

Elizabeth Hart
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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)

23 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
- Craig Emerson, Federal Minister for Competition Policy and Consumer Affairs
- 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
- 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**

Further to your email dated 18 June 2010 in response to my open letter dated 17 June 2010.

Allen, in regards to updating the APVMA's Position Statement on Vaccination Protocols for Dogs and Cats, you advise that "the APVMA has resource and workload challenges that prevent us from making these changes as quickly as you or I would like".

I too have 'resource and workload challenges', and I am becoming increasingly frustrated that Bea Mies and I are having to do your work for you. It is the APVMA's job to ensure that veterinary vaccine products are evidence based, not ours.

Similarly, in the past, in relation to queries regarding companion animal vaccination practice in Australia, I have been advised by Mark Lawrie, Immediate Past President of the Australian Veterinary Association, that “we simply don’t have the resources to respond to detailed technical and scientific inquiries on demand.”¹ If the AVA doesn’t “have the resources to respond to detailed technical and scientific inquiries” about companion animal vaccination practice, one wonders on what basis they claim to provide ‘professional’ advice to pet owners in this area?

It is astonishing that it is up to individual pet owners to do the research on this topic, **and then have to fight for it to be acknowledged by ‘the authorities’**.

Allen, my open letter of 17 June 2010 is the first letter directly addressed to you since my last letter dated 24 January 2010. Since that time you have also had the benefit of receiving a copy of my submission on the National regulatory system discussion paper (February 2010); a copy of my article “Too many needles! Unnecessary vaccination exposed” (published in *National Dog* in April 2010), and a copy of my open letter addressed to Mark Lawrie, AVA (May 2010).

My fully-referenced submission on the National regulatory system discussion paper highlights the failure of the regulatory system to keep abreast of scientific developments in companion animal vaccination ‘best practice’. My fully referenced letter to Dr Lawrie includes discussion on evidence-based medicine and ethics, which appear to be novel concepts in veterinary medicine in Australia, and I hope my letter has provided some enlightenment on these matters. I suggest these concepts are also relevant to the APVMA.

My fully-referenced open letter of 17 June 2010 addresses the problem of **continuing unnecessary, and possibly harmful, vaccination of pets**, and is also my **formal response to the APVMA’s Position Statement**, building upon my extensive research and previous fully-referenced correspondence. This letter contains new information, including reference to the recently published 2010 WSAVA guidelines; reference to an important presentation by WSAVA Vaccination Guidelines Group Chairman Michael Day (at the recent WSAVA congress in Geneva); and discussion about the submissions on the national regulatory system discussion paper by the APVMA, and by consumer advocate CHOICE. There is also a reference to a paper on Good Clinical Practice presented by Ted Whitem at the recent APVMA Science Fellows Symposium, reference to the urgent requirement for education of practicing veterinarians in vaccination ‘best practice’; yet another example of a call for ‘annual’ vaccination for parvovirus in the media; and also a very pertinent reference to ‘disease mongering’.

This additional material is most pertinent to my argument about unnecessary, and possibly harmful, vaccination of pets. My letter also contains information about adverse reactions, previously submitted to the APVMA. This information was repeated as it was obviously ignored in preparation of the APVMA’s current Position Statement, as the current paragraph in the Position Statement on adverse reactions is misleading, **as already explained in my letter**.

The extensive fully-referenced information I have provided to you is now officially ‘on the record’, **and I expect it all to be considered in the redrafting of the APVMA’s Position Statement**.

Allen, you note that:

...it is not APVMA's responsibility to monitor or control news articles in the *Gympie Times*, advice given by veterinarians about the need for re-vaccinations, or the quality of veterinary undergraduate and continuing education.

Do you know **who is** responsible for monitoring or controlling these matters? I would be grateful if you could let me know, because so far I have been unable to find anybody or any organisation who is willing to accept responsibility for regulation of these activities. It appears the veterinary

profession is totally unregulated, and answerable to no-one, **and therefore users of veterinary services have no effective consumer protection or means of complaint against unacceptable veterinary practice.** This is a most unsatisfactory state of affairs.

As a result of this lack of regulation, many veterinarians are abusing the trust of their clients, and continuing to coerce pet owners into having unnecessary, and possibly harmful, interventions for their pets.

