduced through other recommendations in this review. These include:		
• accredited assessors who undertake third-party assessment work for the APVMA (see Chapter 6)		
• government auditors engaged to ensuring compliance with licensing requirements under veterinary manufacturing standards, (see Chapter 6), access to internationally registered products (see Chapter 5) and other nationally consistent licensing schemes.		

54. Recommendation	Competency standards	Agree.
The Panel recommends that where similar industry-based accreditations or other qualifications exist or are developed, these may also be recognised as meeting the requirements for the qualification or licence, subject to review by the Commissioner.		
55. Recommendation	Training quality	Agree.
The Panel recommends that the Commissioner work with the ASQA and industry associations responsible for industry-based accreditations to ensure quality of training outcomes, and that training is adapted to meet the needs of pesticides and veterinary medicines users into the future. The Panel suggests that the Commissioner examine the benefits of micro-credentials when developing the standards.		
56. Recommendation	Smart labels	Agree.
The Panel recommends essential information that relates to safety, first aid, disposal, or use restrictions remain affixed to the product container, but that consideration is given to how it could be enhanced through more comprehensive smart-label content.		
57. Recommendation	Smart labels	Agree.
The Panel recommends that the opportunities to enhance labelling through additional smart-label content be actively pursued and implemented with a stronger sense of urgency than has been the case to date. The result should be safer use, a more informed user as well as an improved user experience.		
58. Recommendation	Smart labels	Agree.
The Panel recommends that the Commissioner continues to scan the technology horizon to identify additional emerging technologies that may assist with labelling reform.		
59. Recommendation	Labelling	Agree in principle, but see following comments.
The Panel recommends that the regulatory assessed elements of the label approved by the APVMA be limited to that information which is not assessed by other regulatory systems.		It is essential that the APVMA assess product efficacy and effectiveness as well as safety and quality. The AVA understands that the GHS labelling system is not required for veterinary medicines

60. Recommendation	Labelling	Agree.
The Panel recommends the product label must comply with general conditions of registration to ensure the risks of the product can be managed. To implement this, the Panel recommends the establishment of general statutory conditions of registration to which the product label must comply, along with urgent completion of a labelling standard. Where relevant, compliance with the labelling standard would be made a condition of registration (or form part of the licence to supply overseas registered products). More details of these proposed conditions are provided in Annex 6.		
61. Recommendation	Labellling	Agree.
The Panel recommends manufacturers should be permitted to (and indeed, should be encouraged to include) include additional personal protective information on product labels, provided it is not inconsistent with the regulatory assessed label elements.		
62. Recommendation	Labellling review	Agree.
The Panel recommends that every 5 years, at a minimum, the registration holder must conduct a review of label content to ensure the information on the label is current and remains correct – noting that emerging scientific evidence or consumer concerns could also trigger a review, including a labelling review, at any time (see chemical review discussion in Chapter 3).		
63. Recommendation	Labellling	Agree.
The Panel recommends regulatory action to ensure responsible stewardship and control-of-use be considered against the regulatory assessed elements of label requirements and not against the 'approved label'.		
64. Recommendation	Pesticides	Agree.
The Panel recommends that the Commissioner be empowered to publicly report a list of companies importing or manufacturing pesticides in Australia that are not participating in the current voluntary industry programs, addressing container management, recycling, and disposal or their equivalent.		
• The list would be published on the Commissioner's website or as part of the Commissioner's biennial statutory public assessment reports on the state of the system.		
65. Recommendation	Good disposal practice	Agree.
The Panel recommends encouraging industry QA schemes to include requirements and guidance on good disposal practice as part of being deemed to meet General Product Obligations (see Section 4.1).		

66. Recommendation	Good disposal practice	Agree.
The Panel recommends good disposal practice be considered as conditions for relevant licences.		
67. Recommendation	Product stewardship	Agree.
The Panel recommends that the Commissioner consult with industry and manufacturers to enhance safe recovery, recycling, and disposal arrangements for Intermediate Bulk Containers.		

