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**An open letter to representatives of the Australian Pesticides and Veterinary Medicines Authority
and representatives of the Australian and international veterinary profession / industry**

Attention: Allen Bryce, Program Manager, Veterinary Medicines *
Australian Pesticides and Veterinary Medicines Authority (APVMA)

17 June 2010

cc:

- Tony Burke, Federal Minister responsible for the APVMA
- Eva Bennet-Jenkins, Chief Executive Officer, APVMA
- James Suter, General Counsel, APVMA
- Phil Reeves, Principal Scientist, Residues and Veterinary Medicines
- Simon Cubit, Manager, Public Affairs, APVMA
- Jenni Mack, Member of the APVMA Advisory Board
- Heather Yeatman, Chair of the APVMA Community Consultative Committee
- Ted Whittem and Glenn Browning, APVMA Science Fellows
- Michael Day, Chair of the Scientific Advisory Committee, and Chair of the Vaccination Guidelines Group, World Small Animal Veterinary Association (WSAVA)
- Marian Horzinek, Member of the Vaccination Guidelines Group, WSAVA
- Ronald Schultz, Member of the Vaccination Guidelines Group, WSAVA, and the American Animal Hospital Association Canine Vaccine Task Force
- Richard Squires, Member of the Scientific Advisory Committee, WSAVA
- Roger Clarke, Representative for Asia and Co-Chair of the Animal Welfare Committee, WSAVA
- Jolle Kirpensteijn, President and David Wadsworth, Immediate Past President, WSAVA
- Barry Smyth, Incoming President of the Australian Veterinary Association (AVA)
- Mark Lawrie, Director and Immediate Past President of the AVA
- Graham Swinney, President and Policy Councillor of the Australian Small Animal Veterinary Association (ASAVA) and AVA Scientific Committee Member
- Julie Strous, Executive Officer and Peter Punch, Chair, Australasian Veterinary Boards Council
- Sue Millbank, Registrar, Veterinary Surgeons Board of South Australia
- Steven Holloway, Registered Specialist in Small Animal Medicine
- Jane Hern, Registrar of the Royal College of Veterinary Surgeons, UK
- Richard Ford, Member of the American Animal Hospital Association Canine Vaccine Task Force
- Lynne White-Shim, Assistant Director, Scientific Activities Division, American Veterinary Medical Assoc.
- Bernard Rollin, Bioethicist, Colorado State University
- Steve Dean, Chief Executive Officer, Veterinary Medicines Directorate, UK
- Richard Hill, Director, Center for Veterinary Biologics, US
- Peter Bracken, Technical Services Veterinarian, Boehringer Ingelheim Pty Limited
- Aine Seavers, Veterinarian
- Luke Martin, Editor, The Veterinarian
- Jennifer Ritchie, Ag and Vet Chemicals (COAG Reforms), Dept. of Agriculture, Fisheries and Forestry
- Ann Bounds, Senior Advisor, Competition and Consumer Policy Division, The Treasury
- Bea Mies, Co-Advocate for judicious vaccine use

* Please note this letter and your response will also be forwarded to other relevant parties for information and discussion.

Dear Allen

**RE: UNNECESSARY, AND POSSIBLY HARMFUL, VACCINATION OF COMPANION ANIMALS AND
THE APVMA'S POSITION STATEMENT ON VACCINATION PROTOCOLS FOR DOGS AND CATS**

I see that the Australian Pesticides and Veterinary Medicines Authority has recently uploaded to its website a 'Community Question', i.e.:

“Does my dog or cat need to be vaccinated every year?”

Link: http://www.apvma.gov.au/news_media/community/vaccination_dogs_cats.php

As with the publication of the APVMA's Position Statement on Vaccination Protocols for Dogs and Cats in January this year, ***it is most disappointing that neither Bea Mies nor I were informed***

of this development, particularly in light of our ongoing research and extensive correspondence with the APVMA and AVA on this topic...

The APVMA's past failure to ensure that manufacturers' MLV vaccine product revaccination recommendations are evidence based is at the heart of the continuing problem of unnecessary vaccination of pets, coupled with the reluctance of many members of the veterinary profession to keep abreast of and acknowledge the latest science on duration of immunity and vaccination 'best practice'.

The APVMA's '**Community Question – Does my dog or cat need to be vaccinated every year?**' refers to "*the vet's knowledge of the canine/feline immune system*" in relation to vaccination practice.¹ This reference is ironic given that the World Small Animal Veterinary Association's Vaccination Guidelines Group has warned that "***there is an urgent requirement for education of practicing veterinarians in this area***".²

Allen, can you please advise me what action the APVMA is taking to ***proactively promote information on companion animal vaccination to the community***, particularly after ***all the years of inexcusable delay*** in acknowledging the problem of unnecessary vaccination of pets, ***and with pet owners continuing to be misled about companion animal vaccination?*** Merely posting information on the APVMA's website does not fulfill the government regulator's responsibility in this matter, particularly as most pet owners ***or veterinarians*** are unlikely to come across this information on the APVMA's website serendipitously...

As you are aware from my previous correspondence to both the APVMA and AVA, ***annual*** revaccination with MLV core vaccines continues to be promoted in the media, particularly via local newspapers across Australia.^{3 4} Dubious media advertorials about anecdotal parvovirus reports, which promote indiscriminate revaccination of dogs, appear to be the only publicly accessible information on parvovirus in the community, there is a dearth of transparent and reliable epidemiological data on companion animal disease.

Using the media to create fears about disease is a recognised ploy to sell pharmaceutical products, and is aptly described as 'disease mongering' when there is no scientific basis for a product's use⁵ (e.g. repeated MLV core revaccination of already immunised adult dogs.)

