



ASSURING THE SAFETY, QUALITY AND EFFICACY
OF VETERINARY MEDICINES

Mrs O'Driscoll

By e-mail only

6 September 2010

Dear Mrs O'Driscoll

You describe our exchanges as a long journey but despite this 'journey' our views appear to have only converged to the extent that CHC now seem to accept that vaccination does have benefit. You suggest a greater degree of agreement might be achieved if we met but as my personal opinions do not differ from those applied to my business role this is unlikely. The position paper the VMD has published, although primarily representing the response from the VMD, also encapsulates my personal and professional opinion on pet animal vaccination.

It is noted that the CHC website seems to hold a different view on vaccination from that put forward in your last letter and you are on record as suggesting naturally acquired 'herd immunity' would be acceptable, in place of immunisation, as the answer to the common infectious diseases of pet animals. The CHC website seeks to generally direct owners away from vaccination of their pet animals which does not seem to support even the basic advice in the WSAVA guidance. CHC is invited to clarify its views. Whereas the VMD is able to support the WSAVA guidance in calling for all dogs to be vaccinated at least once and suggesting longer vaccination intervals where appropriate. In taking account of local conditions (nationally or regionally), a veterinary surgeon and the pet owner are the best people to decide how to maintain immune protection for the individual animal. This is a principal that holds true throughout the VMD's approach to the regulation of veterinary vaccines for pet animals and it is not considered to be an area where legislation should generally intervene.

We do not claim to know Prof Schultz's personal intentions whereas you seem confident to predict his thoughts but I will happily state here that my own dogs receive vaccination against leptospirosis annually and will continue to do so as their lifestyle does present a significant risk of exposure to this infection and the UK is largely an endemic area for leptospirosis. Prof. Schultz is a respected scientist and his work deserves due consideration alongside the work of many others. It is perhaps worth listing the members of the WSAVA Vaccine Guidelines Group as set out in an extract from the WSAVA website:

“The VGG is a small expert academic panel that works entirely independent of industry in formulating its recommendations. The VGG is currently chaired by Professor Michael J. Day (University of Bristol, United Kingdom) and includes Professor Ron Schultz (University of Wisconsin Maddison, USA) and Professor Marian Horzinek (formerly of Utrecht University, The Netherlands). Professor Schultz also sits on the American Animal Hospital Association Canine Vaccination Committee and Professor Horzinek is chair of the European Advisory Board on Cat Diseases. Collectively, the VGG has extensive academic expertise in microbiology, immunology and vaccinology.”

The WSAVA website also states: *'It is clear that the controversy surrounding small companion animal vaccination has not diminished and that there is an urgent requirement for education of practicing veterinarians in this area. The members of the VGG are actively engaged in delivering national and international lectures to help address this demand.'* I assume this is what you refer to when you state that: *"[WSAVA] is soon to embark upon an educational tour of vets around the world"*. Although this appears to be a critical point for CHC it is not a surprising approach where leading experts promote their views when they have a message to impart particularly where that requires a paradigm shift in veterinary opinion. It will also be interesting to see where the funding for this educational tour comes from as the WSAVA also confirm: *'The work of the VGG would not have been possible without the generous sponsorship of Intervet-Schering Plough Animal Health'*. You will note that despite the VGG being able to work independent of industry in formulating its recommendations, it nevertheless relies on funding support from the industry to carry out its work. This is not dissimilar to the regulatory role of the VMD which CHC members seek to criticise because the work is paid for by industry charges.

CHC state that science is, ideally, the open pursuit of truth. I say science is a quest for knowledge and perhaps a form of truth lies in the interpretation of the science but personally, speaking as a veterinary surgeon, science provides the possibility of improving the health and welfare of animals and colleagues at the VMD, and I, attempt to do this at all times and I am confident that is the general intent of my professional colleagues in general practice and industry too. Biological science, in particular, requires the weighing of knowledge and, in terms of veterinary medicines, employing the benefit of a treatment whilst attempting to minimise any unwanted side effects. Vaccines authorised for use in the UK achieve this aim when used as directed. Yet the accumulation of knowledge moves on and this is why, after careful evaluation of the product specific evidence, VMD has authorised pet animal vaccines with a recommendation for a reduced schedule to provide life-time protection.

However, quoting a pertinent extract from the WSAVA guidance signals a future opportunity to understand the situation as it currently stands and reach personal conclusions on the benefit:risk assessment for vaccination: WSAVA guidelines state: *'The final outcome of Phase II will be the release of a substantial information document for the owners and breeders of small companion animals. The VGG is well-progressed on the drafting of this document which we believe will be of immense value in education of our clientele'*.

The VMD, as a regulatory body, authorises veterinary medicinal products for the treatment of animals. We do not obstruct the work of the WSAVA and, as we have set out previously, the spirit of the WSAVA guidelines has been included in the authorisation of vaccines for the UK market. Nevertheless, how vaccines are used to protect animals from disease is a matter for the veterinary profession. The VMD does not regulate the clinical decisions of the veterinary surgeon. The responsible use of cat and dog vaccines is quite rightly in the hands of the profession because the science of immunology requires clinical knowledge and expertise to be effectively applied at the level of the individual animal. The VMD's role is to support the animal owner and their veterinary surgeon by ensuring vaccines can be used safely. It is the professional who decides which vaccines to recommend for use, how they are employed and in which circumstances. Therefore the VMD does not adopt a political stance on pet animal vaccination neither does it support the pharmaceutical industry other than to provide a timely service for the assessment of industry data dossiers to ensure safe and efficacious medicines are made available. Perhaps the most important point for CHC to comprehend is that the VMD has no direct regulatory powers over the professional behaviour of the veterinary surgeon. I had hoped this was clear from our position paper but I am grateful to you for the opportunity to add further clarification as this does not appear to have been understood.

As for the VMD stance not making scientific sense, we justifiably disagree with CHC's view. Each vaccine is based on specific strains of organism. They are manufactured through detailed, specified methodologies. Each product has unique antigenic characteristics and therefore must be subjected to individually specific quality checks and testing to establish safety and efficacy. What would not make scientific sense would be to assume that every vaccine behaves identically. This is one of the reasons why the regulatory authorities around the world are rightly reluctant to make broad assumptions based on general research findings in the absence of critical proof.

VMD has responded to the list of CHC statements in your letter and I thank you for distilling your outstanding issues in this way. Attached is an appendix which uses your statements as a template, listing CHC's points with our responses at the appropriate place.

Yours sincerely

A handwritten signature in black ink, appearing to read "S. Dean". The signature is fluid and cursive, with the first letter being a large, stylized 'S'.

Professor Steve Dean

1. **CHC states:** *The WSAVA has laid out guidelines to ensure that all animals receive vaccines against the core viral diseases (in the UK these are distemper, parvovirus and adenovirus for dogs), and that individual animals are vaccinated less frequently by only giving non-core vaccines that are necessary for that animal.*

VMD Response: The VMD has no dispute with this comment.

2. **CHC states:** *Vets in the UK are vaccinating dogs and cats, as the established practice, against both core and non-core diseases on an annual basis. Current science shows that it is neither necessary nor safe to vaccinate against core viral diseases annually. In order for this situation to be rectified, CHC called upon the VMD, in February 2010, to withdraw one-year vaccines for core viral diseases – as immunity persists for much longer than a year and, as you have confirmed yourself, 3-4 year vaccines are available. We have subsequently sought to persuade the VMD that – as stated by the WSAVA - non-core vaccines should not be routinely given, but only when there is a known disease threat in the area. In some cases, the non-core vaccines are of questionable safety, benefit and efficacy (according to the WSAVA and also CHC).*

VMD Response: The evidence for CHC's generalisation that vets are giving core vaccines on an annual basis is not clear. Annual UK sales of core vaccine doses are approximately 3.6 million doses. Estimates of the canine population in the UK vary between 6-8 million and at least 0.5 million puppies are raised annually to maintain this population. Given these figures, it is clear that not all dogs can be vaccinated and certainly not annually. Therefore, although the VMD accepts that a range of vaccine strategies is being employed in the UK, CHC cannot claim with any certainty that vets are vaccinating the national dog population annually with MLV vaccines. The issue of adverse reactions and safety of vaccination is dealt with later.

3. **CHC states:** *It is CHC's contention that the VMD – for some reason – is obstructing adoption of the WSAVA Guidelines whilst giving the appearance of supporting them. If the UK can be seen to be going along with the current science whilst not actually doing so, then annual vaccination can continue ... but with what aim? For how much longer are British dogs and cats to be subjected to unnecessary vaccines?*

VMD Response: The VMD has no objective to obstruct veterinary surgeons from adopting the WSAVA guidance but neither will it seek to force a veterinary surgeon or an animal owner into adopting a specific approach when it is not a legislative requirement. Vaccination of cats and dogs in the UK is optional but is highly recommended by veterinary surgeons (including the WSAVA). For every vaccine, a Summary of Product Characteristics (SPC) is publically available on the VMD website (www.vmd.gov.uk) and this sets out the authorised uses of each vaccine Duration of Immunity (DOI) is defined in a way to suggest it is a minimum period. This does not imply a particular revaccination period is mandatory or necessary. Any decision to vaccinate is for the owner and their veterinary surgeon to decide based on the individual animal's circumstances taking account of the available evidence including the information on the SPC. Annual revaccination may continue where it is considered necessary by the owner and their veterinary surgeon.

