Goat Veterinary Consultancies - goatvetoz

Submission on National Harmonisation of Minimum Veterinary Prescribing and Compounding Regulatory Requirements for Veterinary Practitioners – Treatment of Livestock

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Comments on draft legislation – General

The risk that this legislation aims to address is that of a residue entering the food chain and then endangering either human health or markets for Australian livestock products.

The main risk is however not from veterinarians but from farmers, especially hobby farmers. For example the last detections above Maximum Residue Levels (MRLs) in goat meat as part of the National Residue Survey were from a sheep drench that anyone can purchase from any produce merchant or farm supply store (retail physical building or on-line). Biosecurity legislation in most states now put a general biosecurity obligation on all livestock owners to ensure livestock with MRLs do not leave their property. However without testing to find such animals before they reach the food chain and regulatory action as a deterrent, this legislation lacks teeth. The number of successful prosecutions for incorrect use of veterinary medicines is tiny as documented in the APVMA and state departments' annual reports. Even blatant examples such as this advertisement of an unregistered veterinary medicine were not acted upon - https://rosehipvital-shop.com.au . This website was reported to both APVMA and Biosecurity Qld in October 2017 yet I am still getting Facebook advertisements from them today. Similarly advice offered by non-veterinarians on Facebook groups about higher dose rates than needed and unregistered veterinary medicines for animal treatments remains unmonitored and unacted upon.

Veterinarians are well aware of the risks of chemical residues in the Australian food chain or exports. They risk their veterinary registration and hence their livelihoods if they are caught doing the wrong thing. Most annual Australian Veterinary Association conferences have presentations on this or similar topics. I spoke at one such conference when I was employed in Biosecurity Queensland and was the Standards Officer for Qld (Baxendell, S.A. (2012) "Veterinary Drug Control for Food Animals" Australian Veterinary Association (Qld) Conference, 23 – 25 March at Sofitel Gold Coast, Broadbeach Proc, pages 153-159).

Comments on draft legislation- Specific Section

Re Definition of Major Food and Major Trade species

The goat industry and regulators need clarity. Are goats in this definition or out? I have had different answers from different regulators and even the same regulators but different staff members re goats. Some say no as not listed and some say yes as Australia is the main global exporter of goat meat. The current definition of major trade species of sheep, cattle, pigs and

chickens seems adequate i.e. goat out. Goats must be trade or food species but some allowance should be made for companion animal goats i.e. registered miniature or pygmy goats. The difference between "Major Trade" and "Trade" species needs to be explained and Trade species added to the list of definitions.

Re Under the direct care of a veterinary surgeon

This definition is too restrictive i.e. it is unrealistic to expect farms at long distances from a veterinarian to have each and every animal examined before being treated. I believe if I have visited the property in the last 6 months and am aware of their management, then I can prescribe things such as dry cow therapy based on emailed cell counts or sheep worm drenches at the correct goat higher dose rate based on emailed worm egg count reports without seeing each individual animal. I often collect faecal samples at a visit to a goat farm and then provide enough drench and a prescription if the count is high for the owner to pick up the next day or so. Similarly I can prescribe meloxicam (which is "off label" in goats) for goat kids being disbudded or castrated without a clinical examination of each kid as this definition would require. I can also prescribe veterinary medicines for oestrus synchronization without a clinical exam of each goat. Also if a goat has a local reaction say to a vaccine I should be able to provide a NSAID with a prescription without a clinical examination, esp. if I gave the vaccine a couple of days before. If there is a pink eye, footrot or dermatophilosis outbreak every animal does not need a veterinary examination after the initial diagnosis. Sometimes emailed photos are all that is needed for a preliminary diagnosis of common conditions.

The AVA has a good definition in its policy statement although it is a bit vague i.e. "*The veterinarian has sufficient knowledge of the animal(s) to initiate at least a general or preliminary diagnosis of their medical condition. This means that the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of a clinical examination, or by medically appropriate and timely visits to the premises where the animal(s) are kept."*
So something along the lines of "has clinically examined the animal or has visited the property within at least the last 6 months and is familiar with the management and health of the herd so that a preliminary diagnosis and treatment can be initiated" for clarity and to stop arguments with clients about whether the last visit was soon enough for the definition or not. It could be argued that 12 months is acceptable and even more practical in extensive areas in Northern Australia with long wet periods but it should be a definite number of months so everyone is clear.

Under the General veterinary chemical product controls

13) It should not be just veterinary advice i.e. delete the word "veterinary". I can provide many examples of Facebook groups that give incorrect advice about dose rates and veterinary medicines not registered for that species being offered by well-meaning members of groups but putting meat exports at risk or increasing the chance of developing resistance. Produce merchants should not be allowed to give advice that could cause residues or drug resistance e.g. recommending a sheep drench for goats without a correct dose rate or WHP.

Under Labels and Advice Notes

25) A label must be attached to each container etc.

