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**An open letter to representatives of the
Australian Pesticides and Veterinary Medicines Authority,
Australian Veterinary Association, and Australian Small Animal Veterinary Association**

Attention:

Allen Bryce, Program Manager, Veterinary Medicines
Australian Pesticides and Veterinary Medicines Authority

22 December 2009

cc:

- James Suter, General Counsel, APVMA
- Phil Reeves, Principal Scientist, Residues and Veterinary Medicines
- Simon Cubit, Manager, Public Affairs, APVMA
- Kylie Blakers, Public Affairs, APVMA
- Alan Hill, Public Affairs, APVMA
- Jenni Mack, Member of the APVMA Advisory Board
- Heather Yeatman, Chair of the APVMA Community Consultative Committee
- Elvira Currie, Senior Reviewer, Adverse Experience Reporting Program, APVMA
- John Owusu, Principal Evaluator, Veterinary Medicines Program, APVMA
- Raj Bhula, Program Manager, Pesticides Program, APVMA
- Mark Lawrie, President of the Australian Veterinary Association
- Marcia Balzer, National Communications Manager of the Australian Veterinary Association
- Bruce Twentyman, Deputy Veterinary Director of the Australian Veterinary Association
- Graham Swinney, President of the Australian Small Animal Veterinary Association

Dear Allen

**RE: OVER-VACCINATION OF PETS / APVMA POSITION STATEMENT /
VACCINE PRODUCT LABELLING ISSUES**

Thank you for your response to my email dated 16 December 2009.

I will be very interested to read the Australian Pesticides and Veterinary Medicine Authority's Position Statement on Vaccination Protocols for Dogs and Cats. I hope that the detailed comments on the draft APVMA Position Statement provided by Bea Mies¹ and myself² to James Suter will be seriously considered. **Information contained in this letter may also be relevant to the Position Statement.**

Allen, you say that you are hopeful that the APVMA Position Statement will be finalised before Christmas. Given that I first raised this issue with the APVMA back in October 2008³, can you please advise me when the Position Statement is likely to be published, i.e. **when will the public be warned about the prevalent problem of unnecessary vaccination of pets?**

In the area of companion animal vaccines, the APVMA has failed in its responsibility to provide "rigorous and independent evaluation of scientific information about the safety and efficacy"⁴ of companion animal vaccine products. **The community cannot "be confident that the products are safe and effective when used according to label instructions"**.⁵ Manufacturers' revaccination recommendations on canine MLV vaccine product labels are conflicting with duration of immunity information contained in international guidelines. So far, the APVMA has not taken any effective action to address this situation or warn the public of the conflict, despite the

fact dog and cat vaccination guidelines advising of long duration of immunity have been available since 2003.

Immediate action must be taken to redress this situation.

Vaccine product labelling, vaccine product use, and possible adverse reactions

Allen, I will be very interested to hear about progress on the issue of vaccine product labelling. I understand that companion animal vaccine product labelling has been under review in the United States for many years and has still not been resolved.^{6 7}

(Refer to my report 'Is over-vaccination harming our pets? Are vets making our pets sick'⁸ and my paper 'Over-vaccination of pets – an unethical practice'⁹ for more detail and references on vaccine product labelling.)

The APVMA Annual Report 2008-09 refers to international collaboration on scientific matters¹⁰ – is the APVMA liaising with other government regulators such as the US Center for Veterinary Biologics and Britain's Veterinary Medicines Directorate on this issue?

Allen, you say that you will be 'sounding out' industry organisations about changes to the labels. If vaccine labels are providing misleading and possibly dangerous information, it should be a matter of **telling industry organisations that the labels have to be changed in the interests of consumer protection and companion animal safety.**

For example the vaccine product Protech C4+2CI contains Canine Distemper, Adenovirus and Parvovirus Live Vaccine. The label on Protech C4+2I contains the following recommendation:

It is recommended that dogs be revaccinated annually with Protech C3 or C4 vaccine to **ensure continuity of protection.**¹¹ (My emphasis.)

I have repeatedly asked the APVMA to advise me of the scientific basis for this annual revaccination recommendation for MLV core vaccines for parvovirus, distemper virus and adenovirus 'to ensure continuity of protection'. (Refer to my correspondence with John Owusu, Principal Evaluator, Veterinary Medicines Program, APVMA.)¹²

So far this question has not been answered.

The 2003 AAHA canine vaccine guidelines state that "there is no scientific basis for the recommendation to revaccinate dogs annually with many of the current vaccines that provide years of immunity".¹³

Ronald Schultz, a member of the WSAVA Vaccination Guidelines Group, notes:

The one year recommendation was not determined by any scientifically validated studies **nor will one find in the literature publications that demonstrate a need for annual vaccination with many of the products in use.**¹⁴ (My emphasis.)

As I have advised the APVMA many times previously, vaccine manufacturers' revaccination recommendations conflict with advice in the latest international dog and cat vaccination guidelines. The World Small Animal Veterinary Association (WSAVA) guidelines state that: "Vaccines should not be given needlessly. Core vaccines **should not be given any more frequently** than every three years..."¹⁵ (My emphasis.) (Note: The WSAVA guidelines do not actually recommend revaccination 'every three years'.)

The WSAVA guidelines note that dogs properly vaccinated with MLV core vaccines for parvovirus, distemper virus and adenovirus have very high protection from infection and $\geq 98\%$ protection from disease.¹⁶ The WSAVA guidelines advise that duration of immunity with canine MLV vaccines has been demonstrated to be at least seven years based on challenge and serological testing.¹⁷ The 2003 AAHA guidelines state:

When MLV vaccines are used to immunize a dog, memory cells develop and likely persist for the life of the animal. Resident memory cells respond rapidly providing an anamnestic immune response at the time of challenge (infection) with the pathogen.¹⁸

The 2006 AAHA canine vaccine guidelines advise that vaccines produced by the major biologics manufacturers against parvovirus, distemper virus and adenovirus **all** produce excellent immune responses and can be soundly and reliably administered at the discretion of the clinician in extended duration of immunity protocols.¹⁹ **My understanding of this statement is that canine MLV vaccines with an ‘annual’ revaccination recommendation ‘produce excellent immune responses’ and can be ‘soundly and reliably’ used in extended duration of immunity protocols.**

(Refer to my report ‘Is over-vaccination harming our pets? Are vets making our pets sick?’²⁰ and my paper ‘Over-vaccination of pets – an unethical practice’²¹ for more detail and references on duration of immunity.)

So, on what scientific basis does the vaccine manufacturer recommend that dogs be revaccinated annually with MLV vaccines in Protech C3/C4 ‘to ensure continuity of protection’? Has the vaccine manufacturer demonstrated an endpoint to duration of immunity to justify the annual revaccination recommendation?

I note that Protech C4 contains parainfluenza virus vaccine²². The recommendation to revaccinate annually with this vaccine conflicts with advice in the WSAVA guidelines. The WSAVA guidelines note that Parainfluenza Virus (CPIV) MLV–parenteral is a non-core vaccine. The WSAVA guidelines recommend “revaccination (booster) at 1 year, **then not more often than every 3 years**”. (My emphasis). The WSAVA guidelines note that “use of CPIV (MLV-intranasal) is preferred to the parenteral product as the primary site of infection is the upper respiratory tract”.²³

The WSAVA guidelines define non-core vaccines “as those that are required by only those animals whose geographical location, local environment or lifestyle places them at risk of contracting specific infections”.²⁴ I suggest it is inappropriate for core and non-core vaccines to be combined.

In the case of the combination product Protech C4+2I, I am alarmed to see the 2I component contains Canine Coronavirus and *Leptospira interrogans* Copenhageni killed vaccine.²⁵

According to the WSAVA guidelines, Canine Coronavirus is “Not Recommended. Prevalence of clinical cases of confirmed CCV disease does not justify vaccination.”²⁶ If use of this vaccine cannot be justified why is it on the market and included in a multivalent vaccine product?

