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The Harmonised Agvet Chemicals Control of Use Task Group
Agvet Chemicals Branch
Department of Agriculture and Water Resources
GPO Box 858 Canberra ACT 2601

By email only: agvetpolicy@agriculture.gov.au

Dear Task Group

Submission on the national harmonisation of minimum veterinary prescribing and compounding regulatory requirements for veterinary practitioners – Treatment of Livestock

I am pleased to provide comments from Animal Medicines Australia (AMA) regarding harmonisation of minimum veterinary prescribing and compounding regulatory requirements. We welcome the opportunity to develop regulatory requirements that result in greater harmonisation regarding the use of our member's products.

AMA is the peak body representing the leading animal health companies in Australia. AMA member companies are the local divisions of global innovators, manufacturers, formulators and registrants of a broad range of veterinary medicine products that prevent, control and cure disease across the companion animal, livestock and equine sectors.

AMA notes that The Harmonised Agvet Chemicals Control of Use Task Group (HACCUT) proposals result from the recommendations of the 2008 Productivity Commission (PC) Inquiry[1] and subsequent Council of Australian Governments' Agreement[2] to develop a single national framework for the regulation of agricultural chemicals and veterinary medicines.

We look forward to continuing engagement on this important topic. If we can provide additional information at this time, please do not hesitate to contact me.

Yours Sincerely

Ben Stapley
Executive Director

[1] Productivity Commission 2008, *Chemicals and Plastics Regulation*, Research Report, Melbourne.

[2] http://agriculture.gov.au/ag-farm-food/ag-vet-chemicals/domestic-policy/history-of-coag-reforms/regulatory-model

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22 January 2019

Animal Medicines Australia

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1. Summary and Recommendations

Animal Medicines Australia (AMA) is pleased to contribute to the deliberations of the Harmonised Agvet Chemicals Control of Use Task Group (HACCUT). AMA is the peak industry body representing the leaders of the animal medicines industry in Australia. AMA members innovate, research, formulate, manufacture, and register veterinary medicine products to prevent, control and cure disease across the companion animal, livestock and equine sectors. Our members products:

- contribute $2,668 million to the Australian economy,
- create 9,898 jobs,
- generate more than $578 million in wages, and
- reduce annual average household grocery bills by $270.[1]

In principle, AMA supports the harmonisation of veterinary prescribing rights across Australian states and territories. A single set of prescribing rights applicable in all Australian jurisdictions will improve clarity for veterinarians, especially those that work in multiple jurisdictions. A harmonised system may also assist in rapid deployment of veterinary skills and expertise in response to national animal health emergencies – such as the 2007 equine influenza outbreak.

Harmonisation should allow the Commonwealth, states and territories to implement best practice regulation for the benefit of animal health and welfare.

This submission outlines specific impacts that are associated with key harmonised measures. Our comments seek to:

- maintain and protect the integrity of Australia's pre-market assessment scheme for the registration of veterinary medicines,
- protect animal health, and
- reduce risks to animals, users, consumers and export markets associated with veterinary medicines.

AMA seeks to highlight potential risks associated with some elements of the HACCUT proposal with a view to cooperating with the taskforce to refine and improve the final result. The perspectives presented in this submission make specific recommendations related to:

- **Veterinary product compounding**. Compounded veterinary products present potential additional risks which must be carefully managed. While compounded products may provide some further flexibility for veterinarians when treating animals within their care, this should not occur where it creates additional, unacceptable risks.
- **Protecting export market access.** Australia is a significant exporter of animal products and proposals regarding use of veterinary medicines must consider this risk.
- **Responsible stewardship of antimicrobials.** AMA seeks to ensure that harmonised rules as they relate to antimicrobials are consistent with Australian broader efforts to address antimicrobial resistance. AMA is seeking to confirm how the current proposals operate with respect to antimicrobial use.
- **Prescribing cascades.** Cascades are a potentially useful tool to guide veterinarians when choosing veterinary medicine products. While broadly supporting the prescribing cascade concept, AMA

[1] Acil Allen Consulting (2018), Economic contribution of animal medicines to Australia's livestock industries, 2015-16, June 2018.

seeks to ensure that it is appropriate to Australian circumstances and does not result in unacceptable risks.