This would require labels for syringes left on farm the way it is written. Certainly syringes left on farm must have written instructions but not attached, as it is impractical as my current Qld prescription is 1 A4 page with all the details it requires (including APVMA number and expiry date) and would not fit on any label. Queensland requires the most information on the prescription of any state. Syringes should be stored in a refrigerator and this is not suitable for storing the instructions

and prescription information which are best stored in the office or where movement records are stored.

Controls on use under authorisation

17) Off label use

Either veterinarians must be given more freedom to prescribe even if there is a Do Not Use statement or similar restraint statement that makes no sense

Or

Veterinary medicine companies must not be allowed to add a restraint just because they don't want that product used in that species or they don't want to pay to do the milk with-holding period R&D. They should only be allowed to add a restraint if there is a danger of an adverse reaction or similar reason i.e. aspirin in cats or monensin in horses, and that has research evidence of detrimental effects to justify it.

Many worm drenches and coccidiostats now state "not to be used in sheep/goats whose milk may at some time in the future be used for human consumption" or similar words. This means even dairy goat kids or ewe lambs for dairy sheep cannot be treated, even though they will be over a year or more until they produce milk. Levamisole is a good example. In the USA there is a with-holding period of 3 days for milk and 4 days for meat for goats, yet all levamisole sheep drenches can't be used in goats under the current or proposed legislation. Only "Panacur" or generic white drench equivalents and "Caprimec" are registered for dairy goats and there is widespread resistance to the first. Some of the newer drenches initially had statements against use in goats as the distributor have concerns about resistance developing in goats and then spreading to sheep. Yet this just means dairy goat owners buy Q drench, Zolvix, Startect etc. themselves and use at the incorrect dose rates as vet's can't prescribe for dairy goats at the correct dose rates.

There are currently NO lice treatments registered for dairy goats, which is clearly an animal welfare issue. Governments cannot force registrants of lice treatment to register their sheep lice products for dairy goats and hence veterinarians must be able to prescribe treatments based on available knowledge. Most treatments can be in kids, who have a year or more to go before producing any milk.

For prevention of resistance when treating parasites veterinary medicines from at least three different families are needed so they can be used together or in rotation. Goats do not currently have this for either internal or external parasites. Veterinary prescriptions are therefore essential.

Re specified circumstances

Veterinarians nor their clients should not be asked to choose which single animal in a herd they will save with an unregistered veterinary medicine. There are animal welfare considerations that must overrule current regulation especially as there are ways to ensure treated livestock do not enter the food chain e.g. the PIC system. By all means, stop treated animals from export or require residue tests before sale for slaughter or keep out of the human food chain via other methods but vets must be allowed to use vet medicines if a vet thinks it will save animal lives or prevent suffering. There is a query entry in PICs that can be used i.e. the same one that is used for organochlorine (OC) and lead residues.

Under With-holding Periods (30-32)

I keep a spreadsheet of goat dose rates and WHP based on what information that I have – but only about 1/3 have any published scientific papers. Some just have a website or US or UK WHP and some just an email I have from a vet discussion group. Alpaca vets must face similar problems now alpaca meat is sold. Currently I use sheep WHP plus a safety margin (even though goats are known to metabolize drugs more quickly than sheep). But this may not meet the requirement under 31 as it is worded. In minor species such as goats and alpacas, research is very limited and it is unrealistic to wait for this research to be done as it may never be funded.

What we really need is a default WHP of 45 days as is the case in the UK for veterinary medicines with no data. Similarly New Zealand has a default WHP of 35 days for milk and 91 days for meat and their economy is even more reliant on livestock exports than Australia. Gentamycin or similar prolonged antibiotics would not be captured as we have data showing that an 18 months plus WHP is needed for gentamycin and its use in livestock is not allowed anyway.

Questions

1. How should treatment of Food and Trade Species not intended for human consumption be regulated?

Registered miniature and pygmy goats are highly unlikely to enter the food chain and would have the same probability as miniature ponies. As each property has a Property Identification Code (PIC), owners could state that no animals would leave the property to be sold at saleyards or sent to a meat works and this could be recorded on their PIC in the query section. This would allow miniature goats to be treated with a wider range of veterinary medicines, thereby improving their welfare.

2. If the *'single animal'* **specified circumstance** was to be harmonised across jurisdictions, how should this be interpreted and implemented in legislative controls?

   Choosing a single animal and preventing all other animals in a herd from being treated with a veterinary medicine likely to cure it cannot be allowed from an animal welfare point of view.

3. Use of certain veterinary chemical products that are not registered for Food or Trade Species may result in residues for periods of years e.g. gentamicin. Should these uses be permitted and under what conditions?

If treatment with ordinary antibiotics or other veterinary medicines has been tried and was unsuccessful, and a veterinarian believes that gentamycin or similar would be successful, then this should be prescribed and the with-holding period (WHP) set for the required years with each animal correctly identified on the prescription. In addition, the relevant state authority should be notified and a query status added to the PIC. There is also the option for either the veterinarian or the state authority to require fat or milk testing before the query status is removed.

4. Can you propose any alternative **specified circumstances** to extend the rights of veterinary practitioners that should be introduced as an alternative to the *'single animal'* limitation?

Yes – any veterinarian treating more than a single animal should notify the relevant department and request that a query be added to the PIC and to keep a record of this request for 2 years.