4. **CHC state:** *At the beginning of the 21st Century, veterinary bodies around the world began to speak out with regard to the known science, although Kirk's Veterinary Therapy carried research nearly **four decades ago** to confirm that immunity to core canine viral diseases persists for years or life. CHC has been reflecting this information repeatedly since 1994.*

VMD response: Scientific confirmation of a theory or hypothesis is challenging and time consuming. The publication of a finding in a peer reviewed journal is insufficient on its own to change established veterinary policy. The time period from 1994 to the present day is not exceptional for the verification and general adoption of a new science based policy and paradigm shifts in behaviour do take time to achieve. However such changes of clinical opinion are for the veterinary profession to adopt and not for the regulatory bodies to enforce.. The WSAVA Guidance was published first in 2007 and this has already been adjusted in 2010 demonstrating how opinion is changing even over this brief period. Regulatory standards inevitably lag behind developing scientific opinion as they reflect the accepted scientific understanding. Furthermore the drive for change is less where there is a low incidence of problems as a result of vaccination,. Another dimension to any change of policy is the status of population immunity, which is reliant on many factors not least the prevalence of the disease, vaccination status and the health of the in-contact animal. Population immunity will be determined in part by the vaccine programmes being used and these can change the epidemiology of a disease. Such change may justify, in some regions, an adaptation of a routine schedule of vaccination And it is possible this point has been reached for some of the MLV vaccines in some regions of the world. Although immunity may possibly be induced by vaccination for many years against some diseases and lifetime protection is possible, this is yet to be reliably proven. In regulatory terms, for a claim to be made for a vaccine justification is required through specific research data and this will include a claimed duration of immunity (DoI)..Lifetime studies in animals, such as dogs and cats, are prohibitively expensive and ethically questionable and it is not surprising these studies have not been routinely provided. It is, therefore, quite justifiable for regulatory bodies and the veterinary profession to proceed with caution and require adequate proof before taking action that could adversely affect the health of pet animals.

CHC have relied upon the announcements of other organisations and these are worth deeper consideration to take into account their entire view to ensure selected quotes are taken in context.

5. **CHC state:** *The American Animal Hospital Association, the American Veterinary Medical Association, the Australian Veterinary Association and the World Small Animal Veterinary Association have made official pronouncements to confirm that annual vaccination is neither necessary nor without harm.*

VMD response: The American Animal Hospital Association and the American Veterinary Medical Association, the Australian Veterinary Association and the WSAVA are all professional veterinary bodies. Similar organisations in the UK would be the British Veterinary Association and the British Small Animal Veterinary Association.

Appendix II provides a more complete extract from the AVA website as an example so that the CHC assertion can be viewed in context. Careful reading will reveal AVA's view is very similar to that of the VMD.

6. **CHC states:** *This year, the Australian VMD equivalent – the APVMA – officially stated that it “does not support the retention of label statements that direct or imply a universal need for life-long annual revaccinations with core vaccines”.*

VMD response: The full quote includes the statement:

‘The APVMA is working with vaccine registrants with a view to updating labels’.

This is in line with the VMD’s actions over the past decade where vaccine companies have been encouraged to update their data supporting DoI. Where this has not yet happened the SPCs indicate a DoI of **at least one year** and do not recommend annual revaccination for the core vaccines (in line with the WSAVA guidelines).

There seems to be little to justify the CHC inference that the VMD, as a regulatory body, is not making progress in line with the information flowing from other international bodies.

7. **CHC state:** *The basis of the WSAVA stance – which can be seen in full at <http://www.wsava.org/VGG1.htm> - is that:*

VMD comment: The VMD note that in this section CHC has paraphrased the WSAVA guidance but in doing so has modified the advice in ways that may mislead the public. For clarity the VMD has reproduced those parts of the WSAVA guidance under the CHC paraphrasing but would advise the entire WSAVA guidance is read so that undue emphasis is not placed on any particular sentence or that a meaning of a sentence is not taken out of context. The bullet points are reproduced in italics as CHC state them.

- *Dogs should be vaccinated no more frequently than every three years against the core viral diseases, namely distemper, parvovirus and adenovirus.*

VMD comment: A representative extract from the WSAVA guidance states: “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.” (VMD has inserted bold highlight for emphasis)

The VMD has no objection to the WSAVA statement and has actively encouraged the development of vaccines that facilitate an immunisation interval for MLV vaccines of 3 years or more. Veterinary surgeons in the UK are empowered to take account of the WSAVA guidance. In the UK veterinary surgeons can select vaccines with a stated DoI in line with this recommendation. Best practice recommendations suggest owner consent should be obtained for off-label use of a medicinal product (including vaccines).

- *Once immune, dogs vaccinated against the above core diseases are likely to remain immune for many years, and **in all probability for life**. Revaccination confers no added benefit to already immune dogs (and cats), **and may be harmful**. **Serology tests will confirm if circulating antibodies are present**. (bold highlight added by VMD – see comment below)*

VMD comment: The WSAVA actually state (VMD has added bold to highlight points): “Dogs **that have responded to vaccination** with MLV core vaccines maintain a solid immunity (immunological memory) for many years in the absence of any repeat vaccination. Following the 12 month booster, subsequent revaccinations are given at intervals of 3 years or longer, **unless special conditions apply**. It should be emphasized that the considerations given above do not generally apply to killed core vaccines nor to the optional vaccines, and particularly not to vaccines containing bacterial antigens. Thus *Leptospira*, *Bordetella* and *Borrelia* (Lyme disease) products, but also parainfluenza virus components, require more frequent boosters for reliable protection. **Therefore an adult dog may today still be revaccinated annually, but the components of these vaccinations may differ each year.**”

THE VMD agrees with the WSAVA guidance but in the UK, some authorised vaccines have been shown to provide immunity in young dogs without the need for a 12 month booster vaccination. However some specific comments are needed related to the CHC wording above (see bold highlights):

- **... in all probability for life:** the question for a dog owner is how this can be relied upon. Some data quoted by WSAVA suggest up to 6-9 years of immunity for the recommended puppy course but how much this is reproduced across the canine population and what local conditions are necessary is not clear. Thus even WSAVA frequently mention vaccination at three yearly intervals as a recommended maximum.
 - **.... and may be harmful:** This comment by WSAVA does not support the view that vaccines are often harmful and later in this response it is clear the WSAVA guidelines accept that adverse reactions are rare.
 - **Serology tests will confirm if circulating antibodies are present.:** VMD agrees but would point out that the presence of antibodies show either the dog has responded to vaccination or has been exposed to disease, it does not always demonstrate protective immunity.
- *The WSAVA “has defined non-core (optional) 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”.*

VMD comment: The WSAVA Guidance has an Executive Summary which states: “The VGG has also classified some vaccines as not recommended (where there is insufficient scientific evidence to justify their use) and has not considered a number of minority products which have restricted geographical availability or application.”

This additional WSAVA quote demonstrates that the WSAVA guidance views some vaccines as unnecessary and others as optional and thus supports the use of non-core vaccines (which includes leptospirosis) where they are needed. The VMD is of the view that the need to use these vaccines and the frequency of their use is for a veterinary surgeon to decide taking account of the pet owner’s views.

- *Non-core canine vaccines in the UK are for the Parainfluenza virus, Bordetella bronchiseptica, and Leptospirosis.*

The WSAVA guidance does not set the non-core vaccines for any particular region of the world but VMD agrees that the list includes some of the optional vaccines for the UK although it is common veterinary policy that leptospirosis and para-influenza are important vaccine components for use in vaccination programmes. An animal's environment and lifestyle may require other vaccine components to be used under veterinary supervision.

The following are areas where the CHC contends the VMD is obstructing the adoption of the WSAVA Guidance in the UK

- 8. Obstruction # 1: the VMD appears to support WSAVA core revaccination guidelines but, materially, does not.**

Of core MLV vaccine schedules, the WSAVA states:

“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.”

In contrast, the VMD states in its Position Paper:

“For the majority of UK authorised dog vaccines the re-vaccination interval for the core vaccines canine distemper (CDV), canine parvovirus (CPV) and canine adenovirus (CAV) is at least every three years. These authorised re-vaccination schedules are in accord with the WSAVA Guidelines which state “not more often than every three years”.”

Discrepancy: “At least every three years”, and “not more often than every three years”, are not in accord.

VMD response: CHC appears to have misunderstood the intent of the comment from the VMD. We invite you to consider the SPCs of the available canine vaccinations. The majority of the vaccines available to the veterinary profession advise a three year duration of immunity has been established while a few have established a four year duration of immunity. Thus for such UK authorised dog vaccines a re-vaccination interval of three (or four) years can be applied with confidence for the core MLV vaccines (canine distemper (CDV), canine parvovirus (CPV) and canine adenovirus (CAV))

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Suitable authorised vaccines are readily available to allow UK veterinary surgeons to tailor individual vaccination programmes for any dog and facilitate the adoption of the guidance provided by the WSAVA.

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- 9. CHC states:** *Whilst theoretically the VMD’s approved schedule might give the impression of reducing the vaccine load on British dogs, **vets in practice continue to vaccinate against core viral diseases on an annual basis**, which means that – in practice – UK dogs are still being over-vaccinated.*

VMD response: The VMD does not have a generic approved schedule. We approve the vaccination schedules recommended for each vaccine authorised on the basis of the scientific data provided by the applicant. How veterinary surgeons reach their decision on the recommendation to vaccinate, which product they chose to use and how they communicate these choices to their clients is a matter for the profession.

CHC’s contention that over-vaccination occurs in the UK is a matter of opinion and conjecture. As each pet animal is an individual and has significant emotional importance within the family environment, it is important that decisions affecting the health of individual animals is a matter for veterinary professional’s clinical judgement taking account of their client’s views and is not an issue where the VMD should intervene.

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- 10. Obstruction # 2: the VMD denies UK vets are over-vaccinating**

VMD comment: There is no accurate data to support or refute claims about how individual pet animals are being vaccinated. Also, there is no legal base for the VMD to challenge veterinary practitioners on their clinical judgement. We would support efforts to provide veterinary surgeons with up to date knowledge on the use of vaccines to achieve effective immunity to serious diseases in the animal population.

11. CHC states:

WSAVA: “there is an urgent requirement for educating practicing veterinarians in this area.”

VMD : “We understand the majority of veterinary surgeons administer vaccines no more frequently than the claimed duration of immunity, unless there are justified health, epidemiological or other risk factors that support a revised schedule.” (Page 6, your letter 30th July)

Discrepancy: On face value it looks as if you are saying that vets don’t vaccinate against core viral diseases on an annual basis in the UK, and that the complaints we pet owners have made are unfounded, and the WSAVA seeks to give guidance where none is needed.

VMD response: The entire WSAVA quote reads: ‘It is clear that the controversy surrounding small companion animal vaccination has not diminished and that there is an urgent requirement for education of practicing veterinarians in this area’.