68. Recommendation	Compounding	Agree. Products compounded by a veterinarian, or by a pharmacist as prescribed by a veterinarian, do not fall within the existing legal definition of a veterinary medicine, and therefore are not currently captured by the regulatory system. As a result, they are not subject to the APVMA safety, quality, efficacy, and risk management controls that apply to registered veterinary medicines. Accordingly, they may not be subject to good manufacturing practice (GMP) controls. Because they are not subject to the same suite of regulatory controls as registered veterinary medicines, these products may pose greater risks in relation to product efficacy, animal safety, and manufacturing quality including heightened risks of contamination and chemical residues. These risks may have negative impacts on animal welfare, food safety and trade. Contamination and chemical residues are a particular concern for food producing species as well as in some other situations such as horse or dog racing, where unintended contamination of registered and compounded products has led to positive doping results. The ability to prescribe such products is a professional privilege

		of a veterinarian but a registered product should always be the first choice, when suitable and reasonably available. The manufacturing quality for compounded products is paramount and compounded products should be subject to minimum manufacturing standards to help assure this. Currently, there are only Australian guidelines for compounded veterinary medicines and the AVA is developing professional standards of practice for compounding veterinary medicines The APVMA should work with the AVA and the Pharmacy Board of Australia to ensure one or more suitable standards are finalised speedily. These recommendations 68-72 are therefore supported.
The Panel recommends that veterinary medicine products compounded by a veterinarian or a pharmacist, for any animal treatment are brought within the scope of the future regulatory system for veterinary medicines but are exempt from requirements of registration where they comply with prescription by cascade.		
69. Recommendation	Compounding cascade – see also ANNEX 9	Agree.
The Panel recommends that the prescription cascade provides that registered products must be considered first and compounded products are prescribed only ~~in order to address an issue that is unable to be addressed through~~in the absence of~~h~~ a suitable and reasonably available registered or exempted products.		Recommend adoption of the AVA decision tree (cascade) – accompanying this submission (SHOWN IN ATTACHMENT C)

70. Recommendation	Compounding cascade	Agree.
The Panel recommends that the prescription cascade is finalised and implemented by the Commissioner under the single national law for control-of-use.		
71. Recommendation	Compounding GCP ADR reporting	Agree.
The Panel recommends that an exemption to the requirement for licensing the production facility should be granted where the facility complies with a good compounding practice standard for veterinary medicines, and there is an arrangement for the reporting of adverse experiences.		
72. Recommendation	Compounding standards	Agree.
The Panel recommends that the APVMA works with the Australian Veterinary Association and Pharmacy Board of Australia to ensure one or more suitable standards are funded speedily to enable the exemption described in recommendation 68.		
73. Recommendation	Responsible use - pesticides	Agree.
The Panel recommends establishing a national rule for pesticides under the single national law for control-of-use that sets out the requirements for a pesticide product's responsible use, including off-label use, and the records that must be kept establishing responsible use.		
74. Recommendation	Responsible use – veterinary medicines	Agree.
The Panel recommends establishing a national rule for veterinary medicines under the single national law for control-of-use that sets out the requirements for a veterinary medicine's responsible use, including a prescription cascade that applies to all animal use, and the records that must be kept establishing responsible use.		

Chapter 5 IMPROVING ACCESS TO PESTICIDES AND VETERINARY MEDICINES (pages 115-163)		
75. Recommendation	Veterinary medicines – risk based regulation	Agree in principle with recommendations 75-80. Vaccines containing GMOs are a growing part of the suite of veterinary medicines and this growth will increase in future. These products would be most appropriately regulated and assessed by the APVMA as veterinary medicines, with the OGTR providing advice and receiving notification of application outcomes.
The Panel recommends refocusing the scope of the future regulatory system to better target assessment effort towards risk, and to provide a stronger identity to the regulatory system, and provide safe access to pesticides and veterinary medicines for Australian primary producers, veterinarians, and home and garden users.		
76. Recommendation	Veterinary medicines - definition	Agree.
The Panel recommends new definitions for pesticides and veterinary medicines as outlined in Annex 5 and excluding product classes or uses that are expected to have low hazard or low exposure or are effectively regulated by other regulators.		
77. Recommendation	Veterinary medicines – low risk exemptions	Agree.
The Panel recommends the provision of exemption pathways which remove premarket regulation for certain low regulatory concern products. This would occur by either exemption from assessment or from registration where established standards are met.		