For example, a recent article titled "Alert on canine virus outbreak" in the *Gympie Times* (11 June 2010) reports that:

*Gympie dog owners are being warned of another outbreak of the deadly canine parvovirus (CPV)...CPV is easily preventable; all dog owners need do is make sure their puppies are vaccinated **and bring older dogs in for their yearly booster shots...***^{6 7}
(My emphasis.)

Alarming, it appears pet owners continue to receive a non-evidence based MLV core revaccination message from members of the veterinary profession who are not keeping up to date with scientific developments in this area. No wonder that repeated (unnecessary) vaccination is suspected to be a "convenient income generator".⁸

Pet owners are not being made aware of a key statement in the APVMA's Position Statement on Vaccination Protocols for Dogs and Cats i.e. that: "*...the aim should be to ensure that all susceptible animals are vaccinated, **rather than that already well-immunised animals are re-vaccinated.***"⁹ (My emphasis.)

The APVMA's Position Statement confirms that: "*State and Territory legislation that controls use of veterinary medicines allows registered veterinarians to use veterinary medicines "off-label" in*

dogs and cats. Veterinarians may therefore use vaccines at whatever interval they (and the client) determine is best for each particular animal. **Veterinarians and pet owners are under no obligation to follow revaccination intervals recommended on vaccine labels.**¹⁰ (My emphasis.)

I suggest the term 'off-label' is inappropriate with vaccines, which are so-called 'preventive' products rather than therapeutic medicines. In the case of MLV core vaccines, it has not been demonstrated that repeated revaccination of adult dogs is efficacious or beneficial.

In its Position Statement, the APVMA has admitted its failure to ensure evidence based regulation of vaccine products, now acknowledging that it **"does not support the retention of label statements that direct or imply a universal need for lifelong annual revaccination with core vaccines"**¹¹. Similarly, **there is no evidence that lifelong triennial revaccination is required.**

It is unacceptable that pet owners continue to be misled and coerced into paying for an intervention which has not been proven to be of benefit, particularly when the intervention has the potential to cause harm. Swift action must be taken by the APVMA **to remove unproven prescriptive revaccination recommendations on vaccine product labels**, and replace them with evidence based information on the **minimum** duration of immunity demonstrated to be provided by these products.

The APVMA's Position Statement notes that: *"The APVMA supports the AVA's vaccination policy."*¹² The AVA's MLV core vaccination policy is ambiguous but ostensibly 'triennial'.¹³ The APVMA reiterated its support for the AVA's 'triennial' revaccination policy in February 2010, in a joint media statement¹⁴ in response to a newspaper story headlined "Too many needles for pets" which reported that *"hundreds of thousands of cats and dogs are being over-medicated with unnecessary annual vaccinations"*.¹⁵ **(Incidentally, Allen, why is there no record of this joint AVA / APVMA media statement on the APVMA's website? Why is it only located externally on the AVA's website and not in the list of APVMA media releases?)**

There is **no** scientific evidence that either 'annual' **or** 'triennial' revaccination of adult dogs with MLV core vaccines is necessary.

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.¹⁶ **It is not necessary to use a designated 'three year vaccine' and it has not been proven necessary to revaccinate 'every three years'.**

In notes discussing the 2006 Canine and Feline Vaccination Guidelines, Richard Ford, Professor of Medicine, North Carolina State University, and a member of the AAHA Canine Vaccine Task Force, states:

It's important to note that the recommendations of the AAHA Canine Vaccine Task Force for triennial booster administration are based on data derived from vaccines that were on the market 5 years ago. Independent studies support the fact that extended durations of immunity (protection) against canine distemper, parvovirus, and adenovirus-2 are provided by all of the licensed (core) vaccines that were on the market between 2000 and 2003.

*Any implication that a "3-year vaccine" must be used when adhering to current vaccination recommendations is wrong...and misrepresents the intent of the 2006 AAHA Canine Vaccine Guidelines.*¹⁷

When the AAHA guidelines were first issued in 2003¹⁸, Richard Ford said that the decision to recommend a three-year cycle for vaccines was a compromise. When asked about the three yearly intervals for vaccination Ford said: *“That’s another embarrassing question. It’s completely arbitrary...I will say there is no science behind the three-year recommendation...”*¹⁹ (My emphasis.)

In other words, effective MLV vaccines with the traditional ‘annual’ revaccination recommendation provide long duration of immunity. ***It has not been proven beneficial for adult dogs that have been properly vaccinated as puppies to be repeatedly revaccinated with so-called ‘annual’ or ‘triennial’ MLV vaccines.***

A recent paper, (published in the Journal of Comparative Pathology in January 2010), co-authored by Ronald Schultz, Professor and Chair of the Department of Pathobiological Sciences University of Wisconsin-Madison, and a member of the WSAVA Vaccination Guidelines Group and AAHA Canine Vaccine Task Force, reiterates what has been well-known within the veterinary industry for years, i.e.: *“In general, adaptive immunity following vaccination with modified live virus (MLV) vaccines develops earliest and most effectively in that it is often complete (e.g. sterile immunity is induced) and duration of immunity (DOI) is often lifelong.”*²⁰ (My emphasis.)

