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Dear Ms Driscoll

Thank you for your letter dated 10th February concerning the vaccination of dogs in the UK. I am providing this response to those points which are directly under the VMD's responsibility but additional time will be required to respond fully to the many wider issues your letter raises and I intend to provide a more comprehensive response by March 31st 2010.

As an opening statement, I vigorously defend the Veterinary Medicines Directorate's (VMD) record on the regulation of companion animal vaccines and more specifically canine vaccines. Over the last decade, the standard authorised vaccination schedule for puppies and adult dogs has moved radically away from the routine annual revaccination for the core canine vaccine antigens towards the more targeted and flexible approach seen today. Core vaccines are defined in your letter as those offering protection against canine distemper virus, adenovirus and parvovirus. This has followed on from significant encouragement of the industry by regulatory authorities following the publication of the WSAVA guidelines and its predecessors.

For most recently authorised canine vaccines, the vaccination schedules are in accordance with the recommendations in the recent WSAVA Guidelines with recommended revaccination dose intervals of 3-4 years for the core vaccine components. These recommendations have been supported by robust scientific data provided by vaccine manufacturers that demonstrate these duration of immunity claims for the modified live vaccine (MLV) fractions for canine parvovirus, distemper and adenovirus.

The VMD has been a leading Regulatory Authority within Europe in assessing and supporting these revaccination intervals, acting as the co-ordinating regulatory body for the majority of new products developed by vaccine manufacturers. In fact we believe the UK was the first European Community country to authorise booster intervals of three and four years for a canine vaccine and has subsequently helped to extend the claims to many other European Member States.

It is important to emphasise the distinction between the extended duration of immunity (DOI) for these components and the epidemiological need to boost non-core vaccine components annually or even more frequently. In the UK these are vaccines principally offering protection against leptospirosis and Kennel Cough both recognised as endemic and therefore common canine diseases in the UK. It is recognised by manufacturers, regulators and the experts that developed the

WSAVA Guidelines that inactivated leptospira and parainfluenza vaccines should be administered more frequently than the core antigens to maintain a protective level of immunity. A routine annual visit to a veterinary surgeon may, therefore, be required if there is a desire to keep all recommended vaccinations up to date. It should also be kept in mind that not all MLV vaccines may behave identically and that the DOI of one product may be longer or shorter than another. For example, it is recognised that the DOI of the new recombinant vaccines may be less than that for the traditional MLVs.

We note your concerns regarding the lack of epidemiological data on the prevalence of canine disease in the UK in order to define an individual pet's vaccination requirements. Nevertheless, leptospirosis is generally recognised as a ubiquitous infection and is also carried by the rat and kennel cough is a frequent infection experienced by dogs annually. A veterinary surgeon can make a clinical benefit/risk judgement based on the local reports of infection and taking account of the age, health, home environment, travel plans and lifestyle for each individual animal presented for vaccination and discuss recommended vaccine schedules with the owner. Thus the decision to vaccinate the individual patient and the frequency thereof is a matter for the veterinary surgeon and his client to discuss. It is not an issue where the VMD should intervene.

In response to your call for greater transparency regarding the recommended uses of the various vaccine brands, the Summary of Product Characteristics (SPC) is a publically available document based on the data package generated during the development of each product. SPCs provide guidance to the veterinary surgeon prescribing the product and are publically available on the VMD website (www.vmd.gov.uk/ProductInformationDatabase). A veterinary surgeon may also take account of the WSAVA Guidelines when devising a vaccination schedule for an animal under his care. However, it is correct that, if departing from the SPC, veterinary surgeons do so under their own responsibility and would be well advised to do so with the client's agreement.

The VMD recognises the ongoing interest, within the veterinary and general pet owning community, in the level of protection afforded by vaccines for companion animals and any potential risks to pets from unnecessary vaccination. In response to these concerns, the VMD established an independent working group on feline and canine vaccination. The full report is available on the website of the Veterinary Products Committee, the independent scientific advisory committee on veterinary medicines, <http://www.vpc.gov.uk/Working/feline.html> . The working group concluded in 2002 that vaccination plays a very valuable role in the prevention and control