



Re Adverse experiences / the Virbac Disease Watchdog

from **Elizabeth Hart**

to Allen.Bryce@apvma

cc Simon.Cubit@apvma,
Bea Mies,
Pauline

date Mon, Jan 31, 2011 at 9:31 PM

subject Re Adverse experiences / the Virbac Disease
WatchDog

mailed-gmail.com

by

Dear Allen

Re my and Bea Mies' email to Mark Kelman, a representative of Virbac Animal Health and of the Australian Small Animal Veterinary Association, (dated 26 January 2011, see below), on which you and others were copied for information.

In my email I refer to (raw) data on cases of Canine Parvovirus reported by Kelman in an article published in *The Veterinarian* in August 2010, i.e.

Animals that have received at least one vaccination represent 28 per cent of puppies infected, and 11 per cent of adults infected.

According to these alarming percentages, this would indicate approximately 197 vaccinated puppies and 11 vaccinated adult dogs were reported to be infected with parvovirus in the period between January 2010 and the time of writing the article, which was published in August 2010.

According to Kelman's article, this information has been collected from only an estimated **20 per cent of veterinary clinics** across Australia. So, considering that, according to Kelman's calculation, **80 per cent of veterinary clinics have not reported to the Virbac Disease WatchDog**, numbers of vaccinated puppies and adult dogs being diagnosed with parvovirus, (or other adverse experience in relation to vaccination), could be considerably higher across Australia, **possibly many hundreds of vaccinated puppies/dogs**.

[The APVMA defines an AERP Vet adverse experience](#) as: "An unintended or unexpected (deleterious) effect on animals, human beings or the environment, including injury, sensitivity reactions or **lack of efficacy** associated with the clinical use of a veterinary chemical product **when used according to label instructions**." (My emphasis.)

Allen, can you please advise me how many adverse experience reports in relation to canine vaccination did the APVMA receive for the period January to August 2010?

I request your acknowledgement of this email and your urgent response to my question.

Also, for your information, Mark Kelman has responded to questions in my email, with the caveat that I do not forward his correspondence to any third party or persons. He has also refused to provide me with a copy of the template used to record cases in the Virbac Disease WatchDog. This lack of transparency is unacceptable. I am currently considering my response to him.

Regards
Elizabeth Hart

----- Forwarded message -----

From: **Elizabeth Hart**

Date: Wed, Jan 26, 2011 at 12:21 AM

Subject: Re the Virbac Disease WatchDog - Urgent request for information

To: mark.kelman@virbac

Cc: glenfb@unimelb, ted.whitem@unimelb, Peter.Bracken@boehringer-ingelheim, Peter.Lourey@sp.intervet, Australia.AnimalHealth@pfizer, Len.Small@biogal, Richard.Brandon@plavacc.com>, cmotto@vet.upenn, allen.bryce@apvma, Eva.Bennet-Jenkins@apvma, James.Suter@apvma, phil.reeves@apvma, Simon.Cubit@apvma, jennimack2, hyeatman@uow, M.J.Day@bristol, schultzr@svm.vetmed, richard.squires@jcu, atsuji@mail.ecc.u-tokyo, rbford@ncsu, bernard.rollin@colostate, roger.bunvet, jollenl, president@ava, asava@ava.com.au, info@vetspecialist, Julie.Strous@avbc, admin@avbc, Sue.Millbank.registrar@vsbsa, glynch@vpb.nsw, vaccines@oakflatsvet, rob@mpvconsulting, luke.martin@vetmag, Bea.Mies, Pauline, The.Hayes.Family

For the attention of: Dr Mark Kelman

- Technical Services Manager for Companion Animals, Virbac Animal Health; and
- Eastern Representative of the Australian Small Animal Veterinary Association

Dr Kelman

RE: THE VIRBAC DISEASE WATCHDOG – URGENT REQUEST FOR INFORMATION

We are contacting you in your capacity as a representative of Virbac Animal Health, and also as a representative of the Australian Small Animal Veterinary Association, in regard to your article about the Virbac Disease WatchDog, i.e. **Australia's national companion animal disease surveillance system – saving lives**, published in *The Veterinarian* in August last year.