78. Recommendation	Veterinary medicines – standards	Agree.
The Panel recommends that relevant standards would be developed by the Commissioner in consultation with industry.		
79. Recommendation	Veterinary medicines – hazards	Agree.
The Panel recommends that in conjunction with this reform, a potentially hazardous or injurious substance (PHIS) list be established.		
80. Recommendation	Veterinary medicines – GMOs	Agree.
In the case of pesticides or veterinary medicines that contain GMOs, the Panel recommends a system where one regulator (the APVMA or OGTR) becomes the decision maker for an application. Depending on the category of 'substance' and the risks it presents, the APVMA may play no role; that is, the substance may be excluded from the scope of APVMA regulation. In other cases, the regulator making the decision could seek the other's advice when assessing an application and notify it if and when the application is approved. For example, whole GM plants would be excluded from the pesticides regulatory system with the APVMA playing no role in their regulation. Conversely, vaccines containing GMOs could be regulated and assessed primarily as veterinary medicines with the OGTR being notified and providing advice as necessary.		

81. Recommendation	Veterinary medicines – overseas review	Agree in principle. Australia has a world class system for pesticides and veterinary medicines regulation, based upon risk assessment and risk management to protect humans, animals, and ecosystems. Improving access to internationally registered, safe, and effective products and uses is important. Recommendations 81-89 are Agreed to in principle, but consideration should be given to the following point:
The Panel recommends creating a licensing scheme to allow for safe and effective pesticides and veterinary medicines registered by equivalent international regulatory systems but not available in Australia, to be supplied and used in Australia.		There is already a system in place within the APVMA for mutual recognition of overseas registrations. This could be enhanced rather than introduce an entirely new system.
Under the licensing scheme, the Commissioner would be responsible for issuing and overseeing licences that allow for products registered by one or more equivalent international regulatory authorities to be supplied and used in Australia. Licence conditions would include the provision of a detailed Risk Management Plan. Licences would be granted under the single national licensing scheme (see Chapter 2) established under the single national law for control-of-use.		
82. Recommendation	Veterinary medicines – prohibited products	Agree.
The Panel recommends that the Commissioner establish a list of prohibited chemistries and classes of products and uses that would not be allowed under licence. This list would be developed in consultation with the Stakeholder Forum.		

83. Recommendation	Veterinary medicines – overseas review	Agree.
The Panel recommends licence holders be required to make available all uses approved by an equivalent international regulator, except where the pest, disease, crop or animal is not present in Australia.		
84. Recommendation	Veterinary medicines – comparable overseas regulators	Agree.
The Panel recommends the Commissioner maintain an instrument setting out international regulators determined to be comparable, and that this be reviewed for currency in line with the Commissioner's reporting arrangements (see Chapter 2).		
85. Recommendation	Veterinary medicines – comparable overseas regulators	Agree.
The Panel recommends the Commissioner's determination of comparable international regulators:		
• be based on criteria developed by the Commissioner in consultation with the APVMA and stakeholders		
• be conducted by the Commissioner		
• give priority to identifying equivalent regulatory systems among major launch markets for pesticides and veterinary medicines.		
86. Recommendation	Veterinary medicines – overseas review, risk management	Agree.
The Panel recommends that licence holders:		

• must develop and implement a risk management plan detailing practices for assessing and controlling risks associated with internationally registered products, with specific consideration of unique Australian circumstances		
• be subject to regular audits to ensure they are complying with the risk management plan and other licence conditions		
• be required to make risk management plans, with exceptions for confidential commercial information or other trade secrets, publicly available to ensure the community has confidence that the full range of risks have been identified and are being managed.		
87. Recommendation	Veterinary medicines – overseas review, DP	Agree.
The Panel recommends an internationally registered product cannot be supplied under a licence arrangement where there is an equivalent Australian registered product while a data protection period is active.		
88. Recommendation	Veterinary medicines – overseas review, IP	Agree.
The Panel recommends that intellectual property protections for products supplied under licence be determined in consultation with industry during implementation.		
89. Recommendation	Veterinary medicines – overseas review, risk management	Agree.
The Panel recommends the Commissioner should have powers to request information for the purpose of confirming the operation and adequacy of the licence holder's risk management and compliance with licence conditions. Information on products supplied under licence will be protected as confidential commercial information (commercial-in-confidence).		

