

**Canine Health Concern
PO Box 7533, Rait, Perthshire PH2 1AD
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10 February 2010

OPEN LETTER

TO STEVE DEAN,
CHIEF EXECUTIVE
VETERINARY MEDICINES DIRECTORATE
Woodham Lane
New Haw
Addlestone
Surrey
KT15 3LS

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Jackie Atkinson, Director of Authorisations, VMD
John Fitzgerald, Director of Operations, VMD
Hilary Benn MP, Secretary of State for Environment, Food and Rural Affairs
Jeff Rooker MP, Minister for Sustainable Farming, Food and Animal Welfare
Kevin Brennan MP, Minister of State, Further Education, Skills, Apprenticeships and Consumer Affairs
Charles Milne, Scottish Executive, Environment and Rural Affairs
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Roseanna Cunningham MSP, Scottish Government Minister for the Environment
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Christianne Glossop, Chief Veterinary Officer for Wales
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Richard Dixon, President, BSAVA

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Dear Professor Dean

We are writing with regard to the unnecessary vaccination of dogs and cats, and calling for decisive and immediate action from the Veterinary Medicines Directorate.

Despite repeated requests over many years, the VMD – a government department - has failed to take action to ensure that veterinary vaccines are administered no more frequently than is necessary, or to warn and protect the public from spurious claims on the part of veterinary vaccine manufacturers and veterinary surgeons. Independent duration of immunity studies have been available since the 1970s to show that immunity to viral disease in dogs and cats persists for years or the life of the animal, and that annual vaccination is not required.

To protect the pet owning public, the VMD must insist upon clarity within datasheets for MLV vaccines, and make it known that MLV vaccines do not need to be routinely 'boosted' every year, or even every three years. We are asking the VMD to withdraw license authorisations, and accompanying datasheets, which do not reflect the known science. We are asking for a public statement from the VMD to protect British citizens and their pets.

Such guidance would enable local authorities and kennels to stop demanding proof of annual vaccinations – which the science shows are unnecessary, and potentially damaging to the animals. Educated pet owners do not wish to be forced to pay for a veterinary procedure which is unnecessary and potentially harmful to their family pets, and nor should they.

We are also asking the VMD to provide clarification and guidance on the subject of non-core vaccines (such as the leptospirosis vaccine) which come with potentially serious adverse effects, and which should only be given in the face of a real disease threat.

The World Small Animal Veterinary Association (WSAVA) guidelines define non-core vaccines as "those that are required by only those animals whose geographical location, local environment or lifestyle places them at risk of contracting specific infections". As such, non-core vaccines should not be routinely administered on an annual basis.

We are aware, however, that no independent data exists to show the prevalence of core or non-core canine and feline diseases in the UK, which means that the public is at the mercy of the vaccine manufacturers' marketing machines and their scare tactics.

You are fully aware that vaccine manufacturers' revaccination recommendations in the UK conflict with the latest international dog and cat vaccination guidelines, as do the recommendations to clients from vets in practice in the UK.

I refer specifically to Intervet's yearly 'National Vaccination Month' which seeks to frighten pet owners into revaccinating pets whose 'boosters have lapsed by 18 months or more'. Our members have written to their MPs to challenge this marketing campaign in the past, and have received a document from yourself in response. You state in your document:

"Directive 2001/82/EC, as amended, is the European framework for the regulation of veterinary medicinal products, including vaccines, and has been transposed into the UK legislation. The legislation determines the quality, safety and efficacy requirements for a marketing authorisation to be granted. In addition, the product must meet the minimum mandatory requirements of the European Pharmacopoeia. Assessment of data provided by the pharmaceutical companies is carried out in the UK by the VMD's veterinarians and scientists."

You add: "... all claims made by the manufacturers must be supported with data from specific trials for each category of each species recommended for vaccination, by each recommended route of administration and using the proposed schedule of vaccination."

This is precisely the problem: The VMD has historically asked for one year's proof of efficacy from vaccine manufacturers – even before EU Directive 2001/82/EC - thereby allowing vaccine manufacturers to market products under the guise that they must be re-administered every year. The same applies to the three-year vaccines. Were you to insist upon longer DOI data, the over-vaccination of companion animals would cease, providing licenses for one- and three-year vaccines were withdrawn. It is known, for example, that only a limited number of veterinary practices in the UK have abandoned yearly boosters in favour of the available three-yearly boosters.