We read this as WSAVA VGG regarding it essential that veterinary surgeons are equipped with the knowledge to deal with owners who have questions concerning vaccination. VMD would support this effort by a veterinary group.

CHC’s ‘face value’ inference is not the intended interpretation of our comment. We have given our understanding based largely on the data that shows insufficient vaccines being sold annually to provide for a significant level of annual vaccination in the dog population with MLV vaccines. The VMD has no comment on any CHC complaints as we have no information upon which to judge them. How veterinary surgeons treat their patients is a matter for the practicing veterinary surgeon and their client. If there is any issue about professional conduct this is a matter for the RCVS and if there is concern that vets are not adequately informed then this is largely a matter for the professional associations.

12. CHC states: **Obfuscation:** *If core one-year vaccines are on the market, and vets use these vaccines annually, then vets are of course “administering vaccines no more frequently than the claimed duration of immunity”! But they are still over-vaccinating! The issue is being clouded.*

VMD response: Once again we cannot comment on your view as it is largely conjecture. A veterinary surgeon should take account of the SPC as this is justified by data but may also take account of guidance from other sources and other professional knowledge. In other words it is a clinical decision taken for each animal. How vaccines are used is a veterinary clinical decision. An important point made previously is that the vet has a choice of vaccines with various periods covering DoI to select from.

13. CHC state: **Discrepancy:** *In our response to the VMD’s Position Paper on Authorised Vaccination Schedules for Dogs, Canine Health Concern detailed the investigations of its members in relation to Intervet’s National Vaccination Month. The findings of these investigations are carried on pages 255 to 261 of our response (available in full on www.petvaccine.weebly.com). These investigations confirm that vets are routinely vaccinating*

against all of the canine diseases, core and non core, on an annual basis. The VMD had sight of these findings before making the above statement but seemingly chooses to ignore them.

VMD response: Looking again at the anecdotal evidence provided on pages 255-261 of your previous correspondence this details a series of telephone conversations with the administrative staff of a small number of veterinary practices. No firm conclusions could be reached from this information which simply demonstrates that veterinary practices were aware of the promotion. The VMD received no complaints at the time of the promotion and as it is was in place for one month in 2009 there seems little point in taking this any further.

14. CHC state: *You also state on page 3 of your letter of 30th July:*

“It is VMD’s understanding that re-vaccination intervals of 3-4 years for core MLV components are routinely practised by most veterinary surgeons in the UK but ultimately it is for the veterinary surgeon, in consultation with the owner, to determine the frequency of vaccination for the agreed disease components, taking account of the health of the animal and the risk of exposure to infection. I am not aware of any data that refutes this assertion.”

Discrepancy: With respect Professor Dean, can you please clarify which part of the above sentence you lack data for, because when you string two concepts like this together, your statements mean one thing but read as something entirely different. Are you unaware of data that refutes the assertion that vets and clients should decide together? Or perhaps you lack data to refute the statement that most veterinary surgeons in the UK are using the 3-4 year vaccines?

VMD’s response: We are not aware of any data that refutes the assertion that re-vaccination intervals of 3-4 years for core MLV components are routinely practised by veterinary surgeons in the UK.

15. CHC states: Discrepancy: *If vets are participating in National Vaccination Month and offering a full puppy or kitten series for the price of a booster if they have “lapsed” by 18 months (which is the sales campaign’s special offer), then they are clearly not telling clients that their pets don’t need vaccinating annually against core viral diseases. Are you aware of this data?*

You preface your statement with ‘if’ which suggests this is hypothesis. The VMD does not scrutinise advertising campaigns in advance, it does not track veterinary surgeon’s advice to their clients and no complaints about the National Vaccination Month promotion were received. It was not therefore not investigated or examined.

16. CHC states: Discrepancy: It is a fact that, in the UK, veterinarians are routinely vaccinating dogs (and cats) against core viral disease more frequently than is necessary and, in the majority of cases, they appear to be telling dog owners that their pets must be vaccinated with distemper, adenovirus, parvovirus, parainfluenza and leptospirosis vaccines on an annual basis. To clarify, pets owners are being sold annual vaccinations for core viral diseases when it is known scientifically that these need not be given annually. Were this not the case, we would not be engaged in this correspondence, or asking for one-year core vaccines to be withdrawn.

Contradiction: In your Position Paper (point 4.4, page 7) you state:

“leptospiral vaccines are in effect commonly used, often in combination with core annual vaccination programmes by most, if not all, veterinary practices for the benefit of the canine and human population in the UK”.

Once again, Professor Dean, you combine two concepts in one sentence, this time appearing to pass off and accept annual vaccination against core diseases – which do not need to be boosted annually – alongside a vaccine that is dangerous and barely justified – and deemed non-core (optional) by the WSAVA.

If we analyse your two sentences:

1. “leptospiral vaccines are commonly used ... in combination with **core annual vaccination programmes by most, if not all**, veterinary practices ... in the UK.”
2. “It is VMD’s understanding that re-vaccination intervals of 3-4 years for core MLV components are routinely practised by most veterinary surgeons in the UK ...”

Discrepancy: you are contradicting yourself. We contend that whilst your statements numbered 1 and 2 above oppose one-another, your sentence 1 is the practiced norm.

VMD response: Annual vaccinations are almost always advised by the veterinary surgeon or requested by the owner. For example, leptospiral vaccination is considered a necessary in the UK (being a geographical region with endemic disease) and is recommended for annual vaccination. In line with WSAVA best practice, each year the need for core vaccines and non-core vaccines should be considered. A vaccination programme should ideally extend through the lifetime of the animal and therefore the use of leptospiral vaccines is considered annually within this programme. However we stress once more this decision to vaccinate is one for the veterinary surgeon and their client.

17. **Obstruction # 3: “Vets departing from the SPC do so at their own risk”**

CHC states: *In tandem with preparing its Position Paper on Approved Canine Vaccination Schedules, the VMD wrote to the veterinary press, warning vets that if they departed from the SPCs, they **did so at their own risk**. This is referenced in our two-part response – www.petvaccine.weebly.com. CHC accordingly accused the VMD of seeking to threaten vets, making it impossible for them to follow the known and current science.*

Thankfully, the WSAVA has covered this thorny dilemma, showing that we weren’t just making the problem up. The following is taken from the WSAVA’s Vaccination Guidelines 2010, which is web-referenced earlier in this document:

“In speaking to practitioner audiences about the 2007 guidelines it is clear that there is widespread confusion about their purpose. Many practitioners are initially alarmed that the recommendations appear contrary to those given on the product data sheet, and therefore feel that if they adopt guidelines recommendations, they are leaving themselves open to

litigation. The distinct difference between a data sheet and guidelines document has been clearly discussed in a recent paper (Thiry and Horzinek, 2007).

“A data sheet (or ‘summary of product characteristics’; SPC) is a legal document that forms part of the registration process for a vaccine. A data sheet will give details of the quality, safety and efficacy of a product and in the case of vaccines will describe the legal DOI of the product. The legal DOI is based on experimental evidence, represents a minimum value and need not reflect the true DOI of a vaccine. Most companion animal vaccines, until recently, had a 1 year DOI and carried a recommendation for annual revaccination. The sensible response of industry to recent discussions about vaccine safety has been to increasingly license products with an ‘extended’ (generally 3 year) DOI. However, for most core vaccines (see below) the true DOI is likely to be considerably longer.

“There are instances, where the guidelines may recommend a triennial vaccination with a product that still carries a 1 year licensed DOI. The simple reason for this is that the guidelines are based on **current** scientific knowledge and thinking, whereas the data sheet reflects the knowledge available at the time that the vaccine received its original license (which may be more than 20 years earlier). Consequently, guidelines advice will often differ from that given in the data sheet; however, any veterinarian may use a vaccine according to guidelines (and therefore current scientific thinking) by obtaining informed (and documented) owner consent for this deviation from legal recommendations (‘off-label use’). Further confusion is often caused by company representatives who will advise, as they are legally obliged to do, that the veterinarian must adhere to the data sheet recommendation.

“A further point of confusion arises where veterinarians compare the recommendations given in different sets of guidelines. There are, for example, subtle differences in recommendations made in the USA and Europe that reflect differences in the opinions of local expert groups and in the perception of lifestyles of pet animals that may make them more or less exposed to infections. The VGG faces the difficult challenge of setting a middle-course through various national or regional guidelines. Its recommendations attempt to provide a balanced perspective to account for global differences in the keeping of small companion animals.

“In summary, veterinarians should feel comfortable about vaccinating according to the schedules given in these guidelines but should cross-reference these with local recommendations where available. Where the VGG recommendations differ from current legal requirements, the practitioner need only obtain informed client consent to provide that client, and the animal, with a current evidence-based vaccination schedule.”

In short, vets can stray from the SPCs without personal risk, so long as the client is aware of the current evidence-based vaccination schedule: so long as the client is given informed consent.

VMD response: The VMD agrees with the WSAVA analysis, especially with the rationale for gaining owner consent to deviate from the recommended schedule indicated in the product’s SPC. This is considered best practice and is why we alerted vets to the need to consider their responsibility when deviating from an authorised use of a product. Owner consent is one method of gaining a level of protection from litigation. It is for individual veterinary surgeons to decide if owner consent is sufficient defence for off label use of a medicine. However there are

vaccines available on the UK market for vets to select that have a DoI of three or more years and therefore this point would appear to be an academic one.

There are other important points to note in the WSAVA quote that CHC has not highlighted. For example the WSAVA guidance states:

*“A further point of confusion arises where veterinarians compare the recommendations given in different sets of guidelines. **There are, for example, subtle differences in recommendations made in the USA and Europe that reflect differences in the opinions of local expert groups and in the perception of lifestyles of pet animals that may make them more or less exposed to infections.** The VGG faces the difficult challenge of setting a middle-course through various national or regional guidelines. **Its recommendations attempt to provide a balanced perspective to account for global differences in the keeping of small companion animals**”.*

The recognition in this paragraph of the remaining disagreement between experts in different regions of the world, the impact of exposure assessments and the effort to reach a compromise in formulating the WSAVA guidance demonstrates the complexity of this subject to the reader and rationalises the various approaches to pet animal vaccination regionally.