90. Recommendation	Veterinary medicines – fast track	Agree. In the current regulatory system, there is no formal mechanism by which an application to register a product filling a critical gap or addressing an unmet key veterinary need, may be recognised as deserving priority consideration. Instead, each application essentially 'joins the end' of the assessment queue when lodged. However, there are mechanisms in place to support access in an emergency situation, such as an exotic disease outbreak. The APVMA can issue an emergency use permit to allow the use of an unregistered product or unapproved active constituent. Therefore recommendations 90,01 are accepted.
The Panel recommends a 'fast track' application process for pesticides and veterinary medicines that meet prescribed criteria (including, but not only, introduction of a new active constituent, use on a crop group, alternatives to chemicals under review, specialised areas classed as minor uses, or controlling pest, weeds or diseases of national significance) to improve access in response to priority needs.		
91. Recommendation	Veterinary medicines – fast track	Agree.
The Panel recommends the criteria for prioritisation be determined by the Minister with advice from the Stakeholder Forum.		
92. Recommendation	Veterinary medicines – use patterns	Agree to 92-94 because there are unnecessary regulatory burden remaining when crossing jurisdictional boundaries.
The Panel recommends the APVMA provide nationally consistent use patterns for pesticides and veterinary medicines as the default arrangement with targeted controls implemented only where warranted by departmental risks.		

93. Recommendation	Pesticides	Agree.
The Panel recommends targeted controls be based primarily on climatic regions, with other regional divisions able to be used where the risk factors to be managed do not correspond to climatic regions.		
94. Recommendation	Veterinary medicines – use patterns	Agree.
The Panel recommends making any pesticide or veterinary medicine use pattern registered in at least 2 jurisdictions lawful for use in all jurisdictions in line with the 2019 decision of the Agriculture Ministers Forum.		

95. Recommendation	Veterinary medicines – access	Agree. It is essential that the future regulatory system provides improved and timely access for emergency, research, and minor use purposes. There is potential to make greater use of the depth of veterinary knowledge and experience, with exemptions drawing on the existing evidence base from published and well-recognised historical clinical practice. There is benefit to Australian biosecurity preparedness in establishing emergency exemptions in advance of a pest or disease incursion however the Biosecurity Act 2015 requires that the Department assess biosecurity risks from importing biological material independently from other post-entry regulatory systems. Conditional on this, recommendations 95-100 are supported, but please note following comments.
The Panel recommends the expanding the support by government to the Improved Access to Agvet Chemicals Initiative, with a view to increasing the industries that benefit from access to the necessary tools for pest and disease management.		The Improved Access initiative is a funding/subsidy mechanism. Is it likely to last for the 30 year time span this review envisages?

96. Recommendation	Veterinary medicines – exemptions	Agree.
The Panel recommends, through the proposed single national law, implementing an exemptions model as a streamlined way of authorising specific activities that would otherwise not be permitted. Exemptions for minor, emergency and research use may be made as legislative instruments by the APVMA.		
97. Recommendation	Veterinary medicines – exemptions	Agree.
The Panel recommends establishing specific criteria to grant an emergency, research, or minor use exemption as long as a use would not jeopardise safety, efficacy, and trade.		
98. Recommendation	Veterinary medicines – exemptions	Agree.
The Panel recommends expanding the authorising of emergency use in advance of the emergency, establishing 2 categories within the public listing of exemptions for 'active emergency exemptions' and 'future-emergency exemptions'.		
99. Recommendation	Veterinary medicines – exemptions	Agree.
The Panel recommends that, in granting an emergency exemption in advance of an emergency (a future emergency exemption), the exemption includes details of the trigger to transition from the 'future' to 'active' exemption category.		
100. Recommendation	Veterinary medicines – research license	Agree.
The Panel recommends the adoption of a licensing scheme that authorises entities to undertake research relating to pesticides and veterinary medicines. The licence is to include a condition that a risk management plan is in place along with quality management systems and regular independent assurance checks including audits.		

101. Recommendation	Veterinary medicines – biological	Agree. Many new biological technologies are being developed, including greater focus on the therapeutic use of monoclonal antibodies, genetically engineered modified live viral vaccines and other gene therapies. Recommendations 101-103 are supported only following a scientific expert panel thorough evaluation.
The Panel recommends the continued investment in expertise and experience with non-synthetic pesticides and veterinary medicines for assessors within the APVMA.		Why is this restricted to non-synthetic veterinary medicines? APVMA Assessors need to be appropriately skilled in all areas, current and emerging.
102. Recommendation	Veterinary medicines – biological imports	Agree.
The Panel recommends that amendments be made to the Biosecurity (Prohibited and Conditionally Non-prohibited Goods) Determination 2016 to expand alternative conditions for imports of biological pesticides and veterinary medicines (and ingredients used to manufacture these commodities in Australia) to facilitate the import of safe material essential to Australian agriculture and manufacturing industries.		
103. Recommendation	Veterinary medicines – biological	Agree.
The Panel recommends that the overall regulatory system performance measures include measuring the system's accessibility to biologically-based products by quantifying the number and growth over time of available biologically-based products.		