For example, recently I have been forwarded a copy of a 'vaccination reminder' letter (dated April 2010) which recommended vaccination for "Parvovirus, Hepatitis, Distemper, Parainfluenza and Bordatella", noting that: "**Annual vaccinations are necessary to provide adequate immunity against life-threatening diseases**".

Because the recipient didn't respond to this first 'vaccination reminder', a second vaccination reminder was forwarded saying: "We feel that it is in the best interests of (dog's name) future health care program, that she be vaccinated against these potentially life-threatening diseases."

Another example of a veterinarian's reminder letter (dated May 2010), this one being directly addressed to the dog, advises:

It's time for your health check-up and vaccination. We understand you can't tell your owner if you are not feeling well, and this is why check-ups are vital for the prevention and early diagnosis of many diseases. We will also provide advice on any concerns your owner may have **as well as give you a VACCINATION to protect you against contagious and in some cases fatal diseases.** (My emphasis.)

This reminder letter includes a P.S. saying "Your owner can also visit our website to find out more about pet healthcare including vaccinations".

Checking the website, the diseases listed are "Distemper, Infectious Canine Hepatitis, Parvovirus and the serious respiratory infection, Canine Cough" and it is noted that "**Adult dogs require an annual vaccination booster every year.** You will receive a reminder when your dog's yearly vaccination is due." (My emphasis.)

What else is the trusting pet owner to do but obey this intimidating advice from the veterinary professional?

An example of unacceptable vaccination practice in action was brought to my attention recently by a woman in Sydney who had been given one of my open letters (i.e. the open letter to Mark Lawrie on the topics of evidence-based medicine and ethics.) This lady advised me that she and her husband had brought their two dogs to the vet for their check-up, as they did every year. They asked the vet about three yearly vaccinations. In her words:

We questioned the vet about this. The vet said something to the effect that they were not offering three yearly vaccinations at this time. As dogs still need annual vaccination for kennel cough and other things they may as well have everything annually. Also the three yearly vaccination is a different vaccine which they do not have at the present time.

While this conversation took place, the vet vaccinated the dogs. They were also given heartworm injections. Three days after the vaccination, one of the dogs, a four and a half year old Bearded Collie, appeared unwell. **Four days later the dog was dead.** Apparently the dog's "immune system had attacked the platelets in her blood. She had developed Thrombocytopenia.". The dog's owners asked the vet what had caused this reaction and, according to the owners, the vet advised them "it was the distemper shot".

As I know only too well, there are veterinarians who will dispute that the vaccination caused the dog to become sick and subsequently die. Regardless of what caused the dog's illness and subsequent death, ***what cannot be disputed is that this dog was given an unnecessary, and possibly harmful, intervention.***

The dog had previously been vaccinated many times, there was no need for it to be subjected to this intervention. However, according to the pet owners' story, they were given no opportunity to consider alternatives, ***in particular the opportunity not to revaccinate at all.***

It is completely unacceptable that pet owners continue to be coerced into these unnecessary, and possibly harmful, interventions for their pets. Pet owners must be given the opportunity to consider information in the scientific literature, and the 2010 World Small Animal Veterinary Association Guidelines for the Vaccination of Dogs and Cats, ***i.e. that core vaccines should not be given needlessly "because duration of immunity (DOI) is many years and may be up to the lifetime of the pet".***²

Pet owners should be advised that ***"...we should aim to reduce the 'vaccine load' on individual animals in order to minimize the potential for adverse reactions to vaccine products"***³ and that we should ***"vaccinate each individual less frequently by only giving non-core vaccines that are necessary for that animal"***.⁴

Allen, returning to your response, you suggest I should 'target my message at specific audiences'. For your information, over the past 20 months, I have undertaken a great deal of time consuming research and 'targeted' correspondence.

For example, since my own dog's death after unnecessary vaccination in September 2008, I have targeted correspondence to:

- the Australian Pesticides and Veterinary Medicines Authority;
- the Australian Veterinary Association;
- the Department of Agriculture, Fisheries and Forestry's Product Safety and Integrity Committee;
- Craig Emerson, the Federal Minister for Competition Policy and Consumer Affairs;
- State Veterinary Surgeons' Boards;
- the Australasian Veterinary Boards Council;
- Heads of Veterinary Schools in Australia and in the United States;
- the World Small Animal Veterinary Association;
- the American Veterinary Medical Association;
- the US Center for Veterinary Biologics;
- the British Veterinary Association;
- the Royal College of Veterinary Surgeons;
- the UK Veterinary Medicines Directorate;
- the Animal Welfare League;
- industry magazine *The Veterinarian*; and
- academics in Australia and overseas; etc.