Regarding *Leptospira interrogans* Copenhageni, I cannot see any specific reference to this serovar in the WSAVA guidelines. However, the guidelines do refer to “*Leptospira interrogans* (combined with serovars canicola and icterohaemorrhagiae) (killed bacteria). (Also available in the USA with serovars grippotyphosa and Pomona)”. The guidelines note that this vaccine is non-core and vaccination should be restricted to use in geographical areas where a significant risk of exposure has been established or for dogs whose lifestyle places them at risk. The guidelines note that “this product is associated with the greatest number of adverse reactions to any vaccine. In particular, veterinarians are advised of reports of acute anaphylaxis in toy breeds

following administration of leptospirosis vaccines. Routine vaccination of toy breeds should only be considered in dogs known to have a high risk of exposure”.²⁷

The WSAVA guidelines also note that “this vaccine is the one least likely to provide adequate and prolonged protection, and therefore must be administered annually or more often. Protection against infection with different serovars is variable”.²⁸

Given the dubious efficacy and risks associated with this vaccine, I suggest it is questionable whether the benefits outweigh the risks. **Certainly pet owners should be advised to give careful consideration to use of this vaccine.**

Again, I suggest it is inappropriate for core, non-core and not recommended vaccines to be combined. **This is especially so given the questionable knowledge and proficiency of many veterinarians regarding best vaccination practice.** Given there are risks associated with the use of vaccine products, core and non-core vaccines should be given separately to ensure that proper thought and justification is given to their application. I can see no justification for the use of ‘not recommended’ vaccine products.

On the subject of risks of vaccination, I am concerned that vaccine product labels do not contain adequate warnings about the possibility of adverse reactions when using vaccine products.

The WSAVA guidelines warn “we should aim to reduce the ‘vaccine load’ on individual animals in order to minimise the potential for adverse reactions to vaccine products”. The WSAVA guidelines acknowledge that “**there is gross under-reporting of adverse events which impedes knowledge of the ongoing safety of these products**”.²⁹

In its ‘Vaccination Principles’, the American Veterinary Medical Association recognises that:

Adverse events may be associated with the antigen, adjuvant, carrier, preservative, or a combination thereof. Possible adverse events include, but are not necessarily limited to, failure to immunize, anaphylaxis, immuno-suppression, autoimmune disorders, transient infections, long-term infected carrier status, and local development of tumors. The role of genetic predisposition to adverse events needs further exploration and definition.³⁰

Ronald Schultz acknowledges that: “The risk of adverse reactions from vaccines are not well studied, nor are the adverse reaction rates well documented. Even where documented, the information is not readily available.”³¹

In his 1998 paper ‘Current and future canine and feline vaccination programs’, Schultz notes that “adverse reactions can range from mild, self-limiting illness to **chronic disease or death**”.³² (My emphasis.) Schultz also notes that “there is a reluctance to report reactions, even those that lead to the death of an animal”.³³

Schultz warns that

Vaccines are medical products that should only be given if needed and only as often as necessary to provide protection from diseases that are a risk to the health of the animal. **If a vaccine that is not necessary causes an adverse reaction that would be considered an unacceptable medical procedure,** thus use only those vaccines that are needed and use them only as often as needed....Vaccines are medical products that should not be used as practice management tools.³⁴ (My emphasis.)

(Refer to my report 'Is over-vaccination harming our pets? Are vets making our pets sick?'³⁵ and my paper 'Over-vaccination of pets – an unethical practice'³⁶ for more detail and references on adverse reactions to vaccines.)

In my correspondence to John Owusu of the APVMA³⁷, I raised questions about the precautions and side effects listed on the Protech C4 vaccine product label, i.e.:

- Can you please advise how this list of precautions and side effects was ascertained?
- What type of dogs (and how many) were used in the trial?
- Over what period of time were dogs monitored to observe side effects?

These questions remain unanswered.

I have an additional question:

- Does the APVMA have statistics on canine parvovirus, distemper virus and adenovirus infection in Australia, including statistics on fatalities from these diseases?

Annual revaccination with MLV core vaccines has unaccountably been 'accepted practice' in Australia.³⁸ After years of inexcusable delay, the Australian Veterinary Association announced its new vaccination policy in August 2009.³⁹

Despite the fact that the Australian Veterinary Association's new dog and cat vaccination policy acknowledges that "in most cases, core vaccines need not be administered any more frequently than triennially **and that even less frequent vaccination may be considered...**"⁴⁰ (my emphasis), I am concerned that an '**every three years**' message is going to be pushed by those veterinarians who move from the equally arbitrary 'annual' revaccination recommendation. For example, an article titled 'Vaccination Policy', published in the Summer 2009 edition of the Animal Welfare League's publication *We Care*, notes that:

Some examples of vaccinations that may only be needed **every three years** are distemper, parvo-virus and adenovirus for dogs...⁴¹ (My emphasis.)

The author of this article, Julia Nicholls, notes "there is one three-year vaccine for dogs already in the market place".⁴²

Checking APVMA's PUBCRIS Registered Products Database I have found two three year vaccines:

- Duramune Adult C4 Canine Distemper, Adenovirus, Parainfluenza and Parvovirus Live Vaccine (first registered on 25 July 2005)⁴³
- Nobivac DHPPi Continuum Vaccine (first registered on 6 July 2006)⁴⁴

So-called 'three year' vaccines have been registered for years. Why has it taken until now for them to be brought to the attention of pet owners?

What is the scientific basis for the revaccination recommendations on these so-called 'three year' vaccine products? For instance, Duramune Adult has the following revaccination information:

Duramune Adult C3 and C4 vaccines have been demonstrated to provide 3 years' protection against disease caused by canine distemper virus, canine adenovirus type 1, canine adenovirus type 2 and canine parvovirus. These vaccines may therefore be

included in programs of revaccination intervals of three years following the primary vaccination program.⁴⁵

This revaccination information is ambiguous. Does this mean that after a three year trial dogs were challenged with the diseases and shown to have immunity? This information does not provide evidence that there is an endpoint to duration of immunity.

In Britain, there are similar Duramune products with core MLV vaccines which recommend “subsequent booster vaccinations should be administered **at intervals of not less than one year and not more than three years**”.⁴⁶ This recommendation, in effect, supports ‘annual’ revaccination with core MLV vaccines – how can this be justified? **How can the British government regulator, the Veterinary Medicines Directorate, justify a revaccination recommendation that condones unnecessary ‘annual’ and ‘triennial’ revaccination of dogs?**

In Australia, the Duramune label refers to “programs of revaccination intervals of 3 years...”⁴⁷ I suggest it is inappropriate for vaccine manufacturers to refer to revaccination intervals. The latest vaccination guidelines, the WSAVA guidelines, note that: “Vaccines should not be given needlessly. Core vaccines should not be given any more frequently than every three years...”⁴⁸ **The WSAVA guidelines do not actually recommend revaccination ‘every three years’.** (In fact the reference to ‘three years’ in the WSAVA guidelines is ambiguous and confusing and I intend to seek clarification on its inclusion in the guidelines from the WSAVA Vaccination Guidelines Group.) The WSAVA guidelines note that “dogs that have responded to vaccination with MLV core vaccines maintain a solid immunity (immunological memory) for many years in the absence of any repeat vaccination”.⁴⁹ The WSAVA guidelines advise that duration of immunity after vaccination with MLV vaccines for parvovirus, distemper virus and adenovirus is at least seven years, based on challenge and serological studies.⁵⁰ So why does the Duramune Adult vaccine product label refer to ‘programs of revaccination intervals of 3 years’?

(The Duramune Adult label also includes revaccination recommendations for parainfluenza virus, *bordetella bronchiseptica*, canine coronavirus and *Leptospira interrogans* serovar Copenhageni. Refer to my previous comments on Protech C4+2I regarding non-core vaccines.)