18. Obstruction # 4: the VMD sees nothing wrong with giving a full puppy or kitten series if an animal has “lapsed by 18 months”.

CHC states: *Canine Health Concern has repeatedly written to the VMD, and to British political representatives, to halt Intervet’s sales campaign which offers a full puppy series for the price of a booster for dogs whose boosters, according to the sales campaign, have “lapsed by 18 months”. The VMD, and successive Ministers who are advised by the VMD, have failed to act on this matter.*

However, the WSAVA has stated in its updated 2010 Guidelines:

An adult dog that had received a complete course of core vaccinations as a puppy followed by the 12 month booster, but may not have been regularly vaccinated as an adult, requires only a single dose of core vaccine to boost immunity. Many current data sheets will advise in this circumstance that the dog requires two vaccinations (as for a puppy) but this practice is unjustified and simply **contrary to the fundamental principles of immunological memory**. By contrast, this approach may be justified for an adult dog of unknown vaccination history, and when serological testing has not been performed.

Discrepancy: Please note that the WSAVA offers the option of testing the dog’s blood for antibodies, rather than vaccinating for the sake of it. The WSAVA does not support the administration of a full puppy or kitten series to dogs or cats whose vaccination may have “lapsed” by 18 months.

No data sheet or SPC in the UK recommends a full puppy course in the event that vaccination DoI has elapsed for more than 18 months. In the VMD’s view this is a matter for veterinary clinical judgement.

VMD response: This issue of the advertising feature mentioned is dealt with elsewhere in this response. The VMD has not supported the provision of a full puppy course for previously effectively vaccinated dogs and would agree with the WSAVA Guideline. Furthermore in the UK the SPCs do not recommend such action in previously vaccinated adult animals. VMD's view is that where a vaccination is 'out of date', lapsed or an individual animal's vaccination status is in doubt, the decision to vaccinate should be discussed between the veterinary surgeon and the owner.

19. Obstruction # 5: the VMD warns against serology (titre) testing

CHC states: *Serology testing offers an alternative to indiscriminate revaccination, as it will show if the animal has circulating antibodies to the core diseases they would otherwise be vaccinated against. Serology testing would reduce the perceived need to revaccinate, and the potential for adverse vaccine effects.*

The VMD states:

“There is no regulatory barrier to serology being used for this purpose ... we would re-emphasise the need for caution when interpreting results from various serological assays where standardisation is not assured. A serological titre correlated with protection oversimplifies the science of immunology and does not guarantee an individual animal will be protected from infection due to the complexity and involvement of other immunological parameters.” (Page 4, your letter July 30th)

The WSAVA states:

Antibody tests are useful for monitoring immunity to CDV, CPV-2, CAV-1 and rabies virus. Antibody assays for CDV and CPV-2 are the tests of greatest benefit in monitoring immunity, especially after the puppy vaccination series. During recent years, many laboratories have standardized their methodologies for such testing. There are legal requirements for rabies antibody testing for pet travel between some countries.

In-practice testing will probably become more popular as soon as rapid, simple, reliable and cost-effective assays are more widely available. A negative test result indicates that the animal has little or no antibody, and that revaccination is recommended. Some of these dogs are in fact immune (false-negative), and their revaccination would be unnecessary. A positive test result on the other hand would lead to the conclusion that revaccination is not required. This is why robust yes/no answers must be provided by any assay. With CDV and/or CPV-2 tests, an animal with a negative result, regardless of the test used, should be considered as having no antibody and is susceptible to infection.

On completion of the puppy series at 14–16 weeks of age, an animal should have a positive test result, provided the serum sample is collected 2 or more weeks after vaccination. Seronegative animals should be revaccinated and retested. If it again tests negative, it should be considered a non-responder that is possibly incapable of developing protective immunity.

Discrepancy: Whilst we understand the VMD's desire to exercise caution with regard to serology testing, we find the WSAVA's guidance to be more positive and inspirational in terms of their ethos of reducing vaccine-associated risk – especially in view of the potential life-long DOI of core vaccines.

The WSAVA points out that many laboratories have standardised their methodologies for such testing; in-practice testing will probably become more popular as soon as rapid, simple, reliable and cost-effective assays are more widely available; and a positive test result on the other hand would lead to the conclusion that revaccination is not required. We would point out that in-practice testing would also mitigate booster income loss for veterinary practices.

Selectivity: Therefore, rather than appear to resist serology testing, would it not be better for the animals, and more suited to the VMD's remit, if the VMD were to lead the way in having such tests standardised, and encouraged the uptake of in-practice testing – rather than emphasising the objections?

After all, reliable titre tests are currently available at a very reasonable price from at least one of the UK's distinguished experts, Dr Hal Thompson of Glasgow University in the UK. If other laboratories cannot be trusted, vets can be advised to use the one that can be.

Selectivity: Would it not be better, for the sake of the animals, that we worked towards reducing the number of core vaccines given to the animals – in order to minimise any likelihood of an adverse reaction? It sends out entirely the wrong message when the VMD issues warnings of caution with regard to titre testing, as opposed to leading the way towards better standardisation.

Selectivity: Would it also not be appropriate if the VMD acknowledged, whilst cautioning against titre testing, that vaccines themselves do not guarantee protection – for the very same reason?

Your words, “A serological titre correlated with protection” oversimplifies the science of immunology and does not guarantee an individual animal will be protected from infection due to the complexity and involvement of other immunological parameters”... apply equally to vaccine failure. Vaccines can and do fail due to “the complexity and involvement of other immunological parameters”.

VMD response: There is nothing in the VMD statement that resists serology as an optional method of monitoring immunity but we believe it is important for all concerned to be aware of the weaknesses and variability of the currently available range of testing methods. The use of serological testing is an interesting area of scientific debate. CHC will note that the WSAVA guidance is cautious of recommending this as a substitute for booster vaccination. The VMD response to CHC was intended to draw attention to the fact that, unlike the authorisation of medicines, where data supporting the label claims has been assessed and the product authorised, the majority of serological tests are not subjected to independent scrutiny to ensure their level of specificity and sensitivity is fit for purpose. Standardisation alone will not achieve this level of assurance. In short the veterinary surgeon (and the client) must reach their own conclusions on how to rely on serological testing to indicate the need to revaccinate. To expand on this point for the sake of clarity, immunological memory and the level of antibody response are two different measures and serology only offers a direct measurement of the

latter. A test result may indicate an animal has been infected or vaccinated and it may be possible, in some circumstances, to correlate an antibody level with protection. Serology therefore provides a general indication of the immune status but may not assure resistance to infection. Perversely, absence of antibody does not indicate lack of protection either as not all protective immunological responses require sero-conversion. Intranasal vaccines are not likely to generate a serological response as their antibody response is produced at the mucous membrane level. In the case of rabies vaccination, serology is used to confirm that vaccination has yielded an immune response yet a failure of the test does not necessarily indicate failure of vaccination efficacy. In summary, the VMD is not warning against serology but is justifiably highlighting the short-comings and this is in accord with the WSAVA guidance. Thus in contrast to the view of CHC, our view is that the WSAVA guidance reads as confirmation of the VMD's cautionary tone on serology. The guidance rightly uses terminology suggesting serology **may** offer a credible alternative in the future but points to some of the weaknesses at the present time.

As the VMD has no legal base to authorise serological tests we can neither regulate them nor endorse any particular laboratory. The currently available range of canine and feline vaccines available in the UK offer the veterinary surgeon adequate opportunity to comply with the WSAVA guidelines, thus reduce the risk of potential (but rare) adverse reactions and the VMD would view serology as an aid in this process. The decision to use serology is a matter for the veterinary surgeon and their client.

In response to your comment on vaccines failing to protect, the WSAVA once again offer good guidance. WSAVA Guidance offers three reasons why vaccines might fail to generate immunity (VMD has added bold emphasis):

(1) MDA neutralizes the vaccine virus

*This is the most common reason for vaccination failure. However, when the last vaccine dose is given at 14–16 weeks of age, MDA **should have** decreased to a low level, and active immunization will succeed in **most puppies** (>98%).*

(2) The vaccine is poorly immunogenic

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

(3) The animal is a poor responder (its immune system intrinsically fails to recognize the vaccinal antigens)

*If an animal fails to develop an antibody response after repeated revaccination, it should be considered a non-responder. **Because immunological non-responsiveness is genetically controlled in other species, certain breeds of dogs have been suspected to be poor responders.** It is believed (but unproven) that the high susceptibility to CPV-2 recognized in certain Rottweilers and Dobermans during the 1980s (regardless of their vaccination history) was due to a high prevalence of non-responders. In the USA today, these two breeds seem to have no greater numbers of non-responders to CPV-2 than other breeds, possibly because carriers of the genetic trait may have died from CPV-2 infection. Some dogs of these breeds may be low or non-responders to other antigens. For example, in the UK and Germany, the*

non-responder phenotype is prevalent amongst Rottweilers for CPV-2 and rabies virus as recent studies have shown this breed to have a higher proportion of animals failing to achieve the titre of rabies antibody required for pet travel.

The vaccination strategies employed by UK veterinary surgeons attempt to overcome the MDA effect and the regulatory process minimises failures by assessing the manufacturer's evidence supporting the ability of each vaccine to immunise in the face of MDA. High standards covering manufacturing quality controls ensure batches of vaccine are marketed with the minimum likelihood of errors and post manufacturing errors are minimised by the quality systems operated by the manufacturers as well as regulatory inspection and authorisation of each the elements of the supply chain (wholesalers, and veterinary surgeons). VMD is responsible for the authorisation process, inspecting manufacturing facilities and supply chain elements. However the clinical decision and the genetic disposition of the vaccinated animal are beyond our regulatory remit.

20. **CHC states:** It appears to us that the VMD/government has built a smokescreen that, in all circumstances, no matter the options provided, urges us to vaccinate, vaccinate, vaccinate. Why?

VMD response: The VMD, as a Government Agency, has a clearly defined function to authorise veterinary medicines. Other than the legal requirements for vaccination against rabies, there is no Government requirement which mandates the vaccination of pet animals.