In a recent paper titled “How I Vaccinate an Animal with Previous History of Adverse Reaction”, presented at the WSAVA congress in Geneva (June 2010), Michael Day, Professor of Veterinary Pathology, University of Bristol, and Chair of the WSAVA Vaccination Guidelines Group, provides a telling example ***which is very pertinent to all dogs...***

The first consideration is whether this dog requires revaccination at all. This is an adult dog that was appropriately immunized as a pup and received DHP boosters at 3 and 6 years with LPi boosters annually. Although the licensed duration of immunity (DOI) for the core vaccine components (DHP) is three years, there is now evidence for a minimum DOI of 9 years for CDV and CPV and, in reality, a dog that is appropriately immunized as a pup probably never requires another core vaccine during its lifetime. (My emphasis)

The non-core components of this animal's vaccine schedule (LPi) are also unnecessary. Although they do not have a DOI greater than 1 year, this is a city dog that is never kennelled in a boarding establishment and its lifestyle means that its risk of exposure to Leptospira or the canine respiratory complex is minimal. If the owner is in any doubt as to whether the animal is protected against the core vaccine-preventable diseases, then serological testing may be used to allay any fears. The presence of any titre of antibody to CDV, CAV and CPV is indicative of protection.²¹ (My emphasis.)

In an article published in *The Veterinarian* in September 2009, titled “Fur flies over small animal vaccination”, Richard Squires, Associate Professor in Companion Animal Medicine at James Cook University, and a member of the World Small Animal Veterinary Association's Scientific Advisory Committee, acknowledged that the Australian veterinary profession had lagged behind the rest of the world in accepting that there is no scientific justification for annual revaccination of pets, and noted ***“there is strong and mounting evidence that most vaccinations administered to adult dogs and cats serve no beneficial ‘immunological’ purpose whatsoever.”***²² (My emphasis.)

Given that the Australian veterinary profession has blatantly ignored the developing scientific knowledge on companion animal vaccination for many years, I suggest it is inappropriate for the APVMA to rely on the AVA for advice on vaccination ‘best practice’, particularly as the AVA has only very reluctantly acknowledged international dog and cat vaccination guidelines in recent times.

I suggest it would be more appropriate for the APVMA, and other international government regulators, **to consult directly with the WSAVA Vaccination Guidelines Group on this matter**, (although it must be acknowledged that the updated 2010 WSAVA guidelines²³ contain some ambiguous and inconsistent information which requires clarification).

Pet owners must be properly warned that **neither 'annual' nor 'triennial' revaccination** of adult dogs with MLV core vaccines has been proven to be necessary. Pet owners must be given the opportunity to consider information on long duration of immunity in the scientific literature and international dog and cat vaccination guidelines. **It is unacceptable that pet owners continue to be badgered into having unnecessary, and potentially harmful, repeated MLV core revaccination for their pets.**

The APVMA's Position Statement also states that **"...veterinarians should provide pet owners with pertinent, up-to-date information on vaccination best practice to assist in a joint decision as to whether and when to re-vaccinate their pet"**.²⁴

In this regard it is relevant to refer to an article, (published in the April edition of *The Veterinarian* magazine), by **pro-annual vaccination** veterinarian Aine Seavers, **who makes the outrageous demand that the AVA remove the information on vaccination currently openly available on its website**,²⁵ i.e. the AVA's policy on vaccination of dogs and cats ratified by the AVA Board in June 2009, and publicly released in August 2009.²⁶

For information, I attach a copy of my 'Letter to the Editor' of *The Veterinarian* in response to Seavers' article and the vaccination controversy. My letter also refers to comments made by Peter Bracken, a vaccine manufacturer representative, in his 'Letter to the Editor' in response to Seavers' article.²⁷

My letter to *The Veterinarian* seeks to give a 'pet owner's perspective' of the vaccination controversy, a perspective **that has been completely disregarded by the veterinary industry in past years...** This disregard for the rights and views of pet owners is unacceptable, particularly as pet owners are the major stakeholders in pets' health and wellbeing.

My letter to *The Veterinarian* includes commentary about the APVMA's Position Statement, and about the 2010 World Small Animal Veterinary Association (WSAVA) Guidelines for the Vaccination of Dogs and Cats (recently published online in the June 2010 issue of the *Journal of Small Animal Practice*, and expected to be freely available soon on the WSAVA website) which include the following **updated key statements**:

- **Vaccines should not be given needlessly. Core vaccines should not be given any more frequently than every three years after the 12 month booster injection following the puppy/kitten series, because the duration of immunity (DOI) is many years and may be up to the lifetime of the pet.**²⁸ (My emphasis.)
- **We should aim to vaccinate every animal with core vaccines, and to vaccinate each individual less frequently by only giving non-core vaccines that are necessary for that animal.**²⁹ (My emphasis.)

In his letter to *The Veterinarian*, Peter Bracken encourages **"veterinarians to use evidence based medicine and the latest science to guide vaccination decisions"**.³⁰ Which begs the obvious question, **what action have vaccine manufacturers taken over the many years of the vaccination controversy to correct non-evidence based 'annual' and 'triennial' prescriptive revaccination 'recommendations' on modified live virus (MLV) vaccine product labels?** Little or none as far as I am aware...

In this regard, it is alarming that, in its response to the discussion paper “A National Scheme for Assessment Registration and Control of Use of Agricultural and Veterinary Chemicals”, the APVMA believes:

...it should be the responsibility of each individual product registrant to ensure the ongoing safety of their products and adequacy of their labels in-line with contemporary scientific thinking and evidence.³¹

Isn't this the equivalent of leaving the foxes in charge of the chicken coop? There is an obvious conflict of interest here in that it is hardly likely that vaccine manufacturers will voluntarily take action which will decrease sales of their products.