While AMA welcomes discussion on the merits of each harmonisation proposal, the costs and benefits of each cannot be fully assessed without an understanding of how each reform might be implemented. AMA therefore encourages HACCUT to further consult with all stakeholders on implementation options.

In principle, greater harmonisation of veterinary medicine rules should result in better animal health and welfare outcomes. AMA looks forward to working with the taskforce to refine the proposals to minimise risks and maximise net benefit to governments, industry and the community.

AMA encourages further dialogue in progressing the objectives of these important reforms.

AMA's recommendations to HACCUT are as follows:

Recommendation 1: HACCUT should comply with the Commonwealth Government's commitment to best practice regulation and prepare a Regulatory Impact Statement for harmonisation of veterinary prescribing and compounding.

Recommendation 2: HACCUT should provide greater clarity for the definition of '*exceptional circumstances'.* This may include identifying examples where exceptional circumstances apply.

Recommendation 3: Controls designed to minimise the risk of development of AMR should be limited to products that are relevant to human medicine and should not apply to veterinary products with no relevance to human medicine.

Recommendation 4: HACCUT should enhance flexibility of the prescribing cascade by adding "or if the only products available are not clinically appropriate" to the end of cascade levels (a), (b) and (c).

Recommendation 5: HACCUT should develop a transparent framework for collecting and managing quarterly reporting of use in exceptional circumstances.

Recommendation 6: Further consideration should be given to trade impacts throughout the proposal to ensure that harmonisation of prescribing guidelines does not result in increased risk to trade with key export markets.

2. About Animal Medicines Australia

Animal Medicines Australia Ltd (AMA) is the peak industry body representing the leaders of the animal medicines industry in Australia. AMA member companies are the innovators, manufacturers, formulators and registrants of a broad range of veterinary medicine products that prevent, control and cure disease across the companion animal, livestock and equine sectors.

In the Australian livestock sector, AMA member company products increase farm productivity and deliver improved environmental, health, safety and animal welfare outcomes. These animal medicines also underpin the quality and safety of Australian livestock products for local consumption and for export.

In the companion animal sector, veterinary medicines produced by member companies facilitate longer and better-quality partnerships between humans and animals.

A recent report[2] commissioned by AMA confirms the essential role of animal medicines in supporting Australia's livestock industries. The analysis and report demonstrate that animal medicine products:

- contribute **$2,668 million to the Australian economy;**
- create **9,898 full time jobs;**
- generate more than **$578 million in wages; and**
- resulted in costs savings on an average grocery bill of **almost $270 per annum**.