21. **Obstruction # 6: Non-core vaccines: VMD says: “give them annually irrespective of the unquantified risks”.**

CHC states: *Of the Leptospirosis vaccine, the WSAVA states:*

“Non-core. Vaccination should be **restricted to use** in geographical areas where a **significant risk of exposure** has been established or for dogs whose lifestyle places them at significant risk. These dogs should be vaccinated at 12–16 weeks of age, with a second dose 3–4 weeks later, and then at intervals of 9–12 months until the risk has been reduced. This vaccine is the one least likely to provide adequate and prolonged protection, and therefore must be administered annually or more often for animals at high risk. Protection against infection with different serovars is variable. **This product is associated with the greatest number of adverse reactions to any vaccine.** In particular, veterinarians are advised of reports of acute anaphylaxis in toy breeds following administration of leptospirosis vaccines. Routine vaccination of toy breeds should only be considered in dogs known to have a very high risk of exposure.”

By contrast, the VMD states:

“For leptospirosis, a serious endemic disease in dogs and a zoonosis, **annual vaccination may be recommended by most veterinary surgeons** to ensure an adequate level of protection is maintained. Leptospirosis has a number of wildlife reservoirs and is a particular risk to animals and humans exposed to water contaminated with rat urine. (Point 4, page 37, your letter of 30th July)

“The epidemiology of these leptospires in the UK is largely unknown although some research is being undertaken to identify leptospire serovars circulating in foxes (personal communication).” (Point 4.1, page 15 of your letter of 30th July)

The VMD adds:

“The WSAVA Guidelines suggest that vaccination against leptospirosis should be restricted to geographical areas where a significant risk of exposure has been established or for dogs whose lifestyle places them at risk. Given the risks of infection to both dogs and their owners and the albeit limited information on the prevalence of disease in the UK, which suggests veterinary practices are seeing clinical cases, leptospiral vaccines are in effect commonly used, often in combination with core annual vaccination programmes by most, if not all, veterinary practices for the benefit of the canine and human population in the UK.” (Point 4.4, page 15 of your letter of 30th July)

Selectivity: It seems to us that the VMD recommends the indiscriminate use of the leptospirosis vaccine, even though the prevalence of this disease in UK dogs is very low indeed. Quoting a vaccine industry vox-pop, the VMD states:

“An ongoing pharmaceutical industry funded project, CICADA (Computer-based investigation of Companion Animal Disease Awareness, www.cicadasurvey.co.uk), aims to collate information submitted by veterinary practices on numbers of both confirmed and unconfirmed (suspected) reports of major infectious disease. During the nine months leading up to March 2010 veterinary practices participating in this survey reported 1544 cases of Kennel Cough, 117 cases of canine parvovirus, 27 cases of leptospirosis, 2 cases of infectious canine hepatitis and 1 case of canine distemper.” (Point 10, page 19, your letter of 30th July)

Let us look at the risk-benefit analysis here:

An industry-funded telephone survey, which actively sought to find cases of leptospirosis in UK dogs in order to sell product, found only 27 cases of leptospirosis. Accepting that leptospirosis is a terrible disease, and death is a potential consequence if the veterinarian fails to diagnose and treat with the appropriate antibiotics, the VMD suggests that millions of UK dogs should risk this vaccine every year, even though **this product is associated with the greatest number of adverse reactions to any vaccine. The VMD offers no warning with regard to the dogs most at risk from this vaccine, or the seriousness of the adverse effects caused by this vaccine.**

Discrepancy: Yet, by contrast, the WSAVA tells us that the leptospirosis vaccine should be **restricted to use** in geographical areas where a **significant risk of exposure** has been established or for dogs whose lifestyle places them at significant risk. The words ‘significant risk’ bear repeating.

VMD response: Despite the nuance in CHC’s comments suggesting a contrast between the WSAVA guidance and the VMD information provided in our first response to your open letter, it is clear they are in accord. Both WSAVA and CICADA are industry supported but that does not make their information any less valuable. CICADA is not intended to identify the number of cases across the UK but this information demonstrates that leptospirosis and the other significant canine diseases, are present in the UK. It is an arguable point on what constitutes a ‘significant risk’ but as the WSAVA Guideline recognises ‘*Non-core vaccines are those that are*

licensed for the dog and whose use is determined on the basis of the animal's geographical and lifestyle exposure and an assessment of risk-benefit ratios'.

This supports the fact that the use of the vaccine in the UK should be considered. Veterinary professional opinion in the UK is leptospirosis is a significant disease and endemic in the UK and vaccination is therefore recommended. To be clear this is not a VMD recommendation but we would not disagree with the assessment.

CHC highlight the fact that for leptospirosis vaccines: *'This product is associated with the greatest number of adverse reactions to any vaccine'* and your comment is well founded but to put this comment in context the number of reported adverse reactions are low. Adverse events do not render these products unusable but do justify such vaccines being restricted to veterinary use. It is generally well recognised that killed bacterial vaccines are often associated with greater opportunity for adverse reactions and veterinary surgeons have the responsibility to be aware of this.

Your brief risk assessment is interesting but uses data insufficient for the purpose and fails to take adequate account of the low likelihood of a serious vaccine reaction. Nevertheless warnings do appear on product labelling and the SPCs. CHC's simplified risk assessment correctly recognises that leptospirosis is a terrible disease but fails to acknowledge that the damage to organs during infection can only be limited by **prompt** antimicrobial therapy. However the early symptoms of leptospirosis are vague and so early diagnosis is not always possible. Vaccines offer the ability to prevent overt disease from occurring and perhaps the low incidence of clinical cases of leptospirosis in the telephone survey indicates a better efficacy for the vaccines than CHC has assumed. It is not disputed that this vaccine is not associated with the same level of efficacy and DoI as the MLV vaccines and this is reflected in the pathogenicity of natural infection. The end result is that leptospirosis vaccines, to provide a protective level of immunity, require more frequent re-vaccination than the MLV vaccines and protection is incomplete but this is no reason to discount vaccine use. In a country where leptospirosis is considered to be an ever present risk it is not surprising to find vaccination is routine.

- 22. CHC states:** *Perhaps pet owners should be given informed consent sheets to help **them** decide which option poses the greatest danger. Given the choice of a vaccine to protect against a very rare disease in the UK, a vaccine which comes with the potential of serious adverse events – including brain damage and death – what would we choose, do you think? Death at our own hands and at our own expense, or a small risk of contracting a disease that is rare in the UK? Let us not forget that leptospirosis is effectively treated if diagnosed and treated with antibiotics.*

VMD response: The VMD would support the provision of information to pet animal owners to assist them to understand the benefits and risks associated with medicines (including vaccines) and we ourselves seek to inform pet owners by producing leaflets that demonstrate our work and related issues. These can all be found on the VMD website (www.vmd.gov.uk). The VMD's contribution to ensuring canine vaccines are used safely is delivered through the restricted access to veterinary surgeon prescription and the provision of definitive information on the SPC on a publically available website.

- 23. CHC states:** *Whilst on the subject of leptospirosis, and answering your assertion that there is no evidence of the efficacy of homoeopathy, a study has only just been published to show that the nosode has proven to be very beneficial in Cuba. See <http://avilian.co.uk/2010/08/large->*

[scale-application-of-highly-diluted-bacteria-for-leptospirosis-epidemic-control/](#).

VMD response: Thank you for drawing this to our attention. The results would be of greater value if they could be published in a peer reviewed scientific format but let me provide some quotes from the site that relate to some of our exchanges on leptospirosis –

*“Vaccination is an effective option but of reduced effectiveness in emergency situations. Homeoprophylactic interventions **might help to control epidemics by using highly-diluted pathogens** to induce protection in a short time scale”.*

and

*“CONCLUSIONS: The homeoprophylactic approach was associated with a large reduction of disease incidence and control of the epidemic. The results suggest the use of HP as a feasible tool for epidemic control, **further research is warranted**”.*

and

“The first phase of non-specific flu-like symptoms includes headaches, muscle aches, eye pain with bright lights, followed by chills and fever. Watering and redness of the eyes occurs and symptoms seem to improve by the fifth to ninth day. The second phase begins after a few days of feeling well. The initial symptoms recur with fever, aching and neck stiffness. Some patients develop serious inflammation of the nerves to the eyes, brain, spinal column (meningitis), or other nerves. Right upper area abdominal pain may occur and less common symptoms relate to disease of the liver, lungs, kidneys, and heart”.

and

*“**Immunisation and chemoprophylaxis with antibiotics are effective against Leptospirosis, but they are expensive**”.*

This is a reported human outbreak which hints at another good reason to control leptospirosis in dogs. These extracts also prompt the following thoughts. Nosodes are dilutions of pathogenic bacteria which could be a risk if administered to those in lower risk areas. Even the study recognises further work is needed to evaluate this finding. It is also interesting to see the authors feel vaccination and antibiotic therapy are both effective but in some countries price represents a problem. Finally the symptomology described, although derived from human cases, demonstrates how challenging it can be to reach a diagnosis for leptospirosis.

The WSAVA guidance is also interesting: ‘Nosodes cannot be used for the prevention of any disease. They do not immunize because they do not contain antigen’.

VMD would simply add an important omission: ... do not contain **sufficient** antigen.

In summary the VMD encourages the flow of information to the public and publishes on-line the SPCs for products and general information leaflets related to medicines regulation. In fact one reason we are keen to maintain this debate in the public forum is to ensure the public have access to accurate and substantiated information.

Kennel Cough vaccines

- 24. CHC states:** Bordetella bronchiseptica and parainfluenza vaccines are given to protect against kennel cough. Both are deemed non-core (optional) by the WSAVA.

Discrepancy: In our response to your Position Paper, we reflected the VMD's own datasheet information which states that kennel cough vaccines, when administered to dogs, are not entirely safe for the humans living with those dogs. In particular, the Bordetella vaccine is a danger to immunocompromised adults and children, as stated in approved datasheets. Humans can become infected via the kennel cough vaccines given to their dogs. Further, when dogs receive kennel cough vaccines, they are liable to infect other dogs with whom they come into contact. You chose not to respond to our concerns in this regard.

It is understandable that the vaccine industry survey you quote found that, "During the nine months leading up to March 2010 veterinary practices participating in this survey reported 1544 cases of Kennel Cough". This vaccine is keeping the disease in the ecosystem. It is causing outbreaks, as the datasheets warn can happen.