In his summary of a presentation on Good Clinical Practice at the APVMA's recent Science Fellows Symposium in April 2010, Ted Whitem, Professor of Veterinary Clinical Sciences, University of Melbourne, notes:

*To consolidate end-user confidence in the use of veterinary medicines, **the consumer requires effective implementation of the registration process. Effective regulation relies on both consumer pressure for and industry acceptance of quality standards. Self imposed quality standards can be either an individual or industry lead practice. Self imposed quality standards lay the base of the regulatory pyramid for registration of veterinary medicines.**³² (My emphasis.)*

Whitem also warns:

*However, self imposed quality standards have potential to lead to an uneven base-level quality since some sponsors apply higher standards than others. In evaluation of regulatory rigour, **self imposed quality systems are usually regarded as less rigorous than enforced codes or mandatory laws.**³³ (My emphasis.)*

In other words, vaccine manufacturers are unlikely 'to ensure the ongoing safety of their products and adequacy of their labels in-line with contemporary scientific thinking and evidence' unless there is **an effective regulatory system** in place to enforce this.

The APVMA notes:

Under the existing arrangements there is no clear legislative path that allows the APVMA to require that underpinning scientific knowledge...be brought in line with or reviewed for compliance with contemporary standards. The APVMA first needs some indication of likely undue harm that would warrant taking regulatory action against the product.³⁴

Firstly, it is a significant failure in the regulatory system that agvet products are not regularly reviewed to ensure that they are in line with contemporary scientific knowledge.

Secondly, in the case of MLV vaccines, I suggest the APVMA is justified in taking **immediate action** to remove prescriptive 'annual' **and** 'triennial' revaccination recommendations from these products on safety grounds, as the original regulatory process failed to ensure there was evidence underpinning the prescriptive revaccination recommendations, or adequate safety testing. **This matter is particularly urgent in that vaccine products have known (and unknown and unacknowledged) risks.** It is unacceptable that dogs be placed at **any** unnecessary risk in having these products because repeated revaccination of adult dogs with MLV vaccines has not been proven to be efficacious or beneficial.

Consumer advocate CHOICE makes the point that:

*CHOICE believes that public and environmental safety is the overriding concern and products whose neither efficacy nor safety is proven should not be allowed on the market. No data, no market. **CHOICE very strongly believe the regulator must continue to require efficacy data. How could they ever be regarded as an effective regulator without looking at efficacy? The discussion paper notes that it is of critical importance to the user (pages 29,30). Efficacy is of prime importance to the entire community.** Moreover it is one thing to risk manage a chemical that is both efficiently and effectively serving a purpose. **It borders on negligent to allow chemicals – all of which have risks attached – into the environment for no ostensible purpose.**³⁵ (My emphasis.)*

I argue that these sentiments are also applicable to veterinary products such as companion animal vaccines.

It is unacceptable that potentially harmful vaccine products, that have not been proven to be efficacious and beneficial with repeated application, be allowed to have prescriptive revaccination recommendations. Due to a failure in regulation, pet owners are continuing to be misled into having unnecessary and potentially harmful vaccinations for their pets, and this situation is compounded in that members of the veterinary profession use their influence and authority to coerce pet owners into having these products for their pets, a practice which is to veterinarians' financial advantage.³⁶

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, and possibly harmfully, revaccinated over and over again. In regards to checking the status of dogs with an unknown vaccination history, the 2010 WSAVA guidelines advise:

*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'.³⁷*

On the topic of vaccine safety, in his letter to *The Veterinarian*, Peter Bracken attempts to play down "misconceptions about safety" of vaccine products.³⁸ Similarly, in its Position Statement on Vaccination Protocols for Dogs and Cats, the industry-funded APVMA makes assertions about the low incidence of adverse experiences with dog and cat vaccines, i.e.:

The incidence of adverse experiences associated with dog and cat vaccines reported to the APVMA's Adverse Experience Reporting Program (AERP) is low: less than 1 in 10,000 doses. The incidence of more serious reactions such as anaphylaxis is very low, and appears to be similar for initial vaccinations and revaccination, which is also true for human vaccines.³⁹

A low 'reported' incidence of adverse experiences is no excuse for prescription of so-called 'preventive' products that have not been proven to be efficacious or beneficial with repeated application.

Aside from this, I also dispute the APVMA's statement on 'reported' incidence of adverse experiences. As I have previously pointed out to the APVMA in my correspondence and papers (refer to links at the end of this letter) this scant information is misleading.

The 2010 WSAVA guidelines acknowledge that:

...there is gross under-reporting of adverse events which impedes knowledge of the ongoing safety of these products.⁴⁰

and

...we should aim to reduce the 'vaccine load' on individual animals in order to minimize the potential for adverse reactions to vaccine products.⁴¹

Who really knows how many adverse reactions result from unnecessary vaccination? Inadequate vaccine safety trials and ineffective post-marketing surveillance mean that many adverse reactions, ***including delayed adverse reactions and long term health problems***, are likely to go unacknowledged and unreported.

The failure in regulation and post-marketing surveillance means veterinarians who unnecessarily vaccinate and over-service continue to get away with this unethical practice, ***particularly as it has been recognised that 'some' veterinarians are reluctant to acknowledge and report adverse reactions.***^{42 43 44} The status quo is being protected from scrutiny.

I suggest the paragraph on adverse experiences in the APVMA's Position Statement should be replaced with a more thoughtfully worded statement that adequately reflects the lack of knowledge of the full range of potential adverse reactions, including possible delayed reactions and long term health problems, and the shortcomings of a voluntary adverse experience reporting system.