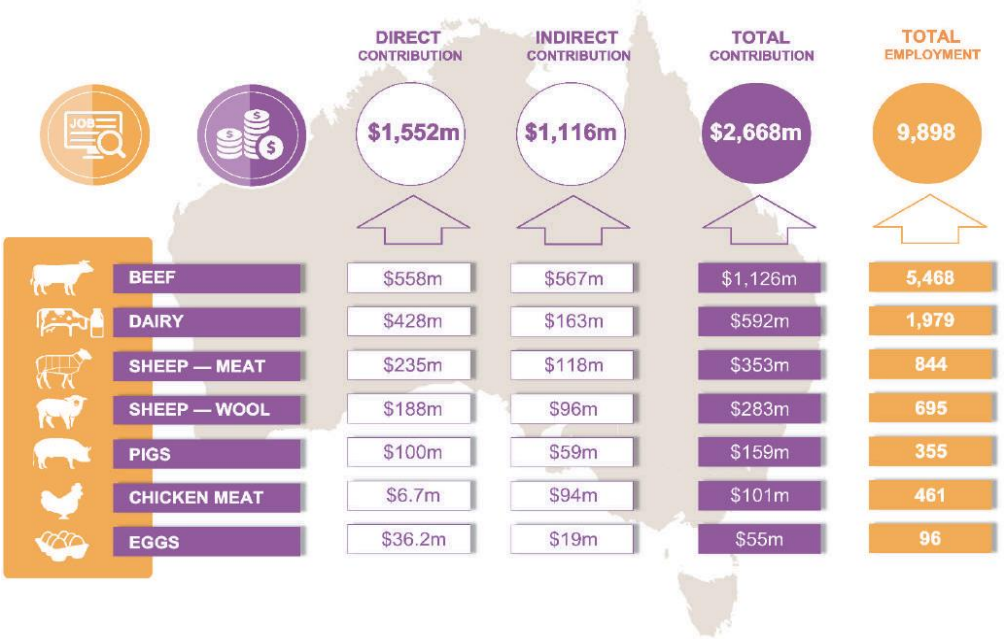

Figure 1: The total economic and employment contribution attributable to animal medicines in 2015-16

3. HACCUT Process and Next Steps

AMA expects that all regulatory proposals will follow agreed policy development processes consistent with the Government's Deregulation Agenda. While AMA considers that there is merit in many of the proposals developed by HACCUT, and recognises the significant work already completed by the taskforce,

[2] Acil Allen Consulting (2018), Economic contribution of animal medicines to Australia's livestock industries, 2015-16, June 2018

it is difficult for AMA to effectively understand all the potential costs, benefits and impacts in the absence of a comprehensive regulatory impact analysis.

As a next step, AMA expects HACCUT to comply with the Commonwealth Government's commitment to best practice regulation and prepare a Regulatory Impact Statement for harmonisation of veterinary prescribing and compounding. The taskforce may also need to apply the Commonwealth Regulatory Burden Measure and Regulator Performance Framework to ensure that these proposals do not create excessive compliance costs for the regulated community or result in an excessive regulatory burden.

AMA expects that the HACCUT analysis must include a description of proposed implementation of the harmonisation reforms, as well as an analysis of the relative costs and benefits of all options considered, and is accompanied by further stakeholder consultation.

Complying with these frameworks and processes assist in keeping the Australian economy as efficient, flexible and responsive as possible.

4. Harmonisation perspectives

In principle, AMA supports the harmonisation of veterinary prescribing rights across Australian states and territories. A single set of prescribing rights that apply everywhere will provide greater clarity for practising veterinarians, especially those who work in multiple jurisdictions. This is particularly important for those working in border regions (for example, Albury/Wodonga), veterinary specialists who provide multi-state or national consulting services, and those who provide outreach veterinary services in remote communities in other states and territories. A harmonised system will also facilitate rapid engagement with the national veterinary workforce to organise and co-ordinate effective responses to national animal health emergencies, such as the 2007 equine influenza outbreak.

Harmonised prescribing rights should also be underpinned by common issues that the harmonisation activity is intended to address. This includes clear identification of the risks associated with the use of veterinary chemicals in different jurisdictions, and justification of a national approach in response. A national response may not be appropriate if the risks identified are regionally-specific and could be more effectively addressed in other ways.

5. Comments on specific items

Definitions

Item 8 - Exceptional circumstances
In the context of a prescribing cascade, the definition of 'exceptional circumstances' is critical. AMA recommends that this definition may be enhanced with examples of when exceptional circumstances may be applicable.

Item 24 – Withholding periods (WHP)

Point (c) should be amended to an explanatory statement (not a sub-point) and reworded:

"If no specific period of time can be determined when the product's residues fall to or below the MRL, or at or about the Limit of Quantification (LOQ) if there is no appropriate Australian MRL, the WHP for the animal and its products is permanent and must not be used for human consumption."