104. Recommendation	Veterinary medicines – benefits	Agree. This recommendation is supported because consideration of benefits at the critical point where an application may be facing refusal will still allow the regulator to make a balanced judgement about a registration. It should not override refusal based on animal health and welfare concerns.
The Panel recommends that the APVMA must consider national benefits and the consequences of not having access to a product if the APVMA is proposing to either refuse an application for registration, or to suspend or cancel a registration for reasons other than as an administrative sanction.		
105. Recommendation	Veterinary medicines – data protection	Agree. Innovative new veterinary medicines require substantial investment to develop, and have high regulatory costs for approval, yet they are relatively easy to copy. Pesticide and veterinary medicine producers rely on intellectual property (IP) rules to protect their investment and recover their development costs. The smaller the market (i.e., the lower the potential economic returns) and the higher the costs of market entry – including developing the molecule or use, generating data to satisfy the regulator and fulfil the company's duty of care, and regulatory charges – the more valuable this protection is. Recommendations 105-111 are supported.
The Panel recommends a simple, consistent approach to data protection for the new pesticides and veterinary medicines regulatory system. The ability to limit the regulator's use of certain information will remain a valuable component of the		

future system and will continue to be of great importance to industry. This is vital to protect the value of industry investments and ensure that Australians gain access to the latest innovations in pesticides and veterinary medicines.		
106. Recommendation	Veterinary medicines – CCI	Agree.
The Panel recommends that if a party provides confidential information to a regulator and that if information is used by the regulator for a relevant regulatory decision, then there should be limits on the regulator's use of that information to support a regulatory decision for a competitor's products.		
• These should be consistent with Australia's established international agreements.		
• Information in minor use and emergency exemption applications are a special case and while this may (as is the case for current permit applications) be considered confidential commercial information, it will not qualify for data protection.		
107. Recommendation	Veterinary medicines – limits on regulator use of CCI	Agree.
The Panel recommends that the limits on the regulator's use of information should be the minimum needed to encourage new uses or chemicals but not needlessly impede flow-on innovation (e.g., new applications of established chemistry), competition, and access to alternative chemical products.		
• Equivalent protection periods should be provided for pesticides and veterinary medicines.		
• The same arrangements should apply irrespective of how the information has been provided to the regulator (e.g., associated with a registration application or a chemical review).		
• These periods should only be extended as an incentive to bringing priority uses to Australia, as per the measure in the Bill currently before parliament.		
108. Recommendation	Veterinary medicines – limits on regulator use of CCI	Agree.
The Panel recommends that the periods of limitation on the regulator's use of information should be:		

• 10 years for information relied on by the regulator to register new pesticides or veterinary medicines containing a new active constituent or to approve a new active constituent.		
• 5 years for information:		
– relied on by the regulator to vary an active constituent, register or vary pesticides or veterinary medicines containing an existing active constituent or to issue a research exemption		
– provided in support of a chemical review		
– which is new information provided to the regulator that contradicts the information in the Record or Register or shows the active constituent or product may not meet the statutory criteria.		
109. Recommendation		
The Panel recommends that if there is a public interest reason for the regulator to use information, then the regulator should be able to use that information irrespective of whether it would otherwise be subject to protection.		
• For example, information about a product that is unfavourable (does not support continued registration of a product or use) should not be treated as protected.		
110. Recommendation	Veterinary medicines – IP	Agree.
The Panel recommends that the Commissioner be tasked with ensuring that any intellectual property protection measures for the new scheme to supply internationally registered products under licence align with the other recommendations (including consistency with international obligations), in consultation with industry.		
111. Recommendation	Veterinary medicines – access to IP	Agree.
The Panel recommends discontinuing the APVMA's role in arbitrating data access and compensation agreements between parties with similar products and uses that are under review. Negotiation of data access and compensation is best left as a private negotiation matter between companies.		

