Dear Allen

RE: UNNECESSARY VACCINATION OF PETS AND THE APVMA’S POSITION STATEMENT ON VACCINATION PROTOCOLS FOR DOGS AND CATS


However, I am extremely concerned that the APVMA continues to refuse to answer my legitimate questions about the unnecessary vaccination of pets.

The APVMA is unable to provide me with any evidence to support manufacturers’ revaccination recommendations on MLV core vaccine product labels. It is my understanding from reading the scientific literature that there is no evidence that repeated ‘annual’ or ‘triennial’ revaccination of adult dogs with MLV core vaccines is required. The scientific literature indicates MLV core vaccines provide long duration of immunity, probably lifelong.

Repeated ‘annual’ or ‘triennial’ vaccination of adult dogs with MLV core vaccines is of no benefit to the animal, and needlessly places it at risk of an adverse reaction to vaccine products. Unaccountably, many members of the veterinary profession continue to ignore scientific evidence of long duration of immunity with MLV core vaccines, and to withhold this information from pet owners’ consideration. Many veterinarians continue to urge pet owners to have unnecessary and possibly harmful interventions for their pets. This is a betrayal of pet owners’ trust.

The pet-owning public is being deceived on a massive scale, this is an international scandal.
Allen, re your response:

I have considered all of your and Beate’s suggestions in developing a new version of the APVMA’s Position Statement. I now expect that the Statement should be finalised and published in January. While I have accepted many of the suggestions, there are some that I have not accepted, for a range of reasons, including –

- Minimising the APVMA’s intrusion into areas that are outside APVMA’s sphere of responsibility;
- Not repeating some information from the WSAVA guidelines and the AVA policy and guidelines that is not part of APVMA’s position – but certainly referring to both documents.

As the Federal government regulator, it is the APVMA’s duty to sound the alarm that revaccination recommendations on MLV core vaccine labels are not evidence-based, and that veterinarians are unaccountably continuing to use these revaccination recommendations as an unacceptable excuse to unnecessarily revaccinate pets.

Many veterinarians urge pet owners to have their pets unnecessarily revaccinated with MLV core vaccines, and fail to obtain “informed consent” from their clients before carrying out vaccination. Pet owners are being exploited by those veterinarians who manipulate their clients into having unnecessary and possibly harmful interventions for their pets. The government regulator, the APVMA, has been complicit in this practice by allowing vaccine products with unsubstantiated revaccination recommendations on the market.

When is the pet-owning public going to be warned about this serious problem?

I look forward to being advised of the APVMA’s position on this serious issue, including pertinent references to the WSAVA guidelines and the AVA policy.

Allen, re your response:

As I indicated when we met, I sympathise with your concerns. Nevertheless, it is important for APVMA to maintain a balance in its position.

It is important for the APVMA to fulfill its responsibilities as the Federal government regulator. So far, the APVMA has failed in its responsibility to provide “rigorous and independent evaluation of scientific information about the safety and efficacy”1 of companion animal vaccine products. The community cannot “be confident that the products are safe and effective when used according to label instructions”.2

Allen, re your response:

“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?” This is a matter not only for APVMA, but also for the AVA, individual veterinarians, and State regulators....

Yes, you are right, “this is a matter not only for the APVMA, but also for the AVA, individual veterinarians and State regulators”. (My emphasis.)

So who is going to take responsibility for warning the public that crucial information on long duration of immunity and possible adverse reactions has been withheld from them for years?
I suggest that, as the Federal government regulator, it is the APVMA’s responsibility to get the ball rolling on warning the public about this matter, particularly after the inexcusable years of delay. In this regard, I look forward to the APVMA’s Position Statement on Vaccination Protocols for Dogs and Cats being published in January 2010.

Allen, re your response:

*The WSAVA indicates that vaccinated dogs have at least 98% protection from disease. If 10,000 dogs with this level of immunity are exposed to an infective dose of disease, up to 2% of them, or 200 dogs, may succumb to infection – with diseases that are potentially fatal. If these dogs were to be re-vaccinated, the vaccination would be unnecessary for 98% of them, but potentially life-saving for those 200 dogs.*

Allen, your argument is illogical. Are you seriously suggesting that thousands of dogs should be unnecessarily revaccinated with MLV core vaccines because a minority of dogs might not respond to vaccination? This is nonsensical.

The WSAVA guidelines note that vaccines may fail for various reasons:

1. **MDA neutralises the vaccine virus**
   This is the most common reason for vaccination failure. When the last vaccine dose is given at ≥12 weeks of age however, MDA should have decreased to a low level, and active immunisation will succeed in most puppies (>98%).