5. What controls should be in place to ensure that a veterinary practitioner is accountable for setting an appropriate withholding period?

Veterinarians already have to hold prescriptions for 2 years in some jurisdictions. As an additional safeguard, the owner should also sign for receipt or alternatively a copy of the email reinforcing the

vet's instruction should be kept.

6. How could knowledge of residues and withholding periods by veterinary practitioners be improved to assist when prescribing unregistered veterinary chemical products or off-label use?

Regulators should liaise with the Deans of Australian vet schools and the Australian Veterinary Association. Also veterinary conferences should continue to have lectures on therapeutics and relevant laws as is the case now. The WormBoss team has a document they provide to registered veterinarians that explains how to prescribe sheep drenches for goats in every state of Australia.

7. What controls should be placed on compounding rights so as to not deter registration of new veterinary chemical products, the use of existing registered veterinary chemical products, or the use of the APVMA minor use permit system?

   Must be provided only to clients and labelled for one animal only and one specified client only.

8. How could the various off-label and unregistered uses of veterinary chemical products be identified for the purpose of obtaining permits?

   Permits have proved to be very ineffective method for increasing the range of vet medicines available for use in minor species as demonstrated by their very limited number and the holder being in the main government departments as demonstrated by the current search of the permits database for goats (search on 22/5/18 found only Amitraz tick treatment held by NSW DPI and Foot & Mouth Disease Vaccine emergency permit).

9. How could funding be raised to pay for the establishment of minor use permits for recognised unregistered and off-label treatments?

   Give extra year of data protection for every minor species added to the label of any new vet medicine.

10. Which organisations or industry bodies could be responsible for obtaining and maintaining a permit?

    Those animals that need minor use permits most e.g. minor species such as goat and alpaca, have breed societies that lack the skills to make such an application. All APVMA applications are now made totally on-line and information needed belongs to veterinary medicine manufacturers and is not publically available. Supportive scientific references would be difficult and expensive to source.

11. What additional controls could be considered to better manage AMR?

    Australia already has low levels of AMR and hence the system is currently working. The real risks are those about antibiotic use overseas and then their transfer into Australia via people travelling and imported animal products.

    Veterinarians must be able to use higher dose rates or more frequently than on the label whenever required in their clinical judgment (Hardefeldt et al, 2018). Research and conference publications mean vets can be informed of the need for higher dose rates for certain conditions quicker than labels can be changed.

12. All states and territories accept that *'Major Species'* as defined in their control of use legislation includes the four major species - cattle, sheep, pigs and chickens. Is there any

benefit or disadvantage in including other species such as bees and ducks, as occurs in legislation in certain states?

Clarity is needed as goats are often included in the list of major food animal/trade species due to large export numbers of goats.

13. Are there any particular aspects of the veterinary chemical product control of use legislation that impact between state and territory borders that you do not believe have been addressed in this proposal?

- Different states have different data requirements for veterinary prescriptions with Queensland requiring far too much information e.g. APVMA number. The APVMA number can be found on line on the APVMA website and also on the APVMA iPhone app so writing it down on the prescription is unnecessary.

- The requirement for veterinary prescriptions to have an expiry date on it is unnecessary as it is on the side of the container. Also when prescribing sheep worm drenches for goats, veterinarians will give a prescription so the owner knows the correct dose rate and WHP, but generally they do not sell the worm drench as they generally don't stock it and it can be purchased on line by goat owners at the same price that a vet would purchase it from. This means the vet has to wait for the goat owner to email back the with-holding period once received in order to update the prescription and some owners need a lot of prompting to do so.

- Allow sheep drenches without milk with-holding periods and Maximum Residue Limits (MRL) for milk to be used on kids, lambs and unmated goatlings as any residue would be metabolized during the 5 month gestation.
- Change the system where detections of sheep medications in goat meat only need to be below the sheep MRLs. Consumption of goat meat is generally below that of sheep meat and hence this is a justifiable position to take. Alternatively there should be a default MRL of one part per million. New Zealand had a much higher default MRL for decades.
- Allow a veterinary prescription to over-ride a "Do Not Use" statement on the label except in cases of a documented danger to animal health e.g. the use of monensin in horses or to human health e.g. the use of gentamycin. Where "Do Not Use" statements are used merely due to lack of data to establish milk or meat with-holding periods, then veterinarians should be able to use their discretion and overseas recommendations to prescribe for goats.
- If a worm drench has been registered in New Zealand, the United Kingdom, Canada or the USA for 10 years and there have been no significant residue or toxicity issues reported despite being widely used, then registration should be automatic after a call for public submissions and unless the Australian Pesticide & Veterinary Medicines Authority has found justifications to stop registration. If an Australian distributor or manufacturer has not taken up this opportunity within 6 months, then farmers and veterinarians should be able to directly purchase and import this anthelmintic without an APVMA import permit. Monepantel (Zolvix®, Elanco Australasia Pty Ltd) has been available in New Zealand for many years and New Zealand goat owners have access to it with the correct higher dose rate recommendation.