Unfortunately, we are unable to log onto the [Virbac Disease Watchdog](#) for further information, as access to the website is restricted to veterinary clinics only.

We note that you indicate that the case data presented in *The Veterinarian* article represents raw data. **However, given the alarming statistics and time elapsed since publication, we presume that this data has by now been reviewed?**

We request your urgent response to the following questions.

Dr Kelman, you note that there is a lack of available disease prevalence and epidemiology data for companion animals which has “made it impossible for veterinarians to make educated decisions when trying to formulate best practice protocols regarding vaccination and treatment of diseases”.

Question 1: On what evidence have veterinarians decided vaccination protocols and treatment of diseases in companion animals up to now?

The dire need for strong epidemiological data is demonstrated by an article in *The Veterinarian* in October last year, which stated “There are approximately 52,000 cases of canine parvovirus enteritis (CPE) per annum in Australia...” (Richard Brandon – **A better prognostic tool and treatment for canine parvoviral enteritis (CPE)**)

Despite the assertiveness of this introductory sentence, this figure of 52,000 cases per annum was based on no hard data whatsoever, but was rather a guesstimate based on US and Australian dog population data, and an **unverified** reported rate of parvovirus enteritis incidence in the US of one million cases per annum, apparently provided by a vaccine company. (See footnote below for further details.)^[i]

This example demonstrates the need for actual hard evidence of disease and accompanying factors to provide a true picture of the situation.

We hope that Virbac’s Disease WatchDog is being developed **to report accurately on the prevalence of disease in the companion animal population**. The integrity of the data produced by the Virbac Disease WatchDog is particularly important given [Virbac Animal Health’s stance in promoting annual revaccination of adult dogs against diseases such as parvovirus](#), an intervention which has not been proven to be beneficial, and which goes against current recommendations in the [World Small Animal Veterinary Association’s 2010 Guidelines for the Vaccination of Dogs and Cats](#), i.e.

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.** (Emphasis added.)

Note: (The references to ‘every three years’ and the 12 month booster injection are ambiguous in this WSAVA recommendation. We are in the process of raising this matter with the WSAVA Vaccination Guidelines Group.)

Dr Kelman, in your article you describe the method of data collection for the Virbac Disease WatchDog, i.e.

In every veterinary clinic, one individual (a veterinarian or veterinary nurse) takes on the responsibility of the Disease Surveillance Champion – ensuring that cases of disease are recorded and then entered into the database. Cases can be entered monthly (following a reminder email from Disease WatchDog HQ) or disease can be logged as cases present to the clinic. **A template for temporary on-paper recording cases can be easily downloaded from the website.** It takes only 30 seconds to add a case into the system, with participants recording data including the animal’s breed, sex and age details, vaccination history, disease status and the outcome of the case.

Question 2: Can you please provide us with a copy of the template used to record cases of disease since the inception of the database?

Dr Kelman, in your article published in August last year, you note that: “Since January 2010, already 955 cases of disease have been recorded into the database, of which 803 of these were animals diagnosed with Canine Parvovirus.” You also note that two cases of Canine Distemper and two cases of Canine Hepatitis have been reported.

Question 3: Has it been verified that these animals were in fact infected with these diseases? How was this verified, what was the method used?

Re the cases of Canine Parvovirus reported to the Virbac Disease WatchDog. You note that: "Animals that have received at least one vaccination represent 28 per cent of puppies infected, and 11 per cent of adults infected."

According to these percentages, this would indicate approximately 197 vaccinated puppies and 11 adult dogs were reported to be infected since January 2010 at the time of publication in August 2010.

On the matter of vaccinated animals, there is confusion in the veterinary community about the appropriate puppy vaccination schedule, with some vaccine label schedules suggesting a 10 week finish (e.g. [Protech C4](#)), and others a 12 week finish (e.g. [Canigen DH_{A2}P](#) "under normal circumstances"). These recommendations conflict with advice in the WSAVA 2010 guidelines, which currently recommends the final dose be delivered at 14-16 weeks of age or above.