Chapter 6 CONTRIBUTING TO SUPPLY CHAIN RESILIENCE (pages 164-175)		
112. Recommendation	Veterinary medicines – API	Agree. Disruptions can, and do occur, in global supply chains, regardless of the size of the market or the nature of the goods and services provided which can be immediate and far reaching. While the pesticides and veterinary medicines regulatory system cannot, of itself, prevent such disruptions, it is important that the system does not create unnecessary barriers to supply continuity and improves resilience where possible. The focus of the regulatory system should be on safe and consistent active constituent manufacture. Considering and approving active constituents at a 'substance level' will allow for sourcing from any site of manufacture that can meet the approved standards, including the impurity profile When approving an active constituent, the APVMA should establish a minimum compositional standard including expected (and if necessary, prohibited) impurities. Provided these standards are met recommendations are 112 – 114 are supported.
The Panel recommends active constituents be considered and approved at a 'substance level', independent of site of manufacture.		

113. Recommendation	Veterinary medicines – API	Agree.
The Panel recommends that the APVMA establish a standard for each active constituent prior to its inclusion in products. The Panel expects that in establishing standards for active constituents due regard is given to matters of commercial confidentiality and intellectual property protection.		
114. Recommendation	Veterinary medicines – API	Agree.
The Panel recommends that the APVMA apply measures to retain access to necessary information establishing the source of the material and its compliance with the relevant standard.		
115. Recommendation	Veterinary medicines – GMP PIC/S	The AVA recognises the absolute importance of having access to high quality veterinary medicines and appreciates the well-established value of the APVMA code of good manufacturing practice. Building quality into manufacturing comes at a cost and AVA seeks to retain high quality without prohibitive cost. The best way of achieving this important balance should be explored. Until there is evidence to demonstrate the impact of this recommendation (for example, via a regulatory impact assessment) the AVA can neither support nor reject recommendations 115-117.
The Panel recommends the APVMA becomes PIC/S accredited.		
116. Recommendation	Veterinary medicines – GMP PIC/S	See above
The Panel recommends the APVMA develop guidance material through engagement with industry to support a streamlined transition from cGMP to PIC/S.		

117. Recommendation	Veterinary medicines – GMP PIC/S	See above
The Panel recommends both export and domestically focused Australian veterinary medicine manufacturers transition to PIC/S level accreditation over a 5-year time period.		

118. Recommendation	Veterinary medicines – 3rd party assessors	Agree. The assessment of veterinary medicines can be complex and lengthy. Assessments must consider a wide range of scientific data and other information to ensure that the product, when used in accordance with the label directions, is safe and does not unduly prejudice trade. The APVMA has historically undertaken the majority of assessment activities in-house, but currently outsources some work to third-party assessors who are experts in the fields of toxicology, ecotoxicology, efficacy assessment. These contracted experts assess data packages lodged with an application to the APVMA, but the final decision on registration remains with the APVMA. Establishing an open and transparent pre-application third-party assessment process would expand the skills base in Australia for assessments beyond the APVMA. Recommendations 118, 119 are supported as per details in Annex 12.
The Panel recommends the establishment of an open and transparent pre-application third-party assessment process to expand the skills base in Australia for assessments beyond the APVMA.		

119. Recommendation	Veterinary medicines – 3rd party assessors	Agree.
The Panel recommends that the model for a third-party accredited assessor scheme be based on the model that was previously included in the lapsed Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018.		
Chapter 7 FUNDING OF THE REGULATORY SYSTEM (pages 176-189)		
120. Recommendation	Funding	Agree conditionally. The costs of the proposed new funding arrangements in **recommendations 120-139** should not adversely affect the costs of essential veterinary medicines or vaccines or deter their use. This is vitally important not only from human health, animal health and welfare perspectives, but also with respect to maintaining Australia's high standards of biosecurity, and preparedness for future exotic disease incursions. Whether the costs of regulation should be borne by industry, whether a component of the obvious public good or other funding measures should also be included should be part of a thorough and comprehensive regulatory impact assessment.
The Panel recommends that in most circumstances the pesticides and veterinary medicines industry should bear the full and reasonable costs of the regulatory functions under the new regulatory scheme.		
121. Recommendation	Funding	Agree conditionally (see above)
The Panel recommends that the existing levy on product sales be continued but at a reduced rate.		