The parainfluenza vaccine is also of questionable efficacy. Indeed in its own Position Paper, on page 47, the VMD lists licensed parainfluenza vaccines and reports that duration of immunity is "Not demonstrated. Annual booster recommended."

Discrepancy: How does the VMD justify licensing vaccines when their duration of immunity isn't even known? And what sort of logic should lead the VMD to say, effectively, "we don't know if it works, so do it every year"?

No wonder the WSAVA calls these vaccines non-core (optional).

We called in our response to the VMD's Position Paper for the VMD to make this information known to clients, using informed consent sheets since the datasheets warning of these dangers are typically retained and disposed of by the vet. Their language is also obscure to most pet owners.

The VMD remained silent to this request in its letter of 30th July 2010. Why?

VMD response: Live vaccines, especially those administered by aerosol forms, are capable, in rare instances, of infecting immunocompromised people. For clarity, these are generally people who have a defective immune system either as a result of a disease process or through receiving suppressive medication to treat disease. It seems quite correct to warn

people where products offer a special risk. As *Bordetella bronchispetica* is often normally found in the human airways and seems to be passively carried by immune competent humans this adds importance to this information being provided. Obviously the risk for immunocompromised humans should be communicated and it is mentioned on the product labelling, SPC and leaflet. It is also possible that the fact humans can carry *B. bronchispetica* in their airways should be considered as part of the risk factors in the epidemiology of the infectious agent in dogs. Credence cannot be given to the CHC theory of vaccine strains maintaining a prevalence of kennel cough in the canine community as there is a general ubiquitous supply of the infectious agents involved in the kennel cough syndrome in the canine population. Nevertheless the potential for environmental spread of the vaccine strain is considered as part of the risk assessment during the regulatory process. Kennel Cough is a respiratory syndrome where a number of infectious agents are involved. Vaccination is designed to minimise the risk of infection and reduce the severity of the symptoms should infection occur.

The issue with parainfluenza vaccine and DoI is an interesting scientific challenge as it is difficult to reliably infect adult dogs as the conditions for developing a kennel cough infection are difficult to reproduce in a test environment. Thus the traditional methods of measuring the DoI for MLV vaccines do not apply and serology is of little help. This is why DoI is not defined on the SPCs. This difficulty is recognised in the wording of the WSAVA Vaccine Guidelines.

The SPCs for canine and feline vaccines and further information on vaccines are available on the VMD website. CHC is welcome to draw attention to this.

25. Obstruction # 7: Informed client consent

CHC states: The 2010 WSAVA Guidelines state:

“Informed consent should be documented in the medical record in order to demonstrate that relevant information was provided to the client and that the client authorized the procedure (e.g. ‘off-label’ use of products as discussed above). At the very least, this notation should indicate that a discussion of risks and benefits took place prior to vaccination.”

Although the need for written informed consent was raised by CHC in its response to the VMD’s Position Paper, we can see no reference to it in your response of 30th July.

Speaking as users of the veterinary system, CHC and its members can confirm that vets do not, in the vast majority of cases, offer any indication:

- that vaccines might pose a risk
- of what these risks might be
- that, in the case of core vaccines, they are likely to provide protection for very much longer than one year

- that even three/four year vaccines are likely to provide protection for much longer (for life)
- that vaccines for leptospirosis and kennel cough are optional and should only be given in the face of a significant disease threat
- that kennel cough vaccines can spread infection
- that the disease risk for all of the canine diseases we vaccinate against is largely unknown
- that serology tests are an alternative

Discrepancy: Why would a government department, whose existence is predicated on the aim of assuring the safety and efficacy of veterinary medicines, ignore the identified need to make informed consent documents available to the consumers of veterinary medicines, especially when the products in question – vaccines – have a history of unnecessary use and unquantified but serious adverse effects? Why?

VMD response: It is a veterinary surgeon's responsibility to inform clients of the benefits and risks of using any medication. Informed consent is generally reserved for times where veterinary surgeons treat animals 'off-label' or with unauthorised medication. The VMD encourages use of informed consent forms for both of these approaches but there is no legal base for the VMD to demand action of this type. If CHC wishes to progress this demand then it is the professional bodies that should be approached.

26. Obstruction # 8: The VMD claims that CHC's research is based on anecdotes from dog owners, etc.

CHC states: *Significant scientific research exists to confirm that vaccines come with diverse and very serious risks, which is why vaccines should be used **no more often** than is absolutely necessary. The science exists to show that vaccines can cause the following conditions in our dogs:*

Anaphylaxis

Arthritis

Encephalitis, Behavioural changes, Epilepsy

Cancer

Leukaemia

Dermatitis

Dysregulation of humoral and cell-mediated immunity

Organ failure (liver, kidney, heart)

Autoimmune endocrine disorders – especially of the thyroid gland (thyroiditis), adrenal gland (Addison's disease) and pancreas (diabetes).

Bone marrow failure

Haemolytic anaemia

Immune mediated thrombocytopenia

Myasthenia gravis

Systemic lupus erythematosus

Immunosuppression

Paralysis

Autoantibody production/ autoimmunity

Potential genetic damage (antibodies against DNA)

Inflammation and allergies

Risks level recognised by the fact these are POM-V

We should also consider the ability of MLV vaccines to shed in the environment and cause outbreaks, to cause the diseases they are designed to prevent in immunocompromised animals (who may then go on to infect other animals), and/or to mutate and create cross-species infection. For these reasons alone, we should vaccinate **no more frequently** than is necessary.

MLV shedding part of the assessment process. Reversion to virulence is part of this Remember MLV is very low pathogenicity

Whilst you are welcome to use the legitimate argument that we are not trained scientists, and therefore do not always follow the scientific strictures, you cannot disappear the significant body of scientific research on vaccine adverse effects.

We have taken the liberty of separating out the scientific references from Part One of our submission, and attached them to this letter (available in full at www.petvaccine.weebly.com). These references – detailing vaccine adverse effects - number in excess of 500, and take up over 31 pages in small type.

VMD response:

Vaccines have been **associated** with a number of adverse events but clear causal links are yet to be established for the majority of them. The WSAVA guidance is helpful in recognising this in part where it states:

Vaccines themselves do not cause autoimmune disease, but in genetically predisposed animals they may trigger autoimmune responses followed by disease – as can any infection, drug, or a variety of other environmental factors.

The following, which are extracted from the CHC list, are associated with an autoimmune reaction:

Haemolytic anaemia

Immune mediated thrombocytopenia

Myasthenia gravis

Systemic lupus erythematosus

Autoantibody production/ autoimmunity

Autoimmune endocrine disorders – especially of the thyroid gland (thyroiditis), adrenal gland (Addison's disease) and pancreas (diabetes).

However, the VMD view is that there is limited evidence to establish causality between the use of the current canine and feline vaccines available in the UK with the majority these adverse events. The few where evidence of causality reliably exists are well known and warnings appear on the products (e.g. anaphylaxis and immunosuppression)

The potential risks you define for MLV vaccines are taken account of during the assessment process alongside others you do not mention. The scope of the data required to authorise a vaccine are set out in legislation, pharmacopoeial monographs and guidelines. Below are a number of links to data sources that will provide this information. Some of these links are lengthy but take the interested reader to specific pages of the general websites.

The link to the European Pharmacopoeia site is-

<http://online.edqm.eu/entry.htm>

The link to the European Medicines Agency for the veterinary medicines regulatory guidelines is:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/landing/veterinary_medicines_regulatory.jsp&url=menus/regulations/regulations.jsp&mid=WC0b01ac058001ff8a

The link to the European Commission site with the directives is-

http://ec.europa.eu/health/documents/eudralex/vol-5/index_en.htm

A list of references is mentioned in the CHC comments but this was not received with your letter.

27. Obstruction # 9: “Vaccine reactions are very rare” says the VMD

CHC states: *Some of the above illnesses will occur shortly after a vaccine event. Others will develop over time, as the science shows. They are possibly more prevalent in dogs due to the vast number of vaccines our dogs are subjected to. Of those which develop close to vaccination, very few will be reported through the VMD’s SARSS scheme. It is highly unlikely that any which develop over a longer timeframe will be reported at all.*

Therefore, as stated in our previous response, the SARSS scheme is unable to scientifically quantify the level of adverse vaccine reactions. It is guesswork, and not science.

Of the SARSS scheme, you state in your letter:

Having checked, we cannot identify reports on our database on the dogs you claim suffered from adverse reactions whilst owned by you. Can I stress that the SARSS is not limited to reporting from veterinary surgeons (and never has been) and animal owners can complete a report and submit it. I strongly urge you and those who have joined with you in attempting to raise public alarm related to vaccine use to report the suspected adverse reactions you experience to the SARSS. A report form is available on the VMD website. In the interests of the animals you wish to protect, each and every one of the hundreds of people who are supporters of CHC should consider completing a report of the suspected adverse reactions their pets have experienced. To those who already have done so we give our thanks for their help and cooperation.

Discrepancy: Very few pet owners are aware of the SARSS scheme, the SARSS form, the VMD's website, or – indeed – the existence of the VMD.

Taunting us to submit retrospective yellow forms to a system that does not produce meaningful data, Professor Dean, for vaccine-induced deaths that occurred (in my own case) nearly two decades ago, is callous and unlikely to deliver any beneficial result.

Neither does it fix the inadequacies of the SARSS scheme. However, an informed vaccine consent sheet for clients could include mention of its existence, and include data regarding the type of vaccine-induced illnesses they might look out for.

VMD response: The principal of pharmacovigilance (the processes underlying the data collection through suspected adverse reaction (SAR) reporting) is predicated on trend analysis and this does not require an absolute incidence rate to be determined. Using incidence rates from SAR reports is often misleading as it is the underlying detail of each trend in adverse reactions that provides the most useful information. Gathering adverse reactions reports is challenging but it is a basis for assessing the seriousness of an adverse event and is useful in defining actions to be taken as a result. The WSAVA guidance recognises the importance of veterinary pharmacovigilance and it is similar to the methods used in the human medicine field.