An additional item is required for Export Slaughter Intervals (ESI)

An Export Slaughter Interval is the minimum time that should elapse between administration of a veterinary chemical to animals and their slaughter for export. ESIs manage differences between MRLs allowed for chemicals in Australia and the MRLs (or import tolerances) of its trading partners. ESI advice is important for quality assurance schemes and especially for producers when completing the National Vendor Declaration (NVD) forms as part of the whole-of-chain management of exported product.

General Veterinary Chemical Product Controls

Item 28 – insert italicised text:

"Veterinary advice that results in residues in food or trade species that exceed the MRL *after the label or other applied WHP has been observed* must not be provided."

AMA suggests that this amendment be made to clarify that WHPs are an important mechanism to manage residues and are relevant when considering whether an MRL has been exceeded.

Item 31 - Use at a lower rate for antimicrobials

AMA recognises and supports controlling the use of antimicrobials at rates lower than indicated on the product label unless directed by an APVMA permit. This is an appropriate minimum standard to support high quality prescribing and use of veterinary antimicrobials. However, this restriction should not apply to veterinary antimicrobials with no relevance to human medicine (such as ionophore products) and that have no demonstrated risk of contributing to AMR.

Scientific knowledge and understanding of microbiology, pharmacokinetics and pharmacodynamics have changed significantly since some antibiotics were originally registered (i.e. when the label dose rate was determined). Current best practice, guided by the principles of responsible antibiotic stewardship, strongly recommends that clinical judgement, expert prescribing guidelines and consideration of the local conditions are used to determine the most appropriate dose.

AMA notes with approval that this product control would allow vets to retain their ability to use the most appropriate dose for that circumstance, including where that requires a dose higher than that specified on the label.

Item 38 – Off-label use

AMA has some concerns about potential risks from veterinarians or others using veterinary medicines in food or trade species off-label, except in certain circumstances. These would include:

- When there are no, or few, registered options for a species, and veterinarians use expertise and clinical judgement to select an appropriate treatment regimen that considers key animal health, welfare and trade risks. For example, few products are registered for goats, which are often treated off-label (and at different dose rates) with products registered for use in sheep,
- when using antimicrobials, where clinical judgement, expertise, prescribing guidelines and local conditions are used to determine the appropriate dose rate, or
- in exceptional circumstances (such as outlined at item 39).

AMA considers that using products registered for one food species off-label in a similar food species may be necessary to support animal health. There is often some residues data available to support

off-label use with the determination of an appropriate withholding period in similar species. As such, cross-species off-label uses between different ruminant species, for example, may be required. The lack of registered products in Australia for some food and trade species (such as goats and alpacas), is a key driver of off-label use in these species, and this reality should be recognised in harmonisation efforts.

Off-label use of a companion animal product or human medicine in a food species is associated with much greater risks of adverse impacts and potential residue violations and is not supported by AMA *except* in exceptional circumstances. For example, if a particular animal has significant genetic or social value, and will not enter the food chain, then a veterinarian should be able to treat that particular individual off-label, especially if the alternative (to treating off-label) would be to let the animal die.

In principle, allowing off-label use at greater frequency and higher rates has potential to increase risks to target animal safety, residues and access to export markets. Allowing uncontrolled off-label use also runs the risk of undermining the pre-market registration system administered by the APVMA.

In all circumstances, AMA believes that the clinical judgement of the veterinarian and the welfare status of the animals should be of paramount importance. AMA would welcome the opportunity to discuss the objective sought to be achieved with this proposed control with a view to considering whether there may be alternative approaches.

Item 39 - Cascade approach to prescribing

In principle, AMA believes that the risks associated with veterinary medicines are best managed by pre-market assessment by the APVMA. Veterinarians should be able to rely on access to registered products that work reliably and as expected when label directions are followed. AMA does recognise that there will always be a need for veterinarians to consider treatment options outside of the suite of registered products and uses currently available. A prescribing cascade may be a useful tool to promote registered products wherever possible, but also allow additional flexibility where necessary.