This statement regarding adverse events on the US Department of Agriculture's website is an interesting example to consider:

*Good estimates of the rates of various types of adverse events after the use of veterinary immunobiologics are not readily available. The information we have is based on voluntary spontaneous reports to manufacturers and the USDA. While it may be possible to calculate a reporting rate, the relationship between a reporting rate and an incidence rate is not clear. This relationship may vary by type and severity of event, species, manufacturer, and even from one month to the next...*⁴⁵

The true range of possible adverse reactions is unknown because it appears there was little pre-licensure safety testing done to test short-term and delayed effects of vaccination. According to a paper titled "Epidemiological approaches to safety investigations", James Wood and Vicki Adams note:

*Most safety testing is undertaken prior to granting of a marketing authorisation and is generally on a small scale. Field trials are usually much larger, but still involve relatively low numbers of animals compared to the number to which authorized products are administered. Safety testing is generally aimed at detecting common events; the numbers of animals used in the tests are too small for detection of all but the most common reactions. The efficiency of the tests depends on the frequency and severity of the adverse reaction and the ability to associate the adverse event with the product. **The latter is affected by the period of time between administration and the event**, as well as by its underlying frequency.⁴⁶ (My emphasis.)*

In a paper titled "Postmarketing surveillance for dog and cat vaccines: new resources in changing times", Moore et al note:

Adverse events that are relatively uncommon or that occur in high-risk subgroups (eg. elderly animals or specific breeds) are usually only detected through postmarketing

*surveillance. The full safety profile for a given vaccine can only be determined after the vaccine has been licensed and administered to large numbers (often millions) of individuals.*⁴⁷

In other words, dogs in the community are the guinea pigs for these vaccines. They (and their owners) are unknowingly part of a huge unregulated trial, the results of which are not being reported...

In a paper titled "Vaccine-associated adverse events", Kathryn Meyer advises that the results of safety testing are not routinely required on product labelling. This means that "rare events, events that occur after repeated exposure, and events that occur in a subgroup (e.g. specific breed, age)" are not noted on product labels. Meyer also notes that adverse event information derived from postmarketing surveillance is also not routinely required on the product's label.⁴⁸

David Husted, who at the time of writing his paper "What you can and cannot learn from reading a vaccine label" was International Technical Director of Fort Dodge Animal Health, admits that ***the biologic necessity to revaccinate annually has not been demonstrated.***⁴⁹ Husted also notes that "the quality and quantity of safety information on an animal vaccine label is much less than that found on the labels of common human vaccines". According to Husted "***it is not unusual for an animal vaccine label to essentially ignore the safety concerns of vaccine administration with the exception of anaphylaxis***". Animal vaccine labels contain only "***a few short safety statements, that in all probability do not accurately reflect the clinical safety of the product as observed by all users***".⁵⁰ (My emphasis.)

Due to limited testing, vaccine labels generally only include details of possible immediate side effects, they do not include details of possible ***delayed*** adverse reactions to vaccination.

In an article discussing adverse reactions to vaccination, Jean Dodds states "*beyond the immediate hypersensitivity reactions, other acute events tend to occur 24 to 72 hours afterward, or 7 to 45 days later in a delayed type immunological response*".⁵¹ (My emphasis.)

The 2010 WSAVA guidelines acknowledge that hypersensitivity reactions after vaccination "*can occur much later (e.g. hours to months)*".⁵² (My emphasis.)

Richard Ford notes that "*...delayed-onset (days-weeks-months) adverse events are much less likely to be recognized, reported, and studied*".⁵³

In the case of older animals, David Husted notes:

*Rarely does a vaccine label address expected responses in older animals, because there is a dearth of information about the vaccine needs of older animals and the responses that vaccines are likely to induce.*⁵⁴

Ronald Schultz states that:

*The risks of adverse reactions from vaccines are not well studied, nor are the adverse reactions rates well documented. Even where documented, the information is not readily available.*⁵⁵

The 2010 WSAVA guidelines provide a definition for adverse reactions:

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.***⁵⁶

In his 1998 paper “Current and future canine and feline vaccination programs”, Ronald Schultz provides a brief overview of suspected adverse reactions to vaccination:

*Postvaccination neurologic disorders, immunosuppression, dermatologic abnormalities, and other problems have been demonstrated to occur after administration of canine and feline vaccines. **These adverse reactions can range from mild, self-limiting illness to chronic disease or death.** A certain low percentage of these reactions are expected with biologicals (also with pharmaceuticals), and they occur in every species including people. **Some vaccines, however, have a greater likelihood of causing adverse reactions, and some animals are at greater risk. So the risks vs. benefits of every vaccine must be determined for each patient.***⁵⁷ (My emphasis.)

In a later paper Schultz lists a broader range of possible adverse reactions:

The immune mediated hypersensitivities caused by vaccines are well known and occur in every species. The most commonly observed hypersensitivity is a type I (immediate) reaction which is most often caused by IgE antibody resulting in a local or generalized anaphylaxis. The most common signs of local reactions are facial edema, hives, itching and rarely sneezing; signs of a systemic reaction include urination, vomiting, diarrhea, which is sometimes bloody, dyspnea and collapse. According to a recent survey we have conducted, the most common vaccination reactions observed in dogs include pain, soreness, stiffness and/or lethargy at variable times after vaccination. Swelling, a persistent lump, irritation, hair loss and/or color change of hair at site of injection were also observed as common reactions. A change of behavior was reported in a small percentage of dogs after vaccination. Post-vaccinal neurologic disease (e.g. encephalitis) was rare. All of the reactions noted above generally occur within minutes, hours or days after vaccination; they were, therefore, likely to have been associated with a vaccination. More recently, it has been shown experimentally that dogs develop an autoimmune response after vaccination, something that was known to occur in other species.^{58 59}