Nobivac DHPPi revaccination recommendations are also problematic, i.e.:

It is recommended that dogs be revaccinated against distemper, hepatitis and parvovirus **every 3 years**. It is recommended that dogs be revaccinated for the parainfluenza component **every 12 months**...⁵¹ (My emphasis.)

What is the scientific basis for the Nobivac DHPPi recommendation to revaccinate against distemper, hepatitis and parvovirus ‘every three years’?

Similarly, what is the scientific basis for the Nobivac DHPPi recommendation to revaccinate for the parainfluenza component every 12 months? This conflicts with advice in the WSAVA guidelines.⁵² (I reiterate my previous suggestion that it is inappropriate for core and non-core vaccines to be combined.)

In the Animal Welfare League’s article ‘Vaccination Policy’, Julia Nicholls states that “the vaccinations against canine cough (kennel cough) will still be required every year”.⁵³ This appears to be a blanket command that all dogs should have kennel cough vaccinations every year. Kennel cough vaccines are non-core. The WSAVA guidelines define non-core vaccines “as those that are required by only those animals whose geographical location, local environment or lifestyle places them at risk of contracting specific infections”.⁵⁴ It is inappropriate to dictate that all pet owners have non-core vaccinations for their dogs if they have not been proven to be necessary in each individual situation.

On the topic of distemper, parvovirus and adenovirus vaccines, Nicholls states that “many commercially available vaccines are not yet registered” for the extended intervals and that pet owners may have to sign a consent form that they have agreed to waive certain annual vaccinations.⁵⁵

Pet owners are not being clearly informed that canine MLV vaccines have been demonstrated to provide long duration of immunity regardless of the manufacturers’ ‘annual’ or ‘triennial’ revaccination recommendations. As mentioned previously, the 2006 AAHA canine vaccine guidelines advise that vaccines produced by the major biologics manufacturers against parvovirus, distemper virus and adenovirus **all** produce excellent immune responses and can be soundly and reliably administered at the discretion of the clinician in extended duration of immunity protocols.⁵⁶ It is not necessary to use a designated ‘three year vaccine’ and it has not been proven necessary to revaccinate ‘every three years’.

Immunological memory does not automatically ‘switch off’ after one or three years, so how can unnecessary ongoing revaccination with MLV vaccines be justified? Why do so many veterinarians persist in compelling their clients to revaccinate their dogs with MLV vaccines when there is no scientific evidence underpinning manufacturers’ revaccination recommendations? It has not been proven that it is necessary to revaccinate dogs annually or triennially with MLV vaccines. There **is** evidence that these vaccines provide long duration of immunity, demonstrated to be at least seven years. **Why isn’t this information being relayed to pet owners for their consideration?**

The Australian Veterinary Association’s new dog and cat vaccination policy acknowledges that:

in most cases, core vaccines need not be administered any more frequently than triennially **and that even less frequent vaccination may be considered appropriate** if an individual animal’s circumstances warrant it. However, local factors may dictate more frequent vaccination scheduling.⁵⁷ (My emphasis).

Despite the fact the AVA acknowledges that “even less frequent vaccination may be considered appropriate...”, the AVA is using its authority and influence to set in place a blanket policy of unjustified ongoing revaccination of pets with MLV core vaccines. For example, in its advice on ‘Pet care businesses and the vaccination policy’, the AVA **strongly recommends** that boarding kennels demand proof of ongoing revaccination, i.e.:

It is strongly recommended that vaccination certificates be photocopied to be sure of the actual brand of vaccine given (triennial/annual booster). **The client’s word that this brand is a ‘three yearly booster’ should not be taken for granted.**⁵⁸ (My emphasis.)

According to its own recommendations to boarding kennels, the AVA is refusing to accept that canine MLV vaccines with a so-called ‘annual’ recommendation have been demonstrated to provide long duration of immunity. **It is not necessary to use a designated ‘three yearly booster’.** The AVA is setting in place recommendations which will enforce unnecessary ‘triennial’ revaccination of pets, even though ‘triennial’ revaccination has not been proven to be necessary.

The AVA’s advice on ‘Pet care businesses and the vaccination policy’ is also likely to encourage pet insurers to continue to demand that pet owners have their pets revaccinated with MLV core vaccines. An article published in *Choice* magazine in July 2009 noted that pet insurers require that pet owners follow veterinarians’ vaccination protocols.⁵⁹ This is problematic as the Australian Veterinary Association’s dog and cat vaccination policy, and advice to pet care businesses, is confusing and contradictory. There is also concern that individual veterinarians will continue to ignore guidelines and continue to dictate that pet owners revaccinate their pets unnecessarily with core or non-core vaccines.⁶⁰ It is unacceptable that pets be put at risk with demands for

MLV revaccination that have not been proven to be necessary. **Pet insurers, boarding kennels and other pet care businesses should acknowledge information about long duration of immunity for MLV core vaccines contained in the WSAVA guidelines.**⁶¹

The AVA regularly issues media releases recommending pet owners have their pets revaccinated. For instance a media release titled 'Vets concerned about deadly dog virus' was released less than a week after the AVA's new dog and cat vaccination policy, stating that: "Parvovirus is an easily preventable disease by having your pet regularly vaccinated."⁶² Again, I ask where is the proof that pets need to be 'regularly vaccinated' with MLV core vaccines? Surely the emphasis should be on attracting the attention of pet owners who have never had their pets properly vaccinated, rather than urging other pet owners to have their pets unnecessarily revaccinated again and again?

The AVA's vaccination policy also states: "...local factors may dictate more frequent vaccination scheduling."⁶³ What 'local factors' would dictate more frequent vaccination of already vaccinated adult dogs with canine MLV vaccines? I will be challenging the AVA to provide me with evidence for this statement.

The AVA's so-called 'recommendations', which are not evidence based, are being used to entrench a culture of unnecessary revaccination. Not only is this an unnecessary financial imposition on pet owners, it also places pets needlessly at risk of an adverse reaction to vaccine products. There are serious conflict of interest and professional and ethical issues to be considered here.

Over-vaccination of pets – an international problem

In my article 'The over-vaccination controversy continues...', published in the December 2009 edition of specialist dog breeder magazine, *National Dog*, I suggest that unnecessary revaccination of dogs for parvovirus, distemper virus and adenovirus is also a serious problem in other countries such as Britain and the United States. I suggest that the relevant authorities should collaborate on addressing this problem, e.g. government regulators and veterinary associations.⁶⁴

It appears veterinary associations in other countries are also reluctant to inform pet owners about long duration of immunity with canine MLV vaccines.

The British Veterinary Association's fact sheet on vaccination: 'Vaccination – The Facts' admits that some vaccines achieve life-long immunity, but fails to say which ones.⁶⁵

I contacted the British Veterinary Association to ask which vaccines provide life-long immunity and received this response from John Maslin, Policy Officer:

The BVA does not maintain a list of vaccines and the respective length of immunity they provide. Vaccines are generally licensed for a specified period of immunity depending on the data the company has gathered and submitted to the licensing authority. Whether a vaccine provides life long immunity will of course depend on the life of an animal, that is, for farm animals many are kept for periods less than their biological lifespan.⁶⁶

Given Mr Maslin was well aware my interest was in canine vaccination, I suggest this response was evasive. It is a matter of concern that the association that represents Britain's veterinarians appears to be unaware of international vaccination guidelines, or the duration of immunity of

vaccines that veterinarians are responsible for injecting into people's companion animals every day.

Similar to the situation in Australia, it seems veterinarians in Britain are also using unproven 'annual' and 'three yearly' MLV vaccine label revaccination recommendations to dictate that pet owners revaccinate their pets. The BVA's fact sheet 'Vaccination – The Facts' notes that:

Vets must use vaccines in accordance with the licence stipulations. It should be noted that **it would be negligent of a vet to deviate from the medicinal data available to them and/or use a vaccine not in accordance with the instructions on the label and the summary of the product characteristics or data sheet.**⁶⁷ (My emphasis.)