My colleague Bea Mies has been working on this issue ***since 2005***, after the death of her dog after unnecessary vaccination in 2003. Bea has also targeted correspondence to:

- the Australian Pesticides and Veterinary Medicines Authority;
- Tony Burke, the Federal Minister responsible for the APVMA;
- the Australian Veterinary Association;

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- the Department of Agriculture, Fisheries and Forestry's Product Safety and Integrity Committee;
 - Craig Emerson, the Federal Minister for Competition Policy and Consumer Affairs;
 - the Australian Competition and Consumer Commission;
 - the NSW Veterinary Practitioners' Board;
 - the NSW Department of Primary Industries;
 - the NSW State Ombudsman;
 - the Australasian Veterinary Boards Council;
 - the World Small Animal Veterinary Association;
 - the RSPCA;
 - industry magazine *The Veterinarian*;
 - vaccine manufacturers; and
 - academics in Australia and overseas; etc.

Much of our 'targeted' correspondence has been ignored, or resulted in an unsatisfactory or 'buck passing' response.

Instead, I have found it more productive to target a broader audience with my correspondence, using the concept of the 'open letter'. This saves me from having to repeat the same message to various parties, **and also aids in providing some transparency, and hopefully some accountability**, in dealing with the **international scandal** of unnecessary, and possibly harmful, vaccination of pets.

As for your suggestion that I 'refine my message', I believe I originally succinctly summed up the situation in my email to Simon Cubit, Public Affairs Manager of the APVMA, in my email dated 16 February 2009.

As a consequence of this email, Dr Cubit arranged a meeting of APVMA senior scientific staff and APVMA Science Fellows Professors (in April 2009), to discuss my concerns about unnecessary vaccination of pets, for which I prepared my original report "Is over-vaccination harming our pets? Are vets making our pets sick?" (A copy of my email to Dr Cubit is included in the appendices of my report, as are samples of my early correspondence to Dr Lawrie of the AVA, and to the Heads of Veterinary Schools in Australia):

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

Subsequent to my report for the APVMA, I circulated my paper "Over-vaccination of pets – an unethical practice" (in early June 2009), followed by my open letters, submissions, articles, etc. This additional work has been necessary because **there has been much resistance to acknowledging the problem of unnecessary vaccination of pets, as evidenced by this unacceptable practice continuing today**, despite the AVA's policy on vaccination of dogs and cats (ratified by the AVA Board on 26 June 2009 and publicly released in August 2009), and despite the APVMA's (unpublicised) Position Statement on Vaccination Protocols for Dogs and Cats (dated 21 January 2010, and subsequently revised 25 January 2010).

So, Allen, I think it is disingenuous of you to infer that a 'refined message' would have been sufficient to gain attention for this issue in times past. It has taken a great deal of determination and perseverance on Bea's and my part to get to where we are now.

The evidence on vaccination has now been presented to you and is 'on the record', **as is your refusal to answer specific questions**.

On the topic of a 'refined message', Professor Michael Day, Chairman of the WSAVA Vaccination Guidelines Group, provides a refined message over which there can be little argument, courtesy of his recent presentation at the WSAVA congress in Geneva (June 2010), i.e.:

...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...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.⁵ (My emphasis.)

In his presentation, Professor Day also advises that **non-core** vaccines are **unnecessary** for a city dog that “is never kenneled in a boarding establishment” and with a lifestyle that “means that its risk of exposure to Leptospira or the canine respiratory complex is minimal”.

Professor Day’s message is a summary of advice in the 2010 WSAVA guidelines, and I suggest this message can be succinctly presented to dog owners as follows:

Important information for dog owners – vaccination update

The latest scientific evidence indicates that **core** vaccines for parvovirus, distemper virus and adenovirus (hepatitis) have a minimum duration of immunity of nine years and, in reality, a dog that is appropriately immunized as a pup **probably never requires another core vaccine during its lifetime**. 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 parvovirus, distemper virus and adenovirus is indicative of protection.