In his paper “Vaccine side effects: Fact and fiction”, Michael Day notes that “*vaccination-induced immunosuppression may on occasion be sufficient to permit the development of severe disease in animals that are carrying subclinical opportunist pathogens*”.⁶⁰

In a paper published in January 2010, Day also acknowledges the cumulative effects and consequences of repeated vaccination are unknown saying 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.⁶¹

Bioethicist Bernard Rollin warns there is increasing evidence that over-vaccination can actually be conducive to disease development, not only as a consequence of immunological stress, but also more directly. For example, frequent vaccination has been implicated in the development of autoimmune haemolytic anemia in dogs and injection site sarcomas in cats, both of which can be fatal.⁶²

Michael Day suggests vaccines containing alum may be implicated in cases of vaccine-associated autoimmunity.⁶³ **Aluminium is also associated with cancer in dogs.** A study by Vascellari et al identified distinct similarities between canine fibrosarcomas from presumed injection sites and feline post-vaccinal fibrosarcomas, **suggesting the possibility of the development of post-injection sarcomas not only in cats but also in dogs.** In this study

*“aluminium deposits were detected in eight canine fibrosarcomas from presumed injection sites”.*⁶⁴

Cancer is reported as being the single biggest cause of death in dogs over two years old.⁶⁵

According to information from Texas A&M University, dogs and cats have a higher incidence of many tumors than do humans. Dogs have 35 times as much skin cancer, 4 times as many breast tumors, 8 times as much bone cancer, and twice as high an incidence of leukemia as do humans.⁶⁶ A paper published in the British Journal of Cancer in 2001 ***suggests long-term over-activation of the immune system may be a major cause of cancer.***⁶⁷ This research refers to cancer in humans, but given we are all mammals with similar genes,⁶⁸ perhaps this possibility is also relevant to dogs? ***Could unnecessary vaccination, and the constant assault on the immune system, be causing a variety of cancers in dogs and cats over the long term?*** It is certainly something to ponder. This possibility is also another important reason to cease unnecessary revaccination of animals.

Summarising the incidence of post-vaccination adverse reactions in a paper titled “Predicting the “unpredictable” vaccine reactions”, Will Novak suggests that post-vaccination reactions can be classified into the following five degrees of severity:

- Class I Not related to vaccine
- Class II Lump/swelling at vaccination site
- Class III Facial swelling, generalized urticaria
- Class IV Systemic signs; fever, vomiting, diarrhea
- Class V Anaphylaxis, shock, collapse, death⁶⁹

In a paper titled “Vaccination protocols for dogs predisposed to vaccine reactions”, Jean Dodds reports that a wide variety of breeds of dogs, ranging from Shih Tzus to Great Danes, and a great many in between, may be more vulnerable to suspected adverse reaction to vaccination.⁷⁰

Novak’s study⁷¹ and another by George Moore et al titled “Adverse events diagnosed within three days of vaccine administration in dogs”⁷² report that ***small-breed dogs are at greater risk of an adverse reaction after vaccination.***

Moore et al report the risk of an adverse reaction was inversely related to a dog’s weight and that small breeds had significantly more adverse reactions than other dogs. Young adult small-breed neutered dogs that receive multiple vaccines per office visit were at greatest risk of an adverse reaction within 72 hours after vaccination.⁷³

The risk of an adverse reaction significantly increased as the number of vaccines doses administered per office visit increased; *“each additional vaccine significantly increased risk of an adverse event by 27% in dogs ≤ 10kg (22 lb) and 12% in dogs > 10 kg”.* The risk for dogs that weighed ≤ 5 kg was more than 4 times the risk for dogs that weighed > 45 kg. It was noted that ***“these factors should be considered in risk assessment and risk communication with clients regarding vaccination”.***⁷⁴ (My emphasis).

It was noted that vaccines, in contrast to virtually all veterinary pharmaceutical products, are prescribed on a 1-dose fits all basis, rather than by body weight. Moore et al suggested that the volume of vaccine doses may impact negatively on smaller dogs. It was also suggested that pre-licensing vaccine trials may under-estimate the rate of adverse reactions in smaller dogs.⁷⁵

In his study, Novak reported that *“data from our practice’s national database examining the incidence of post-vaccination adverse reactions in small breeds versus large breeds shows a clear increase in incidence in smaller breeds.”* Data indicates there is a relationship between breed size/weight and incidence of adverse reactions.⁷⁶

Despite the mounting evidence about vaccine adverse reactions and possible long term health problems, many veterinarians continue to deny a link with vaccination.

Jean Dodds, an expert in adverse reactions, notes:

*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.*⁷⁷

Dodds says:

*The veterinary profession and vaccine industry have traditionally emphasized the importance of giving a series of vaccinations to young animals to prevent infectious diseases, to the extent that this practice is considered routine and is generally safe for the majority of animals. Few clinicians are prepared, therefore, for encountering an adverse event and may overlook **or even deny the possibility.***⁷⁸ (My emphasis.)

Ronald Schultz also says “there is a reluctance to report reactions, even those that lead to the death of an animal”.⁷⁹

Members of the vaccine industry are also unwilling to acknowledge the possibility of adverse reaction to revaccination. In an article published in Veterinary Practice News, Tom Lenz, Vice President of Professional Services at Fort Dodge Animal Health says:

*It can be scientifically proven that not vaccinating can cause harm to an animal **but vaccinating per label suggestion has not been shown to be harmful.***⁸⁰

Lenz also says:

*Vaccines are pretty accurate the way they're labeled. These reactions have nothing to do with the frequency as to which the vaccines are given.*⁸¹

Lenz cites no evidence to support his statements. Vaccinating per label suggestion has **not been proven to be harmless**...