This statement is a matter for serious concern. As mentioned previously, there are vaccine products on the market in Britain which have unproven revaccination recommendations. For example, the manufacturer of Duramune DAPPi recommends "...booster vaccinations should be administered **at intervals of not less than one year and not more than three years**".⁶⁸ This recommendation, in effect, supports 'annual', as well as 'triennial' revaccination with core MLV vaccines – how can this be justified? **How can the government regulator, the Veterinary Medicines Directorate, allow a revaccination recommendation that condones unnecessary 'annual' and 'triennial' revaccination of dogs?**

Why isn't the British Veterinary Association acknowledging the advice and recommendations contained in the international WSAVA guidelines, **and ensuring this information is passed onto pet owners for their consideration?** Why isn't the British Veterinary Association raising the alarm on this subject with the Veterinary Medicines Directorate, and calling for unproven manufacturers' revaccination recommendations for vaccine products in Britain to be challenged?

I sought verification of the BVA's statement that it would be 'negligent' of a vet to deviate from the 'instructions on the label', and I posed this question to the British Veterinary Association:

Are members of the British Veterinary Association allowed to administer canine vaccines against the recommendations of the label/SPC under any circumstances? Or would such action always be deemed negligent?

I received the following response from Mr Maslin:

On the 'off-label' use of a medicinal product, veterinary medicinal products must be administered in accordance with the marketing authorisation unless it is administered under the cascade or under other limited circumstances related to research. Again however you can find details about such off label use and the cascade on the VMD's website at <http://www.vmd.gov.uk/General/VMR/vmgn/VMGNote15.pdf>⁶⁹

(Author's note: The link provided might not work in this document – check the VMD's website for "Veterinary Medicines Guidance Note".)

The VMD link provided by Mr Maslin did not provide me with a clear answer. I also sought clarification on this issue from Lorna Shelley, a member of the Legislation Team at the British Veterinary Medicines Directorate⁷⁰ but, as with Mr Maslin, I have so far been unable to obtain a straightforward answer to my question.⁷¹ I have recently resubmitted my query to Ms Shelley and I await a response.⁷²

In a European context, in a footnote in a paper published in 2006, Michael Day, a member of the WSAVA Vaccination Guidelines Group, notes that "it is recognised that any veterinarian with the informed consent of an owner may use a modified protocol in any individual animal".^{73 74} Is this the answer that Mr Maslin and Ms Shelley are unable to give me?

In Australia, the Australian Pesticides and Veterinary Medicine Authority's Fact Sheet on 'Veterinarians and Veterinary Medicines' notes:

Veterinarians may also make treatment recommendations which are inconsistent with the instructions on labels of registered veterinary chemical products. The Agvet Code provides for these actions, as long as they are undertaken for animals under a veterinarian's care* and are allowed under State and Territory laws.⁷⁵

The draft APVMA Position Statement on Vaccination Protocols for Dogs and Cats (not yet published) notes that veterinarians are under no obligation to follow manufacturers' revaccination recommendations – these are only 'recommendations'.⁷⁶

In the United States, the 2006 AAHA guidelines recommend revaccination "every three years or longer".⁷⁷ Despite the reference to 'or longer', my correspondence with US veterinary schools generally indicates an 'every three years' recommendation is in place.⁷⁸ Anecdotal reports on the internet indicate that 'annual' revaccination is still commonplace in the US.

The American Veterinary Medical Association's 'Vaccination Principles' note that:

Biological agents are regulated by USDA, not FDA, and thus are not subject to FDA regulations that address extra label use. It is generally recommended to follow label instructions, **however, in most cases veterinarians may legally use vaccines in a discretionary manner if medically justified** and in compliance with State/Federal restrictions that apply.⁷⁹ (My emphasis.)

The AVMA acknowledges that:

Vaccination is a potent medical procedure with both risks and benefits. While there is evidence that **some vaccines provide immunity beyond one year**, revaccination of patients with sufficient immunity does not necessarily add to their disease protection and may increase the potential risk of post-vaccination adverse events.⁸⁰ (My emphasis.)

Like the Australian Veterinary Association and the British Veterinary Association, the American Veterinary Medical Association also appears reluctant to provide specific information about scientific evidence on long duration of immunity with core MLV vaccines, although it does make a reference to the AAHA guidelines.⁸¹

The AVMA admits that "gaps still remain in our understanding of the immune system's acute and chronic reaction to multiple vaccinations".⁸² In other words, the veterinary profession still does not understand the full impact or consequences of repeated vaccination or the long term effects.

In an article in preprint, Michael Day acknowledges that few "investigations have studied the phenomenon of 'inflammageing' (the effect of cumulative antigenic exposure and onset of late life inflammatory disease)" in dogs and cats.⁸³

The AVMA also notes that:

The USDA must approve labels for biological products. However, current labels frequently contain revaccination interval recommendations based on historical precedence and acceptance rather than specific duration of immunity data; **consequently, some product labels may fail to adequately inform practitioners about optimal revaccination and long-term use of a product.**⁸⁴

In this regard, Etienne Thiry and Marian Horzinek, a member of the WSAVA Vaccination Guidelines Group, suggest that vaccine guidelines "can serve as a bridge between official and unofficial recommendations for vaccine use".⁸⁵

In particular, Thiry and Horzinek note:

It is of primary importance that the vaccination schedules followed by the veterinary practitioners **are the most efficacious ones, even if this means that they do not strictly follow the recommendations of the package inserts.**⁸⁶ (i.e. 'the label'). (My emphasis.)

I suggest many veterinarians are unaccountably **not** following the 'most efficacious' vaccination schedules. This begs the question: **Why are so many veterinarians so eager to follow vaccine manufacturers' unproven revaccination recommendations, and so reluctant to take heed of vaccination guidelines prepared by their own veterinary experts, and information on long duration of immunity?**

Most importantly, why is this crucial information being withheld from pet owners? If pet owners were properly informed of the scientific evidence regarding long duration of immunity and 'immunological memory' with MLV vaccines, and the lack of evidence to support manufacturers' revaccination recommendations, they might choose to cease unnecessary revaccination, particularly if they were also informed of the risks of immediate and delayed adverse reactions to vaccine products. **In many instances, pet owners are not being given this opportunity.**

Who is responsible for protecting consumers of veterinary services, and companion animal safety? Who is responsible for providing effective regulation?

Allen, I am concerned that MLV core vaccines with an 'annual' and 'triennial' recommendation will continue to be used by veterinarians on an annual and triennial basis, despite the fact that MLV core vaccines have been demonstrated to provide long duration of immunity. To provide clarification, labels on these vaccine products must be amended to indicate **that no endpoint of duration of immunity has been demonstrated.** International guidelines (i.e. the 2006 AAHA guidelines) have indicated these vaccines can be used in extended duration of immunity protocols.⁸⁷ The WSAVA guidelines advise that duration of immunity after vaccination with MLV vaccines for parvovirus, distemper virus and adenovirus is seven years or longer, based on challenge and serological studies.⁸⁸ **This information must be made clear to the veterinary profession and the public.** (Given the long duration of immunity with core MLV vaccines, I believe it is inappropriate for core and non-core vaccines to be combined.)

It must be acknowledged that there are ambiguities and inconsistencies in international vaccination guidelines produced by WSAVA and AAHA. For instance, why is there any reference to 'three years' in these guidelines, given that the guidelines admit that there is long duration of immunity with MLV core vaccines, demonstrated to be at least seven years?^{89 90 91} **The reference to 'three years' must be clarified.** (Note: The WSAVA guidelines state they have been formulated "without consultation with industry".⁹² Nevertheless, it is interesting to note the WSAVA guidelines are sponsored by Intervet, the manufacturer of so-called 'three year' vaccine Nobivac DHPPi.)