AMA recognises that there are some merits to the cascade concept as presented in this discussion paper, but recommends some necessary alterations to better manage risks to target animal safety, residues and trade.

The proposed cascade specifies that a veterinary practitioner must select a veterinary chemical product for use in food or trade species in the following order:

(a) A veterinary chemical product registered for the food or trade species requiring treatment; or if there is no product:
(b) A veterinary chemical product available for use under a current permit for the particular food or trade species; or if there is no product:
(c) A veterinary chemical product registered for any major food or major trade species used off label; or if there is no such product;
(d) Under exceptional circumstances, a veterinary chemical product that is:
    (i) Registered by the APVMA for animals other than food or trade species, or
    (ii) Registered by the APVMA and used contrary to a restraint or DO NOT statement; or
    (iii) An unregistered veterinary chemical product.

AMA supports the priority given to registered and permitted products at items (a) and (b). In contrast, use of veterinary chemical products off label as specified at item (c) and (d) in the cascade could increase potential residues and trade risks.

There is a significant increase in risk between cascade items (c) and (c). Under item (c), the use of registered products in another similar species, such as another ruminant, may be supported by residues data to determine an appropriate withholding period for that use. However, the risks of adverse impacts and residue violations are much more likely under (d), where companion animal products, human medicines or compounded medicines may be used in a food animal.

However, AMA does recognise that significant controls are also proposed to reduce the risks, especially in exceptional circumstances (item (d)). AMA discusses these in the next section and would welcome the opportunity to discuss how these risks could be best mitigated while permitting additional flexibility to treat animals appropriately. Such risk mitigation measures may include an automatic withholding period to allow sufficient metabolism of the product within the animal.

HACCUT may wish to consider how compounded medicines fit within the cascade. Compounded medicines are generally not subject to the same quality control measures employed for registered products. Further, a lack of safety, efficacy or residues data are likely to result in increased risks associated with the use of the product. Noting these risks, it may be appropriate for compounded products to be considered as 'unregistered veterinary chemical products' that would only be available in exceptional circumstances within the cascade at Item (d)(iii).

Within the cascade, clinical judgement by the veterinarian remains critical – the use of a prescribing cascade in an industry where there are few registered products could restrict veterinarians to using products that are unsuitable. For example, where there is only one registered antibiotic, and there is known resistance to that antibiotic, the cascade could require a vet to use that antibiotic regardless, rather than choosing another antibiotic that may not be registered for that particular situation, but is far more *appropriate* to use in order to maximise therapeutic effect and reduce the selection pressure for antimicrobial resistance. The same principles apply to the use of anthelmintics and ectoparasiticides, where product rotation is critical to maintaining efficacy of the treatment and reducing the development of resistance in numerous nematode and parasite species.

Any cascade therefore needs a degree of flexibility to allow vets to legitimately bypass a step in the cascade based on their clinical judgement – it should not be compulsory to first 'try' the registered medicine if it is clear that it is not appropriate in that situation. For this reason, we propose the addition of the following to each of the statements in Item 39:

"*, or if the only products available are not clinically appropriate*".

6. *Specific questions raised in the consultation document*

Do you support veterinary chemical products registered for animals other than food or trade species being treated in the same way as unregistered veterinary chemical products?

Yes. While more information about pharmacological behaviour might be available, most products would not have been assessed for residues, target animal safety or human health. These are significant components of risk and justify products not registered in food species being treated as equivalent to unregistered veterinary chemical products.

Do you support the use of veterinary chemical products contrary to a 'Restraint' or Do Not' statement on food or trade species, being treated in the same way as unregistered veterinary chemical products?

The presence of a restraint or DO NOT statement on a product label is the Australian equivalent of maintaining lists of medicines that must not be used in animals and/or in certain circumstances. These statements are carefully regulated by the APVMA and are included on a label to address potential residue issues in food species. However, if that particular animal will not enter the food chain (for example, because it has significant genetic or social value), then a veterinarian should be able to treat that particular individual contrary to a restraint, especially if the alternative (to treating contrary to a restraint) would be to let the animal die.