If a dog’s **core** vaccination status is unknown, concerned pet owners can choose to have serological testing to verify their pet’s antibody status, or a vaccination. 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 vaccination.

Vaccination with **non-core** vaccines only need be considered in individual cases for less serious diseases and less prevalent diseases (e.g. canine respiratory complex and Leptospira). **Non-core** vaccines have limited efficacy, and the risks and benefits of these vaccines should be carefully considered by the pet owner before administration.

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. We should aim to reduce the ‘vaccine load’ on individual animals in order to minimize the potential for adverse reactions to vaccine products.

Veterinarians should provide pet owners with pertinent, up-to-date information on vaccination best practice. It is important that veterinarians tailor vaccination regimens to suit the needs of each animal under their care, and discuss alternatives with their client.

References:

¹Day, M.J. How I Vaccinate an Animal with Previous History of Adverse Reaction. 35th World Small Animal Veterinary Association 2010 WSAVA Congress, Geneva, June 2-5 2010.

²Day M.J., Horzinek, M.C., Schultz, R.D. WSAVA Guidelines for the Vaccination of Dogs and Cats. Journal of Small Animal Practice. Journal of Small Animal Practice. Volume 51 Issue 6 (June 2010). (p 338-356).

This is the refined message that needs to be relayed to pet owners. A simple message, that doesn’t need to be convoluted with tortuously worded position statements or vaccination policies that seek to unjustifiably justify unnecessary ‘annual’ or ‘triennial’ vaccination.

The veterinary industry has known for years that there is no evidence to support repeated revaccination of pets with core vaccines. Animals have been placed needlessly at risk with this useless intervention. ***This is blatant exploitation of pets and pet owners.***

Any further delay in properly attending to this matter is unacceptable.

I have forwarded correspondence on this matter to Tony Burke, Federal Minister for Agriculture, Fisheries and Forestry, and with responsibility for the Australian Pesticides and Veterinary Medicines Authority, requesting that he take ***urgent action*** to ensure the public is warned about unnecessary, and possibly harmful, vaccination of companion animals. This is a matter that is relevant to the 12 million Australians who are associated with pets.⁶

Allen, as requested previously, ***it would be appreciated if you would keep Bea Mies and me informed about developments regarding the APVMA's Position Statement on Vaccination Protocols for Dogs and Cats.***

Yours sincerely

Elizabeth Hart

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

- ***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 Australian Pesticides and Veterinary Medicines Authority on 15 April 2009) of APVMA senior scientific staff and APVMA Science Fellows Professors 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>

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- **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 Mark Lawrie, President of the Australian Veterinary Association re continuing unnecessary vaccination of companion animals** (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
 - **Open letter to Allen Bryce, Program Manager, Veterinary Medicines, Australian Pesticides and Veterinary Medicines Authority re continuing unnecessary vaccination of companion animals; and the APVMA's Position Statement on Vaccination Protocols for Dogs and Cats**
(17 June 2010):
http://users.on.net/~peter.hart/Open_Letter_to_Allen_Bryce_APVMA_June_2010.pdf
 - **Letter to Tony Burke, Federal Minister with responsibility for the Australian Pesticides and Veterinary Medicines Authority, re continuing unnecessary vaccination of companion animals; and the APVMA's Position Statement on Vaccination Protocols for Dogs and Cats**
(17 June 2010):
http://users.on.net/~peter.hart/Letter_to_Tony_Burke_Minister_for_APVMA_June_2010.pdf

Endnotes:

¹ Personal email correspondence from Mark Lawrie, then President of the Australian Veterinary Association, 26 March 2009.

² Day M.J., Horzinek, M.C., Schultz, R.D. WSAVA Guidelines for the Vaccination of Dogs and Cats. *Journal of Small Animal Practice*. *Journal of Small Animal Practice*. Volume 51 Issue 6 (June 2010). (p 338-356). Published Online: Jun 1 2010 1:46PM.

³ *Ibid.*

⁴ *Ibid.*

⁵ Day, M.J. How I Vaccinate an Animal with Previous History of Adverse Reaction. 35th World Small Animal Veterinary Association 2010 WSAVA Congress, Geneva, June 2-5 2010:

<http://www.vin.com/proceedings/Proceedings.plx?CID=WSAVA2010&Category=&PID=56260&O=Generic>

⁶ Petnet Pet Statistics: <http://www.petnet.com.au/pet-statistics>