The WSAVA guidelines note that duration of immunity is seven years or longer based on challenge and serological studies. **It is interesting that the first reference to this important information is buried away on page 15 of the guidelines.**⁹³

The WSAVA guidelines note that "they have been drafted with the objective of educating and informing the profession and to recommend rational vaccine use for individual pets and dog/cat populations".⁹⁴ The WSAVA guidelines are careful to point out that "they do not represent a standard of care or set of legal parameters".⁹⁵ So **who is responsible** for setting a 'standard of

care' for the veterinary profession? There is currently no effective government regulation of this 'self-regulated profession'.

Professional conduct and self-regulation in the veterinary profession must come under scrutiny. In an essay titled 'Professional conduct and self-regulation', Jane Hern, the Registrar of Britain's Royal College of Veterinary Surgeons, notes that professional bodies are granted the privilege of self-regulation, but only in return for an assurance their members set standards of competence and ethical behaviour to protect consumers.⁹⁶ Who protects the consumer when the veterinary profession's 'standards of competence and ethical behaviour' are putting pets needlessly at risk with unnecessary vaccination?

Allen, in the APVMA Annual Report 2008-09, I see that registration of products:

is based on a rigorous and independent evaluation of scientific information about the safety and efficacy of a product. This careful evaluation ensures that the community and users of pesticides and veterinary medicines can be confident that the products are safe and effective when used according to label instructions.⁹⁷

The APVMA Annual Report notes that it is the APVMA's responsibility to review registered chemical products "to ensure that they continue to meet high contemporary standards".⁹⁸

The APVMA Annual Report also states:

For the APVMA to operate to best effect, it is vital that it take into account current and emerging issues of interest and concern that the community has with the regulation of these chemicals. It is equally important that the community be kept fully informed on the rationale that underpins regulatory decisions.⁹⁹

I suggest that in the area of companion animal vaccines, the APVMA is failing in its responsibilities **and that the community cannot 'be confident that the products are safe and effective when used according to label instructions'**. Manufacturers' revaccination recommendations on canine MLV vaccine product labels are conflicting with duration of immunity information contained in international guidelines, i.e. the WSAVA guidelines and the AAHA 2006/2003 guidelines. The limited information listed on vaccine labels re possible adverse reactions is also questionable. **So far, the APVMA has not taken any effective action to address this situation or warn the public of the conflict, despite the fact dog and cat vaccination guidelines advising of long duration of immunity have been available since 2003.**

Until only a few months ago, the Australian Veterinary Association also ignored information contained in these guidelines, and failed to ensure the information was relayed to pet owners.

As I have now outlined numerous times, e.g. in my report 'Is over-vaccination harming our pets? Are vets making our pets sick?'¹⁰⁰ and my paper 'Over-vaccination of pets – an unethical practice'¹⁰¹, plus my articles in the specialist dog publication *National Dog*^{102 103}, and ongoing correspondence with a variety of relevant parties, **it has been well-known for many years that canine MLV vaccines provide long duration of immunity, probably lifelong.**

Unaccountably, vaccine manufacturers and many members of the veterinary profession continue to push pet owners to revaccinate their dogs annually and triennially with MLV vaccines. There appears to be no evidence to support this ongoing intervention. Most importantly, in many instances, pet owners have not been advised of scientific evidence regarding long duration of immunity with canine MLV vaccines.

Unnecessary vaccination of pets is blatant financial exploitation of pet owners.

What makes this situation more heinous and sinister, is not only has the intervention not been proven to be necessary, **it is also possibly harmful**. It just beggars the imagination that so many members of the veterinary 'profession' use their authority and influence to continue to insist that their clients have an unnecessary and possibly harmful intervention for their pets. This is not what pet owners expect when they seek veterinarians' professional advice.

Are veterinarians wilfully disregarding the latest scientific information or are they just plain ignorant? Either way, it is unacceptable. Many veterinarians do not obtain 'informed consent' from their clients before carrying out vaccinations. In many instances, pet owners are not given the opportunity to consider recent scientific evidence on long duration of immunity of MLV vaccines, or information on possible adverse reactions or long term side effects from vaccination.

Australian and international government regulators have failed to protect the pet owning public from exploitation by the veterinary industry. Government regulators allow on the market canine MLV vaccine products which have revaccination recommendations which have not been proven to be necessary, i.e. an endpoint to duration of immunity has not been demonstrated. These revaccination recommendations conflict with the latest scientific evidence on long duration of immunity. Many veterinarians use these unfounded manufacturers' 'recommendations' to attempt to justify ongoing vaccination, even though their own veterinary experts warn them that this intervention is unnecessary and possibly harmful.

Whose interests are best served by this unnecessary intervention?

The veterinary profession, vaccine manufacturers and government regulators benefit financially from ongoing vaccination of pets. For example, in Australia, the APVMA Annual Report notes that in 2008–09, industry contributions were 96 per cent of the APVMA's total revenue.¹⁰⁴ In Britain, 75 per cent of the Veterinary Medicines Directorate income is from industry.¹⁰⁵

A vaccine industry newsletter published in 2005 reported that:

89% of veterinarians indicated that dog and cat vaccinations were indeed the number one contributor to practice turnover and 91% of veterinarians felt that a change from annual vaccination would have an adverse effect on their practice turnover. 80% of veterinarians also indicated that it would be difficult to attract clients on a regular basis should there be a change from annual vaccination.¹⁰⁶ (My emphasis.)

The newsletter concluded:

Annual vaccination appears to be an important source of income for many veterinarians and veterinarians believe that annual vaccination imposes the discipline on the pet owners. The results indicate that veterinarians will continue to vaccinate annually.¹⁰⁷ (My emphasis.)

Have vested interests impeded acknowledgement of international vaccination guidelines, and scientific evidence of long duration of immunity with MLV vaccines, which would significantly reduce unnecessary vaccination of pets?

I am interested to know the value of the companion animal vaccine market in Australia, and I have previously requested this information from the APVMA, but I was advised that the information was 'commercial in confidence'. (Refer to my correspondence with Elvira Currie, Senior Reviewer, Adverse Experience Reporting Program, APVMA)¹⁰⁸

An Australian Bureau of Statistics report provides information on income from veterinary practice for the 1999-2000 financial year:

Income from the provision of professional services (\$865 million) was the main source of income for these practices and represented 87% of their total income. This professional service income included \$229 million from consultation services and \$204 million from the provision of medication used as part of the treatment. These two types of professional service income accounted for 23% and 21% respectively of total income. Other professional service income included \$110 million from surgery and \$97 million from vaccinations.¹⁰⁹

As we are now nearing the end of 2009, this information is very out of date. However it provides some indication of vaccination sales, although it is not clear if the figure of \$97 million for vaccinations is the cost of vaccinations alone or whether it incorporates consultation charges.

It is regrettable that the APVMA does not provide a detailed breakdown of vaccine product sales. Transparency on this subject would be useful to analyse vaccination practice.

I suggest it is safe to say that the companion animal vaccine market is very lucrative for the veterinary industry. An international perspective is provided by US veterinary expert Richard Ford. Commenting on the impact of implementing the 2006 Canine and Feline Vaccine Guidelines in the US, he estimated vaccine sales to veterinarians were worth \$US298 million. This translated to a market worth \$US3.1 billion after veterinarians' 10x mark-up.¹¹⁰ So there is a lot of money at stake here...

Allen, recently I forwarded to you and other attendees of our meeting at the APVMA on Friday 25 September, a small survey I had undertaken to ascertain vaccination practice after the announcement of the AVA's new dog and cat vaccination policy. **It is alarming that eight out of the ten veterinary surgeries contacted indicated that 'annual' vaccination of adult dogs with core MLV vaccines was still common practice.** Only two people contacted acknowledged 'triennial' revaccination, and this was only after I raised the topic. And as I have outlined numerous times previously, so-called 'triennial' revaccination has not been proven to be necessary either.

I suggest the onus of proof is on the veterinary industry to prove that an intervention is necessary, otherwise its use cannot be justified. It is certainly unacceptable for the veterinary profession to withhold crucial information on long duration of immunity and possible adverse reactions and long term side effects from pet owners, and coerce them into having unnecessary and possibly harmful interventions for their pets.