In an article published in 1995, titled “Are we vaccinating too much?”, Carin Smith notes:

*In the past, it was believed that annual vaccination would not hurt and probably would help most animals. **However, concerns about side effects have begun to change this attitude. The incidence of anaphylaxis and other adverse reactions appears to be increasing.***⁸² (My emphasis.)

Commenting in the same article, Ronald Schultz says:

The client is paying for something with no effect or with the potential for an adverse reaction. I believe that adverse effects are increasing because we are putting more and more components into these animals.⁸³ (My emphasis.)

In 2006, eleven years after the publication of “Are we vaccinating too much?”, the veterinary journal *Veterinary Microbiology* published a special issue including papers from an international scientific symposium entitled “Canine & Feline Vaccination – A Scientific Reappraisal”. The Preface of this special issue indicated not much had changed in the intervening years since “Are we vaccinating too much?” had been published:

*Nowadays, the main topic for discussion, both at owner and professional level, is no longer how effective the products are at preventing disease, but on the one hand whether we should be continuing to recommend revaccination in the same way as we have until now, and whether vaccination in fact causes significant side effects to the extent that **we are now doing more harm than good.**⁸⁴ (My emphasis.)*

Despite ongoing warnings, in 2010, 15 years after the publication of “Are we vaccinating too much?”, ***it appears the veterinary profession is still persisting with a scientifically unjustifiable practice that could be doing “more harm than good”...and are being aided in this unacceptable practice by government regulators who have failed to ensure that prescriptive vaccine product revaccination recommendations are evidence based.***

Despite scientific evidence that ‘annual’ (and ‘triennial’) revaccination with MLV core vaccines is unnecessary, this practice persists and continues to put pet dogs needlessly at risk of an adverse reaction.

It appears there have been no longitudinal trials, or effective post-marketing surveillance of dogs in the community, to test the effects of repeated revaccination over the life of an animal. ***So it is unknown if repeated vaccination over a dog’s lifetime can have deleterious consequences or what those consequences might be.***

Due to inadequate vaccine product safety labelling, vaccine certificates provided by veterinarians are also unlikely to provide much detail about the range of possible immediate and delayed side effects, particularly if veterinarians and veterinary associations are not keeping up with the latest scientific information warning of a possible broad range of side effects across different breeds of dogs, including delayed reactions.

This means that pet owners are not being warned of possible side effects of vaccination, and are denied the opportunity to weigh the risks and benefits prior to revaccination. Neither are they being advised of the long duration of immunity of MLV core vaccines. ***This means that veterinarians are not obtaining ‘informed consent’ from their clients before revaccinating their pets.***

The whole system is flawed. We are in a Catch 22 situation. When the vaccines were first licensed, the government regulators did not ensure that the vaccine label revaccination recommendations were evidence-based. Neither was the safety testing process adequate, and post-marketing surveillance is ineffective. In particular, it is unknown what effect ongoing revaccination might have on dogs of different breeds and ages. Side effect warnings on vaccine labels are minimal and do not indicate the possibility of other reactions. If reactions occur after vaccination, pet owners may not be aware of the urgency to seek immediate veterinary attention to address any symptoms.

Compounding the problem of under-reporting of adverse events by veterinarians, many pet owners may not associate adverse events or longer term health problems after vaccination with the vaccine product. ***Many pet owners would follow their veterinarian’s advice, and if the veterinarian does not acknowledge the possibility of an adverse reaction or health problem with vaccination, a pet owner may never recognise the possibility.***

Also, most pet owners would be unaware that they can make their own adverse experience reports to the Australian Pesticides and Veterinary Medicines Authority – are veterinarians telling their clients about the APVMA’s Adverse Experience Reporting Program? Of course, as the situation stands, even if reports of different adverse reactions are submitted, Kathryn Meyer advises us that additional types of adverse reaction are not being included on the vaccine product label.⁸⁵

And the stunning fact is, adult dogs simply don't need to be regularly revaccinated with MLV core vaccines, as they are likely to be protected after the final puppy vaccination at 14-16 weeks.⁸⁶ When adult dogs are revaccinated with MLV core vaccines they are undergoing risk for no benefit. Similarly, dogs undergo unnecessary risk when they are given non-core vaccines that they do not need.

Ronald Schultz notes:

In my opinion, vaccines are used that aren't needed and vaccines are given to animals that don't need them.⁸⁷

*Vaccines are medical products that should only be given if needed and only as often as is 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.⁸⁸***

Unnecessary 'annual' (and 'triennial') revaccination of adult dogs with MLV core vaccines is 'an unacceptable medical procedure'.

When is the pet-owning public going to be properly warned about this unacceptable practice?

Allen, Bea Mies and I have invested an enormous amount of our time into researching and corresponding on the topic of unnecessary vaccination of pets, including travelling to Canberra for a meeting with senior APVMA and AVA representatives in September last year, and attending the APVMA Science Fellows Symposium in April this year. We were also invited to comment on the APVMA's Draft Position Statement on Vaccination Protocols for Dogs and Cats.

It is a sad indictment on the system that members of the public have to work so persistently to try and bring attention to the failure in companion animal vaccine product regulation, and unacceptable veterinary practice.

After the extraordinary and inexcusable delay in addressing the problem of unnecessary, and possibly harmful, vaccination of pets, this matter now requires urgent resolution, as pet owners are being forced to unnecessarily revaccinate their pets to access veterinary services, boarding kennels, pet insurance, and pet grooming facilities. Non-core vaccines of questionable efficacy and safety are also being pushed indiscriminately. This is unacceptable and unethical.