In fact, were you to take the independent DOI studies on board, as adopted by the World Small Animal Veterinary Association, the American Animal Hospital Association, the American Veterinary Medical Association, the Australian Veterinary Association, and now the Australian Pesticides and Veterinary Medicines Authority (your Australian counterpart), such data and their accompanying trials from manufacturers would not be required so long as an appropriate immune response could be demonstrated. You must by now be familiar with the advice of the world's experts in this field, that "once immunity to viral disease exists, it persists for years or life"? Such a statement was based upon the fact that a number of different vaccine brands were used in their DOI studies.

The Position Statement from the Australian Pesticides and Veterinary Medicines Authority states clearly that, "The international veterinary community is now increasingly supporting the position that annual re-vaccination with core vaccines is not required on a life-long basis," and that, as a result, "does not support the retention of label statements that direct or imply a universal need for life-long annual revaccinations with core vaccines" ... "is of the view that product labels should be amended to align with that policy," and "is working with vaccine registrants with a view to updating labels".

See http://www.apvma.gov.au/news_media/news/2010/2010-01-21_vaccination_position.php.

I would like to know why the Veterinary Medicines Directorate has been ignoring the known science in this regard since Canine Health Concern first brought the science to government attention in the early 1990s, and why it has consistently failed to act on behalf of pet owners and their pets.

A survey of vets participating in Intervet's National Vaccination Month by Canine Health Concern and its members last year showed that vets are needlessly giving the full puppy and kitten series to adult dogs and cats 'for the price of a booster'. They are engaged in a sales

promotion that promotes a practice that is not required (annual vaccination), and offers an incentive that is not required (a full puppy/kitten series for adult animals who have 'lapsed' by 18 months). As such, they are obtaining a pecuniary advantage by deceiving the pet owning public.

Intervet is apparently aware of the fact that dogs have not 'lapsed' within 18 months, according to their own research. Please note their statement that protection is provided for a minimum of three years:

Vet Ther. 2005 Spring;6(1):5-14.

Three-year duration of immunity in dogs following vaccination against canine adenovirus type-1, canine parvovirus, and canine distemper virus.

[Gore TC](#), [Lakshmanan N](#), [Duncan KL](#), [Coyne MJ](#), [Lum MA](#), [Sternier FJ](#).

Intervet Inc, 29160 Intervet Lane, PO Box 318, Millsboro, DE 19966, USA.

A challenge-of-immunity study was conducted to demonstrate immunity in dogs 3 years after their second vaccination with a new multivalent, modified-live vaccine containing canine adenovirus type 2 (CAV-2), canine parvovirus (CPV), and canine distemper virus (CDV). Twenty-three seronegative pups were vaccinated at 7 and 11 weeks of age. Eighteen seronegative pups, randomized into groups of six dogs, served as challenge controls. Dogs were kept in strict isolation for 3 years following the vaccination and then challenged sequentially with virulent canine adenovirus type 1 (CAV-1), CPV, and CDV. For each viral challenge, a separate group of six control dogs was also challenged. Clinical signs of CAV-1, CPV, and CDV infections were prevented in 100% of vaccinated dogs, demonstrating that the multivalent, modified-live test vaccine provided protection against virulent CAV-1, CPV, and CDV challenge in dogs 7 weeks of age or older for a minimum of 3 years following second vaccination.

By failing to make a statement of the known science, by failing to require longer DOI data from manufacturers, and by failing to remove one-year vaccines from the market, the VMD is facilitating the unethical practice of annual vaccination.

The WSAVA guidelines recommend: "We should aim to vaccinate every animal, and to vaccinate each individual less frequently." These international guidelines also recommend that, "we should aim to reduce the 'vaccine load' on individual animals in order to minimise the potential for adverse reactions to vaccine products".

UK vets in practice seem reluctant to adhere to international recommendations, and their professional bodies have failed to provide direction to their members in this regard. It therefore lies with the government and its servants to protect the pet owning public and their pets.