I have repeatedly asked members of the veterinary profession to provide me with evidence that triennial revaccination is necessary, but my requests have been ignored. I have discovered that this is a common tactic of the veterinary profession – i.e. to simply refuse to answer inconvenient questions. In fact, much of my correspondence and detailed questions to senior members of the veterinary profession in Australia and overseas, including the Australian Veterinary Association, Australian and US Veterinary Schools, Veterinary Surgeons' Boards and other veterinary contacts has been ignored. There is a complete lack of transparency and accountability from this 'self-regulated profession'.

After years of unaccountable delay, the Australian Veterinary Association only recently changed its dog and cat vaccination policy. It appears the AVA only deigned to act when it realised that members of the public were finding out for themselves the true story about vaccination and spreading the news.

The extraordinary delay in addressing the scandalous problem of unnecessary vaccination of pets is unacceptable. Many people, including conscientious veterinarians and laypeople, have tried to raise the alarm and been ignored. For example, in Australia, Bea Mies has been trying to sound the alarm on this problem with the AVA and the APVMA for many years, after the suspicious death of her own dog after unnecessary revaccination. I have now been

researching and campaigning on this issue for the past 15 months after my own dog's suspicious death after unnecessary revaccination. I have met with stonewalling and obstruction at every turn. Pat Styles has also spent many years trying to get attention for this problem after her dog was affected by neurological problems after unnecessary revaccination. This has been an exercise in determination and persistence on our part. We are just three individual pet owners from across the country (in Sydney, Adelaide and Perth) who are trying to draw attention to abuses committed by the veterinary industry. It is time the government authorities stepped up to the plate and took effective action to ensure these abuses are stopped, and the veterinary industry brought to account.

While the government regulators are failing to provide adequate regulation of companion animal vaccine products, there is also no effective independent watchdog monitoring the activities of the veterinary profession. This 'self-regulated profession' is accountable to no-one. This raises concerns about over-servicing in other areas of veterinary practice.

Vaccination and other interventions

Pet owners are also under pressure to have other interventions for their pets. The necessity and risks and benefits of any intervention must be carefully considered in each individual case.

Is it ethical for pet owners to be urged to have interventions such as non-core vaccinations and heartworm products, flea treatments etc for their pets if they have not been proven to be necessary in their particular pet's situation? There are risks associated with these products, and some non-core vaccines also have dubious efficacy.

For example, in his book, *An Introduction to Veterinary Medical Ethics*, Bernard Rollin queries whether it is ethical for vets to urge their clients to have heartworm treatments for their dogs in regions where the risk of heartworm is negligible.¹¹¹ This is particularly pertinent if there are risks associated with a heartworm treatment.

As with non-core vaccines, 'only those animals whose geographical location, local environment or lifestyle places them at risk' should be considered for heartworm products. Have heartworm products been proven to be necessary on a year round basis?

An article by the APVMA, published in the *Australian Veterinary Journal* in 2004, mentions the susceptibility of small breed dogs to adverse reactions to simultaneous administration of moxidectin and vaccines. The article notes:

The simultaneous administration of a vaccine and moxidectin occasionally results in allergic reactions, particularly in the small and toy dog breeds. The pathophysiology of these reactions is uncertain and is being investigated.¹¹²

In the US, ProHeart 6 (a six monthly moxidectin/heartworm injection) was withdrawn from sale in 2005 amidst some controversy after 500 to 600 dogs died and there were adverse reactions, including seizures and uncontrolled bleeding, in 5,500 to 6,000 dogs.¹¹³

An article published in *US Today* in September 2008 reports:

During the process that took ProHeart 6 off the market, the drug's maker investigated and denounced a Food and Drug Administration scientist who gathered the damning data. And instead of protecting its scientist, the FDA booted her off the case and tried to have her criminally prosecuted.

It's a disturbing tale for anyone who relies on pharmaceutical companies and the FDA to ensure that medicines for animals and humans are safe, one that raises questions about the conduct of a major corporation and its federal regulator.¹¹⁴

ProHeart 6 was subsequently reformulated and returned to the market in 2008, with a range of caveats on its use.¹¹⁵ For example, the client information sheet warns: **“Do not administer ProHeart 6 within 1 month of vaccinations”**.¹¹⁶

The ProHeart 6 product label contains a detailed list of Warnings, Precautions, Adverse Reactions, and Animal Safety issues.¹¹⁷

The News Release regarding ProHeart 6's reintroduction to sale notes:

ProHeart 6 must only be administered to clients whose owners have been advised of the risks of ProHeart 6 and sign an Owner Consent Form.¹¹⁸

In Australia, the product label of ProHeart SR-12 (an annual moxidectin/heartworm injection), states: **“Injection may be administered simultaneously with vaccines or other medications”**.¹¹⁹

Why is simultaneous moxidectin injection with vaccination recommended in Australia, when it is warned against for a similar product in the US?

The ProHeart SR-12 label also notes that, before starting dogs on a ProHeart SR-12 injection program: “All dogs not currently on a heartworm prevention program should be tested for the presence of adult heartworms.”¹²⁰

Are pet owners in Australia being warned of the risks of heartworm products? The ProHeart SR-12 label contains a brief list of precautions and adverse reactions:

- Can you please advise how this list of precautions and adverse reactions was ascertained?
- What type of dogs (and how many) were used in the trials?
- Over what period of time were dogs monitored to observe adverse reactions and possible long-term side effects?
- Does the APVMA have statistics on heartworm infection in Australia, including statistics on fatalities from this disease?

Informed consent – an ethical and legal issue

In many instances, veterinarians are not obtaining informed consent from their clients before vaccinating their pets, or performing other interventions. For example, in an article titled ‘Modern elements of informed consent for general veterinary practitioners’ Martin Fettman and Bernard Rollin state:

The basis for informed consent in medicine is to prevent patients from being treated against their will or the will of their guardians. In veterinary medicine, this principle leads to the objective that owners be provided adequate information so they can make the right decision for their pet and for themselves. Ernst and Cohen made an important point when they said, “The completion of a standard consent form does not, however constitute consent itself; it is merely evidence that consent has been given.” **It is the exchange between owner and veterinarian of the information necessary for informed consent**

that constitutes the real test of whether a concerted effort has been made at effective communication and understanding.¹²¹ (My emphasis).

On the topic of 'anecdotally accepted common practice', Fettman and Rollin suggest:

One could question the ethics of practitioners who recommend conventional diagnostic procedures or therapeutic plans for which no controlled research exists to support claims of efficacy and safety. **Certainly those who persist in advocating treatments that have been proven to be ineffective or even to cause harm cannot find protection in genuine informed consent.**¹²² (My emphasis).

I suggest this comment is relevant to current vaccination practice. It has not been proven that ongoing revaccination with MLV core vaccines is necessary 'to ensure continuity of protection'. Unnecessary vaccination is ineffective and puts pets needlessly at risk of an adverse reaction. The WSAVA guidelines Fact Sheets advise that duration of immunity after vaccination with these vaccines is seven years or longer, based on challenge and serological studies.¹²³ The guidelines note that **"dogs that have responded to vaccination with MLV core vaccines maintain a solid immunity (immunological memory) for many years in the absence of any repeat vaccination"**.¹²⁴

I suggest one could question the ethics of a practitioner who continues to urge his/her clients to have their pets revaccinated if this possibly harmful intervention has not been proven to be necessary, and without passing on crucial information about long duration of immunity or possible immediate and delayed adverse reactions for their clients' consideration.