122. Recommendation	Funding	Agree conditionally (see above)
The Panel recommends that the levy be divided into components relating to the costs incurred for undertaking different activities to minimise cross-subsidisation, with each component of the levy being charged only to those that receive the particular service.		
123. Recommendation	Funding	Agree conditionally (see above)
The Panel recommends that where regulatory effort for an activity reflects the volume or value of products sold, the component of the levy should be based on a volume or value of product sales and may be tiered. In other cases, the component of the levy should ideally be a flat charge.		
124. Recommendation	Funding	Agree conditionally (see above)
The Panel recommends that hourly charging should be introduced for activities where regulatory costs are highly variable, while flat fees should be charged where there is little variation.		
125. Recommendation	Funding	Agree conditionally (see above)
The Panel recommends that the costs for applications for registration be 100% recovered directly from applicants through an assessment fee, charged on an hourly basis.		
126. Recommendation	Funding	Agree conditionally (see above)
The Panel recommends that where Government audits are routine and predictable the costs of this service should be incorporated into the fees for the parent program, for example via licence fees. Where the cost of the audit is highly variable, for example veterinary medicines manufacturing audits, the cost should be recovered on a full hourly fee-for-service basis.		
127. Recommendation	Funding	Agree conditionally (see above)
The Panel recommends that mechanisms be developed to allow more significant fees to be paid over time, such as through payment plans.		
128. Recommendation	Funding	Agree conditionally (see above)
The Panel recommends 100% recovery of the costs of issuing and maintaining licences (both for supply side and use activities), including scheduled audits with predictable costs, via application fees. Flat fees should be charged where there is little variation, and hourly charging for activities where regulatory costs are highly variable.		
129. Recommendation	Funding	Agree conditionally (see above)
The Panel recommends that the assessment of applications for accreditation, together with costs to maintain this accreditation, should be 100% recovered from the accredited parties.		

130. Recommendation	Funding	Agree conditionally (see above)
The Panel recommends that full costs for advice given by the APVMA in relation to an application for registration should be recovered, by fees, charged on an hourly basis, with the first hour's advice provided 'free of charge'.		
131. Recommendation	Funding	Agree conditionally (see above)
The Panel recommends that a substantial level of subsidisation for applications to access minor and emergency uses of pesticides and veterinary medicines is maintained.		
132. Recommendation	Funding	Agree conditionally (see above)
The Panel recommends that minor use exemption applications should attract a discounted application fee with the balance of the costs recovered as an identified component of the levy on product sales payable by the registrant (or licence holder).		It should be recognised that minor uses in a major species (for example, egg producing birds or layers) should qualify for consideration of discounted fees.
133. Recommendation	Funding	Agree conditionally (see above)
The Panel recommends emergency use exemption applications should be fully recovered as a component of the levy. A small appropriation should be sought to offset some of the draw on the levy, in recognition that there is a public good element to this function.		
134. Recommendation	Funding	Agree conditionally (see above)
The Panel recommends that as chemical reviews and APVMA compliance and enforcement activities only exist to manage the risks associated with selling pesticide and veterinary medicine products in the Australian market, the costs of these regulatory activities should be recovered entirely from industry via a component of the levy on product sales.		
135. Recommendation	Funding	Agree conditionally (see above)
The Panel recommends that the cost of control-of-use regulatory activities should generally be recovered entirely from industry, via a component of the levy on product sales. However, wherever possible, where the beneficiary is clearly identifiable, such as applicators licensing, a fee for services approach should be used.		
136. Recommendation	Funding	Agree conditionally (see above)
The Panel recommends that the costs of data mining and analysis for system surveillance and monitoring be publicly funding.		
137. Recommendation	Funding	Agree conditionally (see above)
The Panel recommends that the costs of environmental monitoring be publicly funded.		

138. Recommendation	Funding	Agree conditionally (see above)
The Panel recommends that the cost of domestic produce monitoring should be publicly funded.		
139. Recommendation	Funding	Agree conditionally (see above)
The Panel recommends that activities of the Commissioner such as driving the reform agenda, policy development, and advisory responsibilities should remain Government funded and that all other Commissioner costs, being activities that only exist to manage the risks associated with selling products in the Australian market, should be 100% recovered from fees (e.g., licensing) or components of the levy as appropriate.		