It appears the optimum puppy vaccination/optional titre test schedule has not yet been devised, and it is to be hoped the WSAVA Vaccination Guidelines Group will address this matter at the earliest opportunity, particularly given the recent publicity about an [in-veterinary surgery titre test recently launched on the US market](#). We understand from a company representative that this product has been available on the Australian and UK markets for approximately three years, and lab-based titre testing has been available for many more years. **Most pet owners are unaware of the option for titre testing to assist in verifying a response to vaccination as, unaccountably, they are seldom offered this service by veterinarians.**

Question 4: *Is it known what vaccination protocol was followed in the cases of the vaccinated puppies/dogs reported to be infected, i.e. what was the precise age of each puppy/dog at final vaccination (and at reported infection), and what combination of core and non core vaccines was administered?*

Question 5: *In line with the principles of 'evidence-based veterinary medicine', is it known if the vaccinated puppies/dogs reported to be infected had been appropriately tested for antibody status after core vaccination to assist in verifying a response to vaccination?*

Question 6: *In the case of the vaccinated puppies/dogs reported to be infected, have these cases been reported to the APVMA as possible adverse experiences, i.e. "lack of efficacy"? (Note: [The APVMA defines an AERP Vet adverse experience](#) as: "An unintended or unexpected (deleterious) effect on animals, human beings or the environment, including injury, sensitivity reactions or **lack of efficacy** associated with the clinical use of a veterinary chemical product **when used according to label instructions.**" (My emphasis.)*

Question 7: *Have verified cases of other diseases such as Leptospirosis or heartworm etc been reported to the Virbac Disease WatchDog?*

Question 8: *Are you aware if any of the animals reported to be infected had been subjected to any other interventions prior to illness, e.g. heartworm preventatives such as the heartworm injection or other veterinary products?*

Question 9: *Was the possibility of the vaccination, (or the application of other veterinary products), being implicated in any of these cases of illness considered? If so, were these cases reported to the APVMA's Adverse Experience Reporting Program?*

Dr Kelman, as noted above we are contacting you in your capacity as an official representative of Virbac Animal Health and the Australian Small Animal Veterinary Association.

We request your urgent response to the nine questions listed above.

Your response will be forwarded onto other parties for information.

Yours sincerely

Elizabeth Hart and Beate Mies

Independent Advocates for Judicious Vaccine Use

Attachments:

- Elizabeth Hart's research and open correspondence on vaccination of pets.
- Media articles on pet vaccination in Australia (including a report in CHOICE magazine, a report on ABC Stateline (South Australia), and also reports on ABC Radio South East NSW.
- Media articles about parvovirus, including articles recommending revaccination of adult dogs.

[i] The reported rate of parvovirus enteritis incidence in the US of one million cases per annum was from a paper titled **Recombinant bactericidal/permeability-increasing protein (rBPI2I) for treatment of parvovirus enteritis: a randomized, double-blinded, placebo-controlled trial**, co-authored by CM Otto et al and published in the *Journal of Veterinary Internal Medicine* in 2001; 15:355–360. Elizabeth Hart checked this paper to verify the information but could see no endnote for a reference to provide evidence for the figure of one million cases of parvovirus enteritis per annum in the US. Elizabeth Hart contacted one of the authors of the paper, Cindy Otto, to clarify the matter and she responded: "**that figure was suggested by one of the vaccine companies and supposedly is published but they wanted to charge us a huge amount of money to access the publication**". (Personal correspondence between Elizabeth Hart and Cindy Otto, November 2010.) **So, Richard Brandon's estimate of 52,000 cases of parvovirus per annum in Australia was based on unverified data, and was actually a guess based on no hard evidence.** (Confirmed in personal correspondence between Elizabeth Hart and Richard Brandon, November 2010.)