I suggest that veterinarians who continue to insist their clients have their dogs vaccinated with MLV core vaccines and who do not obtain informed consent from their clients, i.e. do not inform them of vaccination guidelines and information on long duration of immunity, **are misleading their clients and breaking the law.** Taking the *Veterinary Practice Act 2003 South Australia* as an example, I suggest such veterinarians are contravening 'Part 7 – Miscellaneous, 68 – False or misleading statement'.¹²⁵

Also referring to the *Veterinary Practice Act 2003*, I suggest that veterinarians who mislead their clients about vaccination are guilty of unprofessional conduct, i.e. "improper or unethical conduct in relation to professional practice" and "incompetence or negligence in relation to the provision of veterinary treatment".¹²⁶

One would expect the appropriate course of action of a pet owner who believes their pet has been unnecessarily vaccinated would be to make a complaint to the relevant Veterinary Surgeons Board. Information on the Veterinary Surgeons' Board of South Australia website notes:

An important role of the Board is to maintain the public's confidence in the veterinary profession in South Australia. The main way the Board fulfills this role is by ensuring the profession maintains high standards.¹²⁷

The website also notes: "The Board will investigate complaints made by members of the public."¹²⁸

Under the provisions of the *Veterinary Practice Act 2003 South Australia*, it is the Veterinary Surgeons' Board's responsibility to protect "animal health, safety and welfare and the public interest by achieving and maintaining high professional standards both of competence and conduct in the provision of veterinary treatment..."¹²⁹ The functions of the Board include preparing or endorsing codes of conduct and professional standards for veterinary surgeons; and preparing or endorsing guidelines on continuing education for veterinary surgeons.¹³⁰

In this regard I forwarded a copy of my detailed and fully referenced report 'Is over-vaccination harming our pets? Are vets making our pets sick?'¹³¹ to the Veterinary Surgeons' Board of South Australia for comment. I received this response:

The SA Board noted your correspondence at its recent meeting and agreed that it is not the role of the Board to comment on this issue. It may be best for you to approach the Australian Veterinary Association with your report.¹³²

I also forwarded my report to other State Veterinary Surgeons'/Practitioners' Boards in Australia.¹³³ Only two bothered to respond, also declining to comment.¹³⁴

The Veterinary Surgeons' Board of South Australia is failing in its responsibility to protect "animal health, safety and welfare and the public interest by achieving and maintaining high professional standards both of competence and conduct in the provision of veterinary treatment..."¹³⁵ Indeed, the Veterinary Surgeons' Board of South Australia is complicit in maintaining unnecessary and possibly harmful vaccination practice. Four months after the publication of the AVA's new dog and cat vaccination policy, the Veterinary Surgeons' Board of South Australia continues to recommend that boarding kennels require proof of vaccination of dogs against distemper, hepatitis and parvovirus **within the preceding 12 months** of admission.¹³⁶ (This recommendation remains in place as at 22 December 2009, nearly four months after the announcement of the AVA's new dog and cat vaccination policy).

It appears futile to complain about unnecessary vaccination of pets to the Veterinary Surgeon's Board of South Australia, when this organisation is responsible for maintaining this unacceptable practice.

(Refer to my report 'Is over-vaccination harming our pets? Are vets making our pets sick?'¹³⁷ and my paper 'Over-vaccination of pets – an unethical practice'¹³⁸ for more detail and references on professional, ethical and legal considerations.)

Conclusion

I am challenging the authority of the veterinary profession to dictate vaccination practice to pet owners without scientific evidence. Who gave the veterinary profession the mandate to dictate that pet owners have interventions for their pets without any scientific evidence to support their recommendations?

It has been well-known for years in the international veterinary community that ongoing MLV revaccination for diseases such as parvovirus, adenovirus and distemper virus has not been proven to be necessary. **The veterinary profession should be brought to account for withholding this information from pet owners' consideration.**

Allen, I do not claim to be a veterinary expert, I have just analysed the available information. I am very aware of my layperson status, and I try to ensure everything I say is supported with evidence. I am concerned that the information I have discovered is not easily accessible to the general public. For example, I first discovered the WSAVA guidelines serendipitously via a PUBMED search. I suggest many members of the public would not be aware of this facility. Not unnaturally, they would expect their veterinarian to keep them abreast of the latest scientific information about vaccination. Regrettably, this is not happening.

The issue of vaccination of pets appears to be confusing but it should be simple, i.e. my research indicates that after successful puppy vaccination, adult dogs require no further vaccination with MLV vaccines for parvovirus, distemper virus or adenovirus. I have not yet seen any evidence to suggest otherwise. Non-core vaccines should be carefully considered on an individual basis - in

many instances they may not be applicable. I suggest it is telling that the WSAVA guidelines note that "...in cultural or financial situations where a pet animal may only be permitted the benefit of a single vaccination, that vaccination should be with core vaccines at 16 weeks of age or above".¹³⁹

Ronald Schultz, a member of the WSAVA Vaccination Guidelines Group, believes:

that dogs and cats vaccinated as puppies and kittens should be revaccinated at 1 year of age with the vaccines used earlier. **After that I do not believe there is an immunologic need to revaccinate annually with CDV, CPV-2, CAV-2...** My own pets are vaccinated once or twice as pups and kittens, then never again except for rabies... I have used this program since 1974 without incident of an infectious disease in my pets or the pets of my children and grandchildren.¹⁴⁰ (My emphasis.)

Pet owners should also be allowed to choose this minimal core vaccination program, regardless of whether so-called 'annual' or 'triennial' MLV vaccines are used.

Pet owners expect to be able to rely on the professional advice of their veterinarian. Public confidence in the veterinary profession and its 'recommendations' is undermined when its 'professional advice' is seen to be at odds with international guidelines.

The media recently reported on the problem of over-vaccination of pets. For example, in August 2009, the *Sydney Morning Herald* ran two stories on this topic, i.e. 'Vets dogged by criticism over vaccinations'¹⁴¹ and 'Annual vaccinations could be harmful: vets told'.¹⁴² The *ABC News* also picked up on the story, i.e. 'Pet owners dogged by 'unnecessary' vaccinations'.¹⁴³

Criticism of other veterinary services has also been in the news recently, e.g. 'Pet owners hounded by veterinary fees'¹⁴⁴ in the *Sydney Morning Herald* in September 2009, and 'Why I'm ashamed to be a vet: a shocking exposé of the profession that puts pets through 'painful and unnecessary treatments to fleece their trusting owners''¹⁴⁵ in the British publication *Mail Online*, in December 2009.

Veterinary products should not be prescribed indiscriminately, e.g. vaccinations, heartworm products, flea treatments etc. There are risks associated with these products and they should be used judiciously, tailoring to individual need and acknowledging guidelines prepared by experts. (I suggest celebrity vets publicly endorsing veterinary products is also problematic.) The focus should be on wellness and preventative health, e.g. more benign health checks, bloods tests etc. For example, while I am not convinced of the ongoing need for titre testing, a core titre test at an appropriate interval after puppy vaccination may be useful to demonstrate that repeated vaccination is not required.

Unnecessary vaccination of people has also been in the news recently, e.g. *The Australian* reports that: "One dose of the swine flu vaccine is enough to protect children against the disease, prompting calls for the federal government to review its recommendations that they receive two jabs one month apart."¹⁴⁶ Similarly, there has been controversy about the influenza treatment, Tamiflu. *ABC News* reports that a study published in the *British Medical Journal* has found that the data relied on by the flu drugs manufacturer Roche cannot be verified.¹⁴⁷ Commenting on the Tamiflu story in commentary published in the *British Medical Journal*, Peter Doshi provides a valuable insight:

If the public is to trust in public health policies, **the scientific basis informing knowledge of the harms and effects of those interventions must be public and open to independent analysis.**¹⁴⁸ (My emphasis.)

There is a message here for the APVMA and the veterinary profession.

Allen, it is not my responsibility to research veterinary practice and circulate information, although it is a task I have taken on with others because I will not stand by and let this gross exploitation of pets and pet owners continue unchallenged. Over the past 15 months I have spent an extraordinary amount of my time researching and lobbying on this issue, many nights, weekends and annual leave. I have met with resistance at every turn.