Therefore, whilst in principle AMA opposes the use of veterinary chemical products in a food or trade animal contrary to a restraint or DO NOT USE statement, there may be exceptional circumstances in which treating contrary to a restraint may be appropriate. In these circumstances, a lifetime withholding period for that animal would be appropriate.

Indicate which of the two alternative approaches to exceptional circumstance conditions, if either, you support?

AMA notes that Options 1 and 2 both have limitations.

Some conditions are sufficiently subjective or unclear and may result in impractical guidance. For example:

- Point 41 (ii) includes two reasonably objective measures (i.e. "likely to result in death" and "impact on animal welfare"), however "cause a major setback in production" is less clear and could permit a broader implementation of exceptional circumstances than intended.

- Points 41 (vi) and 41 (ix) state 'there are data supporting its therapeutic use for the particular disease' and 'data indicating there will be minimal risk' - if a product is unregistered, or not registered for that particular species, then there is likely no data and, if data did exist, it would not be in the public domain. It may be difficult for a veterinarian to ever satisfy this requirement.

- Point (iv) specifically excludes antimicrobial veterinary chemicals. Antimicrobial medicines are critically important for animal health and welfare, and to support a safe and sustainable food supply. In some cases, the most appropriate product to use *will* be an antimicrobial product, and veterinarians should be able to use them when necessary to protect the welfare of that animal.

In both options (Item 42 in Option 1, and Item 45 in Option 2), there is reference to 'recurrent disease' as the criterion for the need to seek a permit from APVMA. However, 'recurrent disease' is not defined in this proposal. Veterinarians will require additional guidance to understand when they are required to seek a permit. Further, obtaining a permit also requires a significant investment of resources and takes time to be processed by APVMA. These factors clearly pose substantial and unacceptable risks to health and welfare if animals remain untreated while a permit is sought. A veterinarian must have the ability to treat animals when required.

AMA is broadly supportive of Option 2 (excluding point 41(iv)), as it provides more accountability and requires the reporting of higher risk uses. However, the blanket prohibition on the use of antimicrobial chemicals in Option 2 (Point 41 (iv)) should be removed. At a minimum, AMA would recommend that antimicrobials with no relevance to human health should not be excluded from exceptional circumstances requirements.

Do you think the proposed parameters for managing unregistered use, off-label use of veterinary chemical products registered for animals other than for food or trade species, and use contrary to a restraint statement are appropriate?

AMA has provided comment on this issue in earlier sections of this submission.

If you support the reporting of this type of use, at what frequency should reporting occur i.e. monthly, quarterly etc?

AMA believes that quarterly reporting would be appropriate. However, AMA notes that provisions to collate summaries of exceptional use statements by jurisdictions may undermine harmonisation by promoting different approaches and responses to exceptional use reports. The essential requirements for exceptional use reports should be harmonised and be supported by a transparent framework for collecting and managing that information. Any future revisions of the guidelines should always be accompanied by stakeholder consultation and take into account the diversity of risks and issues in different jurisdictions.

Do you believe that a period of 3 months is too short a maximum period for revisiting a property to reassess animals being treated, in relation to ongoing treatment?

AMA does not support this measure. The most appropriate length of time between veterinary visits will vary tremendously, depending on the clinical condition, animal species, farming system, season and location. It is thus inappropriate to impose an arbitrary time period that has no connection to the reason for that veterinary visit.

What forms of cost recovery would be acceptable, to enable increased and nationally consistent government auditing?

AMA supports efficient, effective and consistent monitoring, compliance and enforcement mechanisms. At this point in time, AMA considers discussion of cost recovery arrangements to be premature, but expects them to be prepared in a manner consistent with best practice regulatory principles and cost recovery guidelines applicable in each jurisdiction