The WSAVA guidelines specifically advise that dogs properly vaccinated with MLV core CDV, CPV-2 and CAV-2 vaccines (distemper, parvovirus and adenovirus) "would have $\geq 98\%$ protection from disease". They recommend that dogs should not be vaccinated more frequently than every three years, and that immunity to viral disease lasts for at least seven years, but probably for life. This is based on direct challenge studies, and on serology. They call for annual checkups and possibly titer tests to replace revaccination each year.

Specifically, the WSAVA states:

"Vaccines should not be given needlessly. Core vaccines should not be given any more frequently than every three years." Please note that this does not mean that dogs and cats should be vaccinated every three years. It is a political concession to mollify vets who do not wish to lose all of their booster income.

The 2003 American Animal Hospital Association canine vaccine guidelines state that “there is no scientific basis for the recommendation to revaccinate dogs annually with many of the current vaccines that provide years of immunity.”

Dr Ronald D Schultz, a member of the World Small Animal Veterinary Association Guidelines Group notes:

“The one year [revaccination] recommendation was not determined by any scientifically validated studies nor will one find in the literature publications that demonstrate a need for annual vaccination with many of the products in use.”

The 2003 AAHA guidelines state:

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

The WSAVA guidelines also note: “Most vaccinated dogs will have a persistence of serum antibody (against core vaccine antigens) for many years. For core vaccines there is excellent correlation between the presence of antibody and protective immunity and there is long DOI (duration of immunity) for these products.”

The government, through the VMD, should be advocating titer testing in place of revaccination.

The RCVS, the BSAVA, and their members, are using VMD-approved datasheet guidelines to provide an excuse to revaccinate animals which do not need revaccinating. As UK veterinary bodies and their members cannot be persuaded to acknowledge and act upon the known science as adopted by their international peers, it lies with government and its servants to stop facilitating such acts.

No medical procedure should be performed if it is unnecessary, and all care should be taken to minimise the potential for adverse reactions.

The Veterinary Medicines Directorate has failed in its responsibility. The following paragraph is taken from the VMD website:

“The vision of the VMD is the responsible, safe and effective use of veterinary medicinal products. In working towards achieving this vision the VMD aims to protect public health, animal health, the environment and promote animal welfare by assuring the safety, quality and efficacy of veterinary medicines.”

The British public relies upon the VMD to make the science known when corporations and professional bodies do not. Transparency, and accountability, are the minimum requirements.

I put it to you that the VMD is overly concerned with supporting the financial interests of its ‘customers’. The VMD’s reports and accounts, and its website, clearly illustrate that customers are multi-national corporations, followed at the bottom of the list by the pet owning public and their pets.

In your own document, drafted after members of the public wrote to their MPs about this subject in 2009, you stated:

“Neither the European and national legislation, nor the VMD, requires that vaccines be administered annually.”

It therefore lies with the VMD to stop this practice. It is unnecessary and potentially harmful. Please do not reply to tell us that vaccine reactions are very rare, as this will simply reinforce your allegiance to multi-nationals. The WSAVA report itself recognises “that there is gross under-reporting of vaccine-associated adverse events”.

This letter is written on behalf of the hundreds of pet owners who have contacted Canine Health Concern after their dogs were made ill or died from unnecessary vaccine procedures, and whose illnesses and deaths remain unreported and unacknowledged. It is signed by veterinarians from around the world, and by some of the animal guardians who join us in calling for an end to a needless and potentially harmful veterinary practice.

Yours sincerely

Catherine O'Driscoll, Canine Health Concern, for Oliver, Prudence and Samson
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Lisa Lister, for Puzzle
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Jens and Christina Diron, for Tallinn
Eve Kueh for Trekkie
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Victoria Herbert, for Luna and River
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Bet Hargreaves, for Ailsa
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Wendy & Garry Galt for Bailey, Sandy, Sarah, Carson, and Sage
Jytte Smith, for Zoe
Barbara Burgess for Zilzie and Patch
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Sylvia Walker, for Tailor
Steve and Alison Pearce, for Minx
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Joyce McDowell, for Bailee
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Kath Rayson, for Oliver
Douglas M Decker SLC, for Alex, Casey and Nikko
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Christine Wyndham-Thomas, for Lucky
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Pat White, for Sabre
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