I understand this is a complex issue, but somebody in authority needs to think outside the square and find an effective solution to this serious problem. It is way past time that government authorities met their responsibility and acted in the interests of consumer protection and companion animal safety.

In the interests of transparency and accountability, please note that I will be forwarding this correspondence onto other relevant parties for comment.

Thank you again for giving Bea Mies and myself the opportunity to comment on the APVMA's Position Statement on Vaccination Protocols for Dogs and Cats, and I look forward to being advised when the final version will be made available, and progress on vaccine product labelling issues.

Regards
Elizabeth Hart

Acknowledgements: Thanks to Bea Mies for her useful comments on this document.

Endnotes:

¹ Bea Mies' comments on the APVMA Draft Position Statement on Vaccination Protocols for Dogs and Cats, forwarded to James Suter, General Counsel, APVMA on 16 October 2009.

² Elizabeth Hart's comments on the APVMA Draft Position Statement on Vaccination Protocols for Dogs and Cats, forwarded to James Suter, General Counsel, APVMA on 26 September 2009. Additional comments were forwarded to James Suter on 16 November 2009.

³ Initial contact with the APVMA was with Elivira Currie, Senior Reviewer – Adverse Experience Reporting Program, in October 2008

⁴ Quote from the APVMA Annual Report 2008-09: http://www.apvma.gov.au/about/corporate/annual_reports/2008-09/annual_report_08-09_full.pdf

⁵ *Ibid.*

⁶ Refer to American Veterinary Medical Association letter re Center for Veterinary Biologics Notice Draft No. 327: Studies to Support Label Claims of Duration of Immunity dated October 27 2008:

http://www.avma.org/advocacy/federal/regulatory/practice_issues/vaccines/duration_of_immunity_ltr.pdf

⁷ Jeffrey Harestad, Biologics Specialist, USDA-APHIS-Veterinary Services has advised me Center for Veterinary Biologics Notice Draft No. 327 "is still in process". (Email correspondence received 25 September 2009.)

⁸ Hart, Elizabeth. Is over-vaccination harming our pets? Are vets making our pets sick? 13 April, 2009:

http://users.on.net/~peter.hart/Is_%20over-vaccination_harming_our_pets.pdf

⁹ Hart, Elizabeth. Over-vaccination of pets – an unethical practice. 16 June 2009: http://users.on.net/~peter.hart/Over-vaccination_of_pets_-_an_unethical_practice.pdf

¹⁰ APVMA Annual Report 2008-2009: http://www.apvma.gov.au/about/corporate/annual_reports/2008-09/annual_report_08-09_full.pdf

¹¹ Protech C4 2l label: <http://www2.dpi.qld.gov.au/extra/asp/infopest/nra/labels.asp?prodcode=51489>

¹² Email correspondence to John Owusu, Principal Evaluator, Veterinary Medicines Program, APVMA dated 20 January 2009, 2 March 2009 and 24 March 2009.

¹³ 2003 AAHA guidelines: Paul, M.A., Appel, M.J., Barrett, R., Carmichael, L.E., Childers, H., Cotter, S., Davidson, A., Ford, R., Keil, D., Lappin, M., Schultz, R.D., Thacker, E., Trumpeter, E., Welborn, L. 2003. Report of the American Animal Hospital Association (AAHA) Canine Vaccine Task Force: 2003 Canine Vaccine Guidelines, Recommendations, and Supporting Literature.

¹⁴ Schultz, R.D. 1998. Current and future canine and feline vaccination programs. *Veterinary Medicine*. March 1998, 233-254.

¹⁵ WSAVA Guidelines: Day, M.J., Horzinek, M.C., Schultz, R.D. 2007. Guidelines for the Vaccination of Dogs and Cats, compiled by the Vaccination Guidelines Group (VGG) of the World Small Animal Veterinary Association (WSAVA).

Journal of Small Animal Practice 48 (9), 528-541: http://www.wsava.org/PDF/Misc/VGG_09_2007.pdf

¹⁶ *Ibid.*

¹⁷ *Ibid.*

¹⁸ *Ibid.*

- ¹⁹ 2006 AAHA guidelines: Paul, M.A., Carmichael, L.E., Childers, H., Cotter, S., Davidson, A., Ford, R., Hurley, K.F., Roth, J.A., Schultz, R.D., Thacker, E., Welborn, L. 2006 AAHA Canine Vaccine Guidelines, Revised: <http://www.aahanet.org/PublicDocuments/VaccineGuidelines06Revised.pdf>
- ²⁰ Hart, Elizabeth. Is over-vaccination harming our pets? Are vets making our pets sick? 13 April, 2009: http://users.on.net/~peter.hart/Is_%20over-vaccination_harming_our_pets.pdf
- ²¹ Hart, Elizabeth. Over-vaccination of pets – an unethical practice. 16 June 2009: http://users.on.net/~peter.hart/Over-vaccination_of_pets_-_an_unethical_practice.pdf
- ²² Protech C4 2l label: <http://www2.dpi.qld.gov.au/extra/asp/infopest/nra/labels.asp?prodcode=51489>
- ²³ WSAVA guidelines: http://www.wsava.org/PDF/Misc/VGG_09_2007.pdf
- ²⁴ *Ibid.*
- ²⁵ Protech C4 2l label: <http://www2.dpi.qld.gov.au/extra/asp/infopest/nra/labels.asp?prodcode=51489>
- ²⁶ WSAVA guidelines: http://www.wsava.org/PDF/Misc/VGG_09_2007.pdf
- ²⁷ *Ibid.*
- ²⁸ *Ibid.*
- ²⁹ WSAVA guidelines: http://www.wsava.org/PDF/Misc/VGG_09_2007.pdf
- ³⁰ Vaccination Principles. American Veterinary Medical Association: http://www.avma.org/issues/policy/vaccination_principles.asp
- ³¹ Schultz, R.D. 2000. Considerations in designing effective and safe vaccination programs for dogs. In: Carmichael, L.E. (Ed.), Recent Advances in Canine Infectious Diseases, International Veterinary Information Service: http://www.ivis.org/advances/Infect_Dis_Carmichael/schultz/IVIS.pdf
- ³² Schultz, R.D. 1998. Current and future canine and feline vaccination programs. *Veterinary Medicine*. March 1998, 233-254.
- ³³ *Ibid.*
- ³⁴ Schultz, R.D. 2007. What everyone needs to know about canine vaccines and vaccination programs. 2007 National Parent Club Canine Health Conference: <http://www.spinoneus.org/forum/uploaded/Admin/Vaccinations2007.pdf>
- ³⁵ Hart, Elizabeth. Is over-vaccination harming our pets? Are vets making our pets sick? 13 April, 2009: http://users.on.net/~peter.hart/Is_%20over-vaccination_harming_our_pets.pdf
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- ³⁷ Email correspondence to John Owusu, Principal Evaluator, Veterinary Medicines Program, APVMA dated 20 January 2009, 2 March 2009 and 24 March 2009.
- ³⁸ Australian Veterinary Association's (AVA) "Draft Policies and Position Statements – For members' comment by 13 March 2009" (briefly accessible on the internet) refers to "Responsible use of veterinary vaccines for dogs and cats". This draft policy admits that "annual vaccination is the currently accepted practice in Australia".
- ³⁹ Australian Veterinary Association Vaccination of Dogs and Cats Policy, ratified by the AVA Board on 26 June 2009: <http://avacms.eseries.hengsystems.com.au/AM/Template.cfm?Section=Home&Template=/CM/ContentDisplay.cfm&ContentID=14512> A media release announcing the new AVA vaccination policy was issued on 12 August 2009 – "Important to get vaccination message right": <http://avacms.eseries.hengsystems.com.au/AM/Template.cfm?Section=Home&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTFILEID=4558>
- ⁴⁰ *Ibid.*
- ⁴¹ Nicholls, Julia. Vaccination Policy in the Animal Welfare League of South Australia's publication "We care", Summer 2009.
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