Allen, given Bea's and my ongoing contribution to highlighting this problem, ***it would be appreciated if you would be kind enough to keep us both informed of developments relating to the APVMA's Position Statement on Vaccination Protocols for Dogs and Cats.***

Yours sincerely

Elizabeth Hart

Att: Letter to the Editor of *The Veterinarian*. E Hart, 7 June 2010.

For the record, I present below my papers, articles, submissions and correspondence on unnecessary, and possibly harmful, vaccination of pets:

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- ***Is over-vaccination harming our pets? Are vets making our pets sick?*** (13 April 2009). This report was tabled at a special meeting convened by the APVMA on 15 April 2009 to discuss the problem of unnecessary vaccination of pets:
http://users.on.net/~peter.hart/Is_%20over-vaccination_harming_our_pets.pdf
 - ***Over-vaccination of pets – an unethical practice*** (16 June 2009). This paper is a summary of my ‘over-vaccination’ report with additional information:
http://users.on.net/~peter.hart/Over-vaccination_of_pets_-_an_unethical_practice.pdf
 - ***Over-vaccination: Are vets making our pets sick?*** (June 2009, published in *National Dog* in July 2009):
http://users.on.net/~peter.hart/Over-vaccination_-_Are_vets_making_our_pets_sick.pdf
 - ***Results of a random mini-survey of Adelaide veterinary surgeries’ vaccination practice for adult dogs*** (September 2009):
http://users.on.net/~peter.hart/Survey_of_vet_surgeries_re_vax.pdf
 - ***Submission on the Consumer Voices Issues Paper: Request for consumer protection for consumers of veterinary services in Australia*** (17 July 2009):
http://www.treasury.gov.au/documents/1593/PDF/Elizabeth_Hart.pdf
 - ***The over-vaccination controversy continues*** (published in *National Dog* in December 2009):
<http://users.on.net/~peter.hart/Over-vaccination%20Controversy%20Continues.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>
 - ***Open letter to the Australian Pesticides and Veterinary Medicines Authority, Australian Veterinary Association and Australian Small Animal Veterinary Association*** (8 January 2010):
http://users.on.net/~peter.hart/Open_letter_to_APVMA_AVA_ASAVA_8_Jan_2010.pdf
 - ***Open letter to the Australian Pesticides and Veterinary Medicines Authority, Australian Veterinary Association, Australian Small Animal Veterinary Association, and Competition and Consumer Policy Division, The Treasury*** (24 January 2010):
http://users.on.net/~peter.hart/Open_letter_to_APVMA_AVA_ASAVA_CCPD_24-01-10.pdf
 - ***A Submission on the National Scheme for Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals Discussion Paper in relation to “Unnecessary, and Possibly Harmful, Use of Companion Animal Vaccines”*** (10 February 2010):
http://users.on.net/~peter.hart/PSIC_Submission_E_Hart.pdf
 - ***Too many needles ! Unnecessary vaccination exposed*** (February 2010, published in *National Dog* in April 2010):
http://users.on.net/~peter.hart/Too_Many_Needles_National_Dog.pdf

- **Open letter to the Australian Veterinary Association re continuing unnecessary vaccination** (6 May 2010, with an update added on pages 3-4 on 23 May 2010)
http://users.on.net/~peter.hart/Open_letter_to_the_AVA_re_continuing_unnecessary_vax_May_2010.pdf
- **Letter to The Veterinarian: A pet owner's perspective of the vaccination controversy** (7 June 2010)
http://users.on.net/~peter.hart/Letter_to_the_Veterinarian_June_2010_E_Hart.pdf
- **Media articles re parvovirus Dec 2009 to June 2010** (June 2010)
http://users.on.net/~peter.hart/Media_articles_re_parvovirus_Dec_2009_to_June_2010.pdf

Endnotes:

Note: If internet links do not work, try pasting the link in a web browser address bar, or otherwise search for the document by name in a web search engine.

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http://www.apvma.gov.au/news_media/community/vaccination_dogs_cats.php

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http://users.on.net/~peter.hart/Open_letter_to_APVMA_AVA_ASAVA_CCPD_24-01-10.pdf

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http://www.apvma.gov.au/news_media/news/2010/2010-01-21_vaccination_position.php The statement was revised after my urgent criticism to include the statement: ...the aim should be to ensure that all susceptible animals are vaccinated, **rather than that already well-immunised animals are re-vaccinated.** (My emphasis.)

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¹⁴ Australian Veterinary Association and Australian Pesticides and Veterinary Medicines Authority Joint Media Statement on Vaccination of Dogs and Cats, dated 5 February 2010:

<http://avacms.eseries.hengesystems.com.au/AM/Template.cfm?Section=20104&Template=/CM/ContentDisplay.cfm&ContentID=16206>

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⁸³ *Ibid.*

⁸⁴ Rottier, P.J.M., Sutton, D., 2006. Preface. Veterinary Microbiology, 117, p. 1.

⁸⁵ Meyer, E.K. 2001. Vaccine-associated adverse events. Veterinary Clinics of North America: Small Animal Practice. Vol. 31, No. 3 May 2001, 493-513.

⁸⁶ The WSAVA Vaccination Guidelines Group “recognizes that maternally derived antibody (MDA) significantly interferes with the efficacy of most current core vaccines administered to pups and kittens in early life. As the level of MDA varies significantly among litters, the VGG recommends the administration of three vaccine doses to pups and kittens, **with the final dose of these being delivered at 14–16 weeks of age or above**. 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.” (My emphasis.)

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⁸⁷ Schultz, R.D. 1998. Current and future canine and feline vaccination programs. Veterinary Medicine. March 1998, 233-254.

⁸⁸ 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>