Public awareness of the VMD and the regulation of veterinary medicines is difficult to develop but CHC has assisted in raising the VMD profile through these exchanges and we have a website that is frequently visited. CHC could help direct people to our website to foster the provision of objective information and to assist the reporting of ADRs. In the near future it will be possible to report adverse reactions on-line.

I assure you there was no intent to taunt you over the loss of your dogs but surely reporting the circumstances even to what CHC regard as a flawed system is logical. Currently the trend analyses we have used are denied the data underpinning the cases that many CHC members have communicated to your organisation. In my view this is disappointing and detrimental to your crusade. If CHC is correct in its own claims we would gain several hundred reports from your members that we would not otherwise have. I have constantly stressed that pharmacovigilance is not about absolute numbers and there is a good track record of action where trend analysis has indicated the need for action but we can only detect trends if people report the circumstances.

28. CHC states: *The impartiality of the VMD*

We take no pleasure in calling the impartiality of the VMD or its staff into question. It is,

frankly, horrible to be put in a position for this to be necessary. However, by refusing to withdraw licenses for one-year core MLV vaccines, and appearing to obstruct WSAVA guideline implementation, the VMD leaves us with no choice. The alternative is to stand idly by while our family friends suffer and die. We cannot do this.

The unscientific and damaging practice of annual vaccination will be maintained through the following factors:

1. The knowledge that very few people will read the evidence – it is too complicated and long-winded.
2. Vets in practice are vaccinating unnecessarily, and one-year core vaccines allow this to continue. The VMD denies this, despite evidence to the contrary.
3. The majority of veterinary clients trust the advice they are given.
4. Vets in practice are ill educated on the subject of revaccination and potential adverse reactions.
5. Clients are unaware of the DOI data or the risks of over-vaccination.
6. The VMD will not take practical action to stop unnecessary and potentially harmful over-vaccination.
7. The SARSS scheme does not work, and there is no effective computerised post-vaccination 'results based' system.
8. The VMD is promoting the indiscriminate use of non-core vaccines.
9. The VMD appears to obstruct any moves to reduce vaccine frequency, paying lip service to WSAVA guidelines but opposing these guidelines with doubletalk.

What do you expect us to conclude?

While the VMD defends the practice of employing scientists with known industry ties, and while it cannot be seen to act impartially in the interests of the citizens it exists to protect, such "slurs" are inevitable and justified. The whole setup gives the appearance of corruption. If British citizens are unable to express their concerns about the conflicts of interest within their government's regulatory body, then we have no democracy. We have tyranny – the tyranny of commerce.

Professor Dean, you must – for the sake of democracy and the lives of British citizens and their pets – be seen to be ethical and without bias in favour of industry. Getting indignant and issuing blustering and misleading accusations against those who merely seek to represent their pets' interests is not accountability.

We appreciate why you might have been appointed as head of the VMD. Your CV is impressive and very relevant, as you yourself say. We cannot argue this. We can, though, suggest that your marketing and consultancy background within the pharmaceutical industry, added to speaking at veterinary vaccine industry seminars and helping the industry at press launches whilst head of the VMD (which you failed to address in your letter) oversteps a very important boundary. Overstepping this boundary, and writing Position Papers and letters which employ doubletalk – which make it appear that you are hiding the truth for reasons that can only be speculated upon – represent serious lapses in professional good judgment. Either

this, or you are merely following orders – whose orders we do not know.

There is no reason why this matter cannot be taken forward to the scientific satisfaction of pet owners and veterinarians in the UK, and British citizens have every right to expect this to be the case. The VMD's current stance is unacceptable and we would welcome a friendly response; one that shows a desire to address our very real concerns.

VMD response: CHC stating that the presence of vaccines on the UK market with one year duration of immunity claims is justification for calling the impartiality of the VMD or its staff into question is an astonishing statement. Your comments about impartiality were disregarded as they had little substance otherwise you would have quoted specific examples. The area of impartiality is the one topic where I have personally been very disappointed in CHC's approach to this issue. I can understand why you may struggle to comprehend the immensity of the subject matter and, given your strong opinions, feel frustrated by your perceived lack of urgent progress. Quite astonishing leaps of judgment on the thinnest of scientific facts can be tolerated given the complexity of the subject and the lack of scientific training of your organisation but attempting to slur (your word not mine) the reputation of worthy scientists is a 'cheap shot' and discredits you personally Ms O'Driscoll, the CHC and your crusade.

I am aware that CHC has widely circulated similar defamatory emails calling for support and as a result, although I originally asked your permission to treat our latest exchanges as public documents, I now intend to publish them without further delay on the VMD website to demonstrate that neither VMD, nor I, have anything to hide in terms of our approach to authorisation of veterinary medicines. I also intend to publish my CV so the public reading these exchanges may reach their own conclusions. Furthermore, if you would care to inform me of those occasions where you think I or my staff attended inappropriate meetings, in each case CHC will be provided with justification for a VMD presence. However let me say unequivocally, I have no commercial interest in any pharmaceutical company, I do not work in general practice and I have personally received no financial support from the industry since I started working at the VMD in 1996. All of the VMD's scientists are highly competent, professional people who declare any interests they have or have had when they join the VMD and they are not permitted to work on any topic where a current conflict of interest may arise.

It is inevitable that industry funding may enter into the work of any expert group or organisation and even the WSAVA Vaccine Guideline Group acknowledge their work was funded by a vaccine company. However I am certain of their integrity, my own integrity and that of my colleagues and will defend my colleagues and myself against any unjustified slurs. Ms O'Driscoll I await your list of perceived conflicts of interest so that I can reassure everybody reading this exchange that you are very mistaken in your views.

Extract from AVMA website (bold emphasis applied by VMD):

Vaccination Principles

(Oversight: COBTA; Approved by the AVMA Executive Board April 2001; revised April 2007)

Introduction

Medical decisions concerning vaccine selection and administration protocols are among the most complicated medical decisions facing veterinarians today. The reasons are numerous and include, but are not necessarily limited to 1) continual changes in our understanding of the immune system; 2) changes in local/regional population susceptibilities to various diseases; 3) increased animal valuation with related liabilities; 4) longer animal life expectancies; and 5) improved medical record systems which allows for better tracking of the short, medium, and long-term effects of vaccine use/administration. Other contributing factors include improved, 1) understanding of infectious diseases; 2) knowledge of the biologic regulatory licensing/labeling, and 3) awareness of potential risks associated with vaccine use/administration.

COBTA has studied the issues of veterinary vaccinology and immunology, including a review of the scientific literature with interactive testimony of experts from academia, veterinary vaccine manufacturers, state/federal governments, and veterinary private practice. Topics included safety, efficacy, duration of immunity, research and development of vaccines, vaccine licensing, product labeling, adverse events, adverse event reporting, governmental oversight of manufacturers, and legal issues associated with medical procedures.

Vaccines have played a significant role in enabling people and animals to live longer and healthier lives in this world filled with microbial pathogens. **Vaccine products vary in efficacy and safety and are not necessarily indicated for all patients.** Modern science continues to develop strategies and technologies for safer and more efficacious vaccines. Consequently, thorough evaluations of the potential for disease exposure, individual patient susceptibility to various diseases, and the risks/benefits associated with vaccination, are necessary in order to establish optimal health care programs for each individual patient.

Conclusions

COBTA concludes there are **insufficient data available to scientifically determine a single best vaccination protocol regimen for application to all animals globally.** Despite significant advances in our knowledge of antigens and antigen presentation, gaps still remain in our understanding of the immune system's acute and chronic reaction to multiple vaccinations. The body of knowledge surrounding the genetic variability within individual breeds or species and the resulting idiopathic responses to vaccination (including vaccine-associated adverse reactions), is increasing but remains too inconclusive to make specific recommendations appropriate for all patients. Consequently, COBTA believes that a customized approach to recommended vaccination protocols is the safest and most effective method to medically address the increasing diversity in patients presented for immunization.

Under a veterinarian-client-patient relationship, the practitioner and client must determine the best patient care programs for implementation. Since our knowledge base is constantly evolving, vaccination decisions require a thorough and ongoing review of scientific information and expert opinion in order to appropriately customize vaccine recommendations for individual animal patients.

The one-year revaccination recommendation found on many vaccine labels is often based on historical precedent and was allowed by USDA regulation since it was based on the best scientific knowledge available at that time, which did not necessarily include product specific data. Even in

those cases where scientific data were submitted to qualify a revaccination label claim, the data generally targeted a minimum duration of immunity and did not necessarily resolve the question regarding average or maximum duration of immunity.

Vaccination is a potent medical procedure with both risks and benefits. While there is evidence that some vaccines provide immunity beyond one year, revaccination of patients with sufficient immunity does not necessarily add to their disease protection and **may** increase the potential risk of post-vaccination adverse events.

Serologic titers may not accurately predict immunity from disease. With respect to many infectious diseases, it is not currently possible to determine the immune status of an animal without assessing response to challenge. Due to the emergence of newer and improved antibody tests, serological assays are being used to determine immune status and establish vaccination protocols for animal patients. **Caution should be exercised to make sure that serological titers have been clinically correlated to host-animal protection for the specific disease and species being tested.**

Adverse events may be associated with the antigen, adjuvant, carrier, preservative, or a combination thereof. Possible adverse events include, but are not necessarily limited to, failure to immunize, anaphylaxis, immuno-suppression, autoimmune disorders, transient infections, long-term infected carrier states, and local development of tumors. The role of genetic predisposition to adverse events needs further exploration and definition.

Vaccine program goals include providing optimal immunity against clinically relevant diseases the patient is at-risk to contract, while minimizing the potential for adverse events.

Multiple sources of information can be of value to practitioners in their review of vaccines and infectious diseases, including scientific data and opinion from experts, species and specialty groups, manufacturers, and government agencies. For example, the American Animal Hospital Association and American Association of Feline Practitioners have produced extensive documents giving specific recommendations for companion animals. All sources of scientific information and expert opinion need to be carefully and critically considered to properly prepare the customized vaccine programs animal patients require.

Principles and Practice of Vaccination

Vaccine Application:

The proper application of vaccines to animal populations has enhanced their health and welfare, and prolonged their life-spans. **The risks to animal health from non-vaccination are significant.**

The goal for a vaccination program is to prevent disease and thereby promote optimal patient, herd, and/or public health.