2. **The vaccine is poorly immunogenic**
   Poor immunogenicity may reflect a range of factors from the stage of vaccine manufacture to administration to the animal. For example, the virus strain, its passage history or production errors in the manufacture of a particular batch of product may be a cause of vaccine failure. Post-manufacture factors such as incorrect storage or transportation (interrupted cold chain) and handling (disinfectant use) of the vaccine in the veterinary practice, may result in inactivation of an MLV product.

3. **The animal is a poor responder (its immune system intrinsically fails to recognise the vaccinal antigens)**
   If an animal fails to develop an antibody response after repeated revaccination, it should be considered a non-responder. Because immunological non-responsiveness is genetically controlled in other species, certain breeds of dogs have been suspected to be poor-responders. It is believed (but unproven) that the high susceptibility to CPV-2 recognised in certain Rottweilers and Dobermans during the 1980s (regardless of their vaccination history) was due to a high prevalence of non-responders. In the USA today, these two breeds seem to have no greater numbers of non-responders than other breeds, possibly because carriers of the genetic trait may have died from CPV-2. This may not be true for other countries. For example, in the UK and Germany, the non-responder phenotype remains prevalent amongst Rottweilers.

On the latter point re ‘non-responders’, Ronald Schultz, a member of the WSAVA Vaccination Guidelines Group, estimates about 1 in 1,000 dogs cannot develop an antibody response to MLV CPV vaccines and are susceptible to infection and disease when challenged experimentally or naturally.

The WSAVA guidelines note that:

*Most vaccinated dogs will have a persistence of serum antibody (against core vaccine antigens) for many years. Immunologically, this antibody reflects the function of a distinct population of long-lived plasma cells (memory effector B cells). Induction of immunological memory is the primary objective of vaccination. For core vaccines there is*
excellent correlation between the presence of antibody and protective immunity and there is long DOI for these products.\textsuperscript{5}

The 2003 AAHA guidelines advise that duration of immunity with MLV vaccines is likely to be lifelong:

When MLV vaccines are used to immunize a dog, \textit{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.\textsuperscript{6} (My emphasis.)

The 2003 AAHA guidelines ask a very pertinent question, with a stunning answer:

So why revaccinate animals with (MLV vaccine) products annually when the minimum DOI (memory cells and antibody) is many years, if not a lifetime, for some of the vaccines? \textit{Ironically, there is no scientific basis for the recommendation to revaccinate dogs annually with many of the current vaccines that provide years of immunity (e.g. CDV, CPV-2, rabies)}... \textsuperscript{7} (My emphasis.)

It appears that, not only is there no scientific basis to revaccinate dogs annually with MLV core vaccines, \textit{there is also no scientific basis to revaccinate dogs triennially}...

In his presentation "Canine and Feline Vaccine Questions: Do We Have the Answers?" during the 5\textsuperscript{th} International Veterinary Vaccines and Diagnostics Conference held in Madison, Wisconsin USA in July 2009, Ronald Schultz provided the following question and answer:

\textbf{Q:} Do the current core vaccines (CDV, CPV-2, (FPV for cats), CAV-1/CAV-2) provide a long duration of immunity?

\textbf{A:} Yes, at least 7 to 9 years and \textit{most likely a lifetime}, based on many serologic and challenge studies. These studies include the MLV vaccines from all the major veterinary biological companies... \textsuperscript{8} (My emphasis.)

If a pet owner wants assurance that a dog’s immune system has recognised the vaccinal antigen, they can choose to have serological testing, i.e. antibody testing.

The WSAVA guidelines note that:

Testing for antibody is presently the only practical way to ensure that a puppy’s immune system has recognised the vaccinal antigen.\textsuperscript{9}

The WSAVA guidelines state that:

\textit{…the principles of ‘evidence based veterinary medicine’ would dictate that testing for antibody status (for either pups or adult dogs) is better practice than simply administering a vaccine booster on the basis that this should be ‘safe and cost less’}.\textsuperscript{10}

Serological testing is available in Australia and overseas. Why aren’t pet owners being given this option to check that a dog’s immune system has recognised the vaccinal antigen, rather than being urged to have their pets needlessly revaccinated with MLV core vaccines over and over again?  (This is not a rhetorical question).

On the topic of serological testing, veterinary expert Richard Ford says:
IT’S IMPORTANT TO NOTE…serum antibody titer to a particular antigen, especially a virus, is a relatively crude laboratory method of assessing immunity. Remember: antibody concentration is not necessarily synonymous with immunity. While a “POSITIVE” titer to canine distemper, canine parvovirus, and feline panleukopenia generally correlates with protection, a “NEGATIVE” titer to these antigens does not necessarily correlate with susceptibility. The need to vaccinate a patient with a NEGATIVE titer may not be necessary since cell-mediated immunity, is the principle immune response required to prevent disease.11 (My emphasis.)

Marian Horzinek, a member of the WSAVA Vaccination Guidelines Group, provides more explanation:

The scientific arguments in favour of less frequent revaccinations are traditionally based on antibody titers. Protection against most viral diseases is indeed antibody-mediated, and antibodies are easily measured. In dogs these have been found to persist for more than 7 years, the study did not look later. The high prevalence of adequate antibody response (CPV, 95.1%; CDV, 97.6%) in a large population (>1500 animals) “suggests that annual revaccinations against CPV and CDV may not be necessary” was the authors’ conclusion (Twark and Dodds, 2000)12…The question whether the titers found are protective or not against a field virus challenge is irrelevant for this discussion. It is not the residual serum antibody that determines survival to challenge but the population of memory cells that can quickly expand. The question about the longevity of memory cells has now been answered experimentally; the question was not, if lifelong immunity exists (which is common knowledge), but whether its mechanism relies on a lifelong presence of the antigen in the animal’s organism or of the cells’ longevity. The latter was not found to be the case. “Memory B-cell persistence is independent of persisting immunising antigen”; (Maruyama et al., 2000)13 However, it is not an individual memory B-cell, rather a population of slowly dividing clones that persists during the life of the organism. Like in neurobiology, a paradigm has been shattered: neurons and memory cells can indeed divide.14 (My emphasis.)

Ford also notes:

…substituting antibody titers for annual vaccination is perhaps the most common reason veterinarians submit serum for vaccine antibody titers. This is, however, a ‘self-fulfilling’ venture…eventually, it becomes apparent that most or all patients will have a protective antibody titer at 1 year, 2 years, and 3 years post vaccination.15 (My emphasis.)

A presentation by Bliss Thiel et al, titled “Age as it relates to long-term protective immunity in the dog and cat”, during the 5th International Veterinary Vaccines and Diagnostics Conference, July 2009, states:

Based on many years of experimental studies and on observations in the field, we conclude that previously immunized geriatric dogs and cats do not die from vaccine preventable infectious diseases. A single dose of MLV canine core vaccine (CDV, CPV-2, CAV-2) administered at 16 weeks of age or older will provide life long immunity in a very high percentage of dogs to all 3 vaccine antigens....When dogs and cats vaccinated at a young age were challenged years later with CDV, CPV-2 and/or CAV-1 and cats with FPV, they were completely resistant to both infection and disease. Observations in the field and by examination of necropsy records, as well as controlled studies, do not find old dogs and cats dying from infections caused by any of the vaccine preventable viruses. Infectious diseases are rarely a cause of death in older dogs and cats!16 (My emphasis.)
Given that MLV core vaccines are likely to provide lifelong immunity, it appears neither repeated vaccination nor repeated titer testing is necessary.

If the APVMA is genuinely concerned about dogs not being protected after vaccination, it should note the WSAVA warning that maternally derived antibodies (MDA) neutralize the vaccine virus.17

In this regard, the WSAVA guidelines currently recommend:

…initial vaccination at 8 to 9 weeks of age followed by a second vaccination 3 to 4 weeks later, and a third vaccination given between 14 to 16 weeks.18

The WSAVA guidelines also note:

…by contrast, at present many vaccine data sheets recommend an initial course of two injections. Some products are also licensed with a ‘10 week finish’ designed such that the second of two vaccinations is given at 10 weeks of age.19

An example of this is the Protech C3 vaccine product label, which recommends a third vaccination at 10 weeks of age.20 This is yet another example of vaccine product labels being out of step with the latest scientific advice, particularly as the WSAVA guidelines state that if an individual pet was to “receive only a single core vaccination during its lifetime…this should optimally be given at a time when that animal is most capable of responding immunologically, i.e. at the age of 16 weeks or greater”.21 (My emphasis.)

It is also pertinent to note the key message of the WSAVA guidelines:

We should aim to vaccinate every animal, and to vaccinate each individual less frequently.22

The WSAVA guidelines note that:

…even in developed countries it is estimated that only 30-50% of the pet animal population is vaccinated and this is significantly less in developing nations.23

The WSAVA guidelines recommend that:

We must vaccinate more animals in the population with core vaccines to achieve herd immunity (e.g. 75% or higher) and prevent epidemic outbreaks.24

Veterinary experts have emphasised the need to vaccinate more animals, rather than unnecessarily revaccinate the same animals over and over again.

For example, Rosalind Gaskell says:

Ultimately we need to target vaccination to a greater proportion of the population, rather than repeat-vaccinating the same individual animals.25

Dennis Macy advises:

…it doesn’t do any good to overvaccinate one segment of the population and not vaccinate the rest. Your good clients’ pets will have a higher risk of adverse reactions.26 (My emphasis.)

And Marian Horzinek adds:
It is of course more arduous to solicit new clients than to summon old ones, but it needs to be done.27

If government regulators and veterinary associations are genuinely concerned about animal safety, they should expend greater effort to vaccinate unvaccinated dogs in the interests of herd immunity, rather than unnecessarily revaccinate vaccinated dogs over and over again.

Unnecessary revaccination of dogs with MLV core vaccines cannot be justified. Not only is this an unnecessary expense for pet owners, most importantly, it puts dogs needlessly at risk of an adverse reaction. This is inexcusable.

Allen, re your response:

As Beate points out, the death of 1 animal from a vaccine reaction affects 100% of a family. Similarly, the death of 1 animal as a result of parvovirus affects 100% of a family – and the protection of up to 200 animals, even if it involves unnecessary vaccination of 9,800 dogs, may avert tragedy for many families.

Again, this is an illogical response. As I have already outlined above, there is no scientific justification for unnecessarily revaccinating pets that have responded to vaccination with MLV core vaccines.

Allen, re your response:

“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?” This is not within the scope of APVMA’s responsibility, so again I am assuming it is a rhetorical question – and that others are similarly asked, without expectation of answers from APVMA.

This is not a rhetorical question. Vaccination guidelines advising of long duration of immunity of MLV core vaccines have been available since 2003. Why has the pet owning public continued to be urged to have annual MLV core vaccinations for their pets, when ongoing revaccination of adult dogs with these vaccines has not been proven to be necessary, and needlessly puts pets at risk of an adverse reaction? Why haven’t the APVMA and Australian Veterinary Association, and Veterinary Surgeons’ Boards advised the public that MLV core vaccines with so-called ‘annual’ and ‘triennial’ revaccination recommendations actually provide long duration of immunity, probably lifelong? Why has this crucial information continued to be withheld from the public? None of these are rhetorical questions.

Allen, re your response:

Our Adverse Experience Reporting Program has recorded less than 1 in 10,000 adverse events (mild to severe) associated with (but not necessarily caused by) dog and cat vaccinations. Even taken into account the (inevitably) incomplete reporting of adverse experiences, and the difficulty of identifying adverse events if they occur years after vaccination, the number of severe adverse reactions in the 10,000 dogs may be much less than the level of disease prevented by the vaccination.

I have already provided detailed, referenced information on adverse reactions, including possible delayed adverse reactions and long-term health problems in my report “Is over-vaccination harming our pets? Are vets making our pets sick?”28 and in my paper “Over-vaccination of pets – an unethical practice”29, and also in my recent “Open Letter to representatives of the APVMA, AVA and ASAVA”.30
An open letter to the APVMA, AVA and ASAVA

8 January 2010

The WSAVA guidelines state that:

Adverse events are defined as any side effects or unintended consequences (including lack of protection) associated with the administration of a vaccine product. They include any injury, toxicity, or hypersensitivity reaction associated with vaccination whether or not the event can be directly attributed to the vaccine. Adverse events should be reported, whether their association with vaccination is recognised or only suspected.31

The WSAVA guidelines acknowledge that “there is gross under-reporting of vaccine-associated adverse events which impedes knowledge of the ongoing safety of these products”.32 (I know from personal experience that veterinarians are reluctant to report adverse reactions.)

Veterinary expert Jean Dodds says:

Some veterinarians today still tell their clients there is no scientific evidence linking vaccinations with adverse effects and serious illness. This is ignorance, and confuses an impressionable client.33

Richard Ford notes that “…delayed-onset (days-weeks-months) adverse events are much less likely to be recognized, reported, and studied”.34

In a paper titled: “Epidemiological approaches to safety investigations”, published in 2006, James Wood et al acknowledge that:

Adverse reaction surveillance is critical in monitoring the safety of a marketed product. Most is entirely passive and so reporting rates are likely to underestimate true incidence….Greater emphasis should be placed on active surveillance after product registration.35

The voluntary adverse experience reporting program run by the Australian Pesticides and Veterinary Medicines Authority appears to be just ‘window dressing’. In my opinion, it has not been designed to be a truly effective post-marketing surveillance system.

Who really knows how many adverse reactions, including delayed adverse reactions or long-term health problems, resulting from unnecessary vaccination go unrecognised and unacknowledged? The failure in regulation and surveillance means veterinarians who over-vaccinate and over-service continue to get away with this unethical practice. The status quo is protected from scrutiny.

Allen, re your response:

“How can the British government regulator, the Veterinary Medicines Directorate, justify a revaccination recommendation that condones unnecessary ‘annual’ and ‘triennial’ revaccination of dogs?” APVMA cannot speculate on VMD’s rationale – and therefore I am assuming this is a rhetorical question.

This is not a rhetorical question. The APVMA 2008-09 Annual Report acknowledges that “international engagement” is relevant to developing “international best practice regulations”.36 The APVMA 2008-09 Annual Report also notes that APVMA staff met with the Veterinary Medicines Directorate during the year.37 I suggest it is very relevant to ask the question why the VMD – or any government regulator - allows a “revaccination recommendation that condones unnecessary ‘annual’ and ‘triennial’ revaccination of dogs”. This cannot be considered ‘best practice regulation’.
An open letter to the APVMA, AVA and ASAVA

8 January 2010

Companion animal vaccination practice in other countries such as Britain and the US is very relevant to what is happening in Australia.

From my research, it is obvious that pharmaceutical companies, government regulators and veterinary associations are instrumental in maintaining repeated companion animal vaccination which has not been proven to be necessary. These organisations are also complicit in withholding information on long duration of immunity and possible adverse reactions from pet owners’ consideration.

It is time that this international scandal was exposed.

Allen, re your response:

While I imagine you may disagree with this analysis, it may assist in understanding the difficulty APVMA has in accepting your position in its entirety.

Yes, I do disagree with much of your analysis.

Allen, re your response:

Finally – we have commenced discussions with vaccine companies regarding possible changes to their labels. The initial response has been mixed.

I will be interested to hear the outcome of your further discussions with vaccine companies.

Allen, over the past 15 months I have spent a considerable amount of my time researching and lobbying on the problem of unnecessary vaccination of pets. The results of my research are contained in the following documents:

- **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
- **Open letter to the Australian Pesticides and Veterinary Medicines Authority, Australian Veterinary Association and Australian Small Animal Veterinary Association** (22 December 2009): http://users.on.net/~peter.hart/Open%20Letter%20to%20APVMA%20AVA%20ASAVA.pdf
My concerns are officially “on the record” with you and other representatives of the APVMA, and representatives of the Australian Veterinary Association and Australian Small Animal Veterinary Association. I am also in contact with other Australian and international government and veterinary authorities.

In the interests of consumer protection and companion animal safety, it is time the government authorities took effective action to ensure the public is warned about the problem of unnecessary vaccination of pets, and the veterinary profession brought to account for this prevalent practice.

In this regard, I look forward to reading and critiquing the APVMA’s Position Statement on Vaccination Protocols for Dogs and Cats when it is published in January 2010. Please send me a copy of the Position Statement when it is available.

Kind regards
Elizabeth Hart

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

Endnotes:
2 Ibid.
4 Schultz, Ronald, Professor and Chair, Department of Pathobiological Sciences, School of Veterinary Medicine, University of Wisconsin-Madison. Abstract of presentation on: Canine and feline vaccine questions: Do we have the answers?. Presented at The 5th International Veterinary Vaccines and Diagnostics Conference, July 19-24, 2009, Madison, WI USA.
7 Schultz, Ronald, Professor and Chair, Department of Pathobiological Sciences, School of Veterinary Medicine, University of Wisconsin-Madison. Abstract of presentation on: Canine and feline vaccine questions: Do we have the answers?. Presented at The 5th International Veterinary Vaccines and Diagnostics Conference, July 19-24, 2009, Madison, WI USA.
9 Ibid.
15 Bliss Thiel, Patricia Sharp, Elman Mukhtar, Laurie Larson, Ronald Schultz. Department of Pathobiological Sciences, School of Veterinary Medicine, University of Wisconsin-Madison. Abstract of oral/poster presentation on: Age as it relates to long-term protective immunity in the dog and cat. Presented at The 5th International Veterinary Vaccines and Diagnostics Conference, July 19-24, 2009, Madison, WI USA.
17 Ibid.
18 Ibid.
19 Ibid.
22 Ibid.
An open letter to the APVMA, AVA and ASAVA

8 January 2010

23 Ibid.
24 Ibid.
32 Ibid.
33 Dodds, Jean, Hemopet, Santa Monica, CA. Abstract of presentation on: Compliance or resistance to current vaccine guidelines?. Presented at The 5th International Veterinary Vaccines and Diagnostics Conference, July 19-24, 2009, Madison, WI USA.
37 Ibid.