Unnecessary stimulation of the immune system does not necessarily result in enhanced disease resistance, and may increase the potential risk of post-vaccination adverse events.

Disease carriers, including animals that shed infectious agents but do not necessarily show signs of illness, are sources of infection for susceptible animals. Sufficient immunity within a population of animals is an important component of preventing disease prevalence. Programs targeting immunization of susceptible animals are critical to disease control.

Vaccination protects a population of animals by providing a level of resistance to a disease in those individual patients that are able to respond. Vaccination does not protect every individual patient even when they are properly vaccinated.

There is a critical need for more fully developed, scientifically based, and statistically valid evaluation of vaccine products to provide practitioners with a basis for developing vaccination programs that maximize benefits and minimize associated risks for the patients under their care.

Vaccination is a potent medical procedure associated with both benefits and risks for the patient. Adverse events, including some that are potentially severe, can be unintended consequences of vaccination.

Vaccine Administration

Information about the benefits and risks of vaccination are important to practitioners, owners, and the general public. **Appropriate decisions concerning individual vaccine selection and vaccination program choices are best made under veterinarian-client-patient relationships.**

Vaccines, including polyvalent products, should be selected to include only those antigens appropriate for the specific risk needs of the patient, thereby eliminating unnecessary immune system stimulation and thus lowering potential risks of adverse events. Veterinarians need to be aware of the risk of "endotoxin stacking" with the use of multiple Gram-negative vaccines.

Knowledge of immunology and vaccinology, including associated benefits and risks, and the pathobiology of infectious diseases, are necessary to implement an effective vaccination program. Consideration of exposure, susceptibility, potential severity of disease, vaccine efficacy and safety, related state/federal restrictions, the potential for public health concerns, and owner's preferences are essential components of a customized vaccination program.

Those veterinarians with an established veterinarian-client-patient relationship are in the best position to make recommendations customized to the needs of the individual patient(s) and owner/client.

Revaccination recommendations should be designed to maintain clinically relevant immunity while minimizing adverse event potential.

Additional information, including vaccine-specific scientific data on minimum, average, and maximum duration of immunity is desired to craft optimal revaccination recommendations.

Veterinarians should create a core vaccine program, intended for use in the majority of animals in their practice area. Core vaccines are those that protect from diseases that are endemic to a region, those with potential public health significance, required by law, virulent/highly infectious, and/or those posing a risk of severe disease. Core vaccines have clearly demonstrated efficacy and safety, and thus exhibit a high enough level of patient benefit and low enough level of risk to justify their use in the majority of patients.

Veterinarians should create a non-core vaccine program, intended for a minority of animals in their practice area. Non-core vaccines are those that fit any of the following criteria:

- Targeted for diseases that are of limited risk in the region
- Protects against diseases that present less severe threats to infected patients
- Have a benefit/risk ratio that is too low to justify the use of the product in all circumstances
- Lacks adequate scientific information to fully evaluate the safety and/or efficacy of the product

Multiple-dose Vials

There are numerous advantages associated with the use of single dose vials. If multiple dose vials are used, care must be taken to thoroughly mix vaccine contents and administer the recommended dose according to the product label. Appropriate measures should be taken to minimize the potential for vaccine contamination with extraneous microbes or chemicals.

Regulatory Issues

The vaccine performance claims made by the manufacturers of USDA-licensed products have been substantiated by a variety of testing methods. Careful evaluation of labels and other information is necessary to compare and contrast between the available products. USDA-licensed products should be used if possible.

Current adverse event reporting systems need significant improvement in the capture, analysis and reporting of adverse events. Practitioner commitment to adverse event reporting, and timely access for practitioners to current analysis of adverse event data, are essential to providing optimal patient care.

There is potential legal liability for all medical procedures including vaccination.

Vaccine Licensing and Labeling:

Biological agents are regulated by USDA, not FDA, and thus are not subject to FDA regulations that address extra label use. It is generally recommended to follow label instructions, however, in

most cases veterinarians may legally use vaccines in a discretionary manner if medically justified and in compliance with State/Federal restrictions that apply.

USDA licensing at the full approval level provides a baseline standard for efficacy, safety, purity, and potency, but the clinical need (relevancy) or usefulness (applicability) of a product may not be completely assured by the licensing process. In some instances, the number of animals used in pre-license safety testing might be inadequate to identify rare but relevant safety concerns. In other instances, product efficacy and/or safety can be impacted by the use of concurrent therapeutic approaches that may not be cited as a contraindication or warning on the product label.

The USDA must approve labels for biological products. However, current labels frequently contain revaccination interval recommendations based on historical precedence and acceptance rather than specific duration of immunity data; consequently, some product labels may fail to adequately inform practitioners about optimal revaccination and long-term use of a product. Newer products and some older products with updated labels have revaccination recommendations based on data on file with USDA.

Labels on licensed vaccines make different claims and should be carefully studied when evaluating products. Claims may, for example, declare the product (a) prevents infection, (b) prevents disease, (c) aids in disease prevention, (d) aids in disease control (reduce disease severity, duration, and/or onset), or (e) other (control of infectiousness through reduction of pathogen colonization and/or shedding in animals). Each of these claims represents a different level of performance outcome that might be important in selection of a specific vaccine.

USDA approved products, under conditional licensure, have demonstrated host-animal safety and a reasonable expectation of efficacy. Autogenous vaccine regulations do not require confirmation of 1) efficacy, 2) potency correlated to efficacy; or 3) host-animal safety to the USDA prior to product licensure and use.

Even against the background that some of the authorisation processes are different between the USA and the EU (including the UK) the AVA position is consistent with the VMD position paper bearing in mind the AVA is a professional body. In the UK similar comments have been made by the BVA in a vaccine guide for the public:

Why are there conflicting views on the value of vaccination?

When searching the web and other sources of information about vaccination, it is advisable to exercise caution about what is accepted as true. There are individuals who hold unorthodox views, some of which lack any scientific basis and solely rely on rumour and conjecture. There is no review of anything placed on the internet (unless a particular website requires it) and a well presented website can look very authentic even if it is only presenting the unsubstantiated views of a few individuals.

For instance, it has been claimed on-line that vaccination of dogs is the cause of atopy (an allergic condition in which affected animals are sensitised to allergens, such as house dust mites and pollens). There is absolutely no evidence that vaccination and atopy are linked in any way whatsoever. Likewise, there is no scientific proof that homeopathic products actually stimulate an animal's immunity to a particular disease.

Fortunately, a very significant proportion of the canine population in this country is properly vaccinated by their owners who have chosen to take their vet's advice. The number of vaccinated animals is so high that the level of herd immunity is sufficient to prevent much spread of disease. And as long as that herd immunity is so high, the likelihood of a dog contracting, say, distemper, is much reduced. Of course, if people were to stop vaccinating their pets, herd immunity would drop and the disease would start to spread again – as it did with measles in children. This highlights the value of vaccination even in situations where the chance of contracting a disease may not initially seem high.

How frequently should vaccines be used?

Vaccination plays a very important role in the control of infectious diseases. Whilst it is recognised that adverse reactions such as an allergic response or a lack of efficacy may occasionally occur, an analysis of the overall benefits and risks strongly supports the continued use of vaccination.

Vets should make a thorough assessment of the benefits and risks on an individual case basis and discuss them with clients when deciding the timing of vaccination and the use of particular vaccines. Such an assessment will need to be based on the Summary of Product Characteristics (SPC), often referred to as a data sheet in the UK, a publicly available document giving particulars of the data package submitted by the manufacturer and agreed by the licensing authority during the authorization process. The SPC is unique for every vaccine and will provide precise information on the duration of the immunity that can be achieved when that product is administered. It is this information that the vet will use to decide the frequency of vaccination, along with scientific guidelines that are made available by professional bodies.

Recent trends in data mean that many products now indicate a duration of immunity of 3-4 years for canine distemper, parvovirus and adenovirus after completing the primary vaccination schedule and the subsequent booster in minimum age puppies. However, some veterinary surgeons may also take into account the World Small Animal Veterinary Association (WSAVA) Guidelines by, for example, giving a full first annual booster before applying the extended duration of immunity claims, or by delaying the second vaccination until the animal is at least 12 weeks of age in some high risk areas or where levels of maternally derived antibodies are expected to be high. It is important for veterinary surgeons to understand that, when departing from the SPC, they do so under their own responsibility.

Vets must therefore use vaccines in accordance with the licence stipulations and what they know of the prevailing disease trends in their area. If they deviate from the medicinal data available to them and/or use a vaccine not in accordance with the instructions on the label and the SPCs it must be done with good reason and informed client consent.

Some lobby groups have accused the veterinary profession of over-vaccinating – perhaps using vaccine yearly when there may well be a longer lasting immunity to disease. To challenge this view would involve further testing beyond the scientific evaluations already undertaken by the manufacturer to determine the duration of immunity as specified in the SPC.

What are the benefits of vaccinating dogs and cats?

There is no doubt that the use of vaccination has been of huge benefit to our pets by bringing some very unpleasant diseases under control. The use of 'combination' or 'multivalent' vaccines (where several different vaccines are given together) has transformed the control of many diseases of dogs and cats. Virus diseases such as canine distemper, canine parvo virus and feline respiratory disease used to be a scourge. The development of vaccines and their widespread use has brought the diseases in question under control.

The way in which vaccines have been used in dogs and cats is rather different to the way in which they have been used in farm animals. The difference is that whereas in farm animals the aim is to prevent the spread of disease and to protect the herd, in the dog and cat it is the individual animal that vaccine is being used to protect. However, the uptake of vaccination by responsible dog and cat owners who wish to prevent their pet from catching certain diseases has been so great that it

has reduced the amount of such disease seen by vets. It has produced some herd immunity. Prevention is better than cure, especially with diseases such as distemper where if the animal survives it is often left with permanent damage of some kind.

For the past forty years, vets have been advising their clients to vaccinate their pets; there has been little or no evidence of any level of failure by the vaccine to protect the animal. This has probably contributed to the public view that vaccination is the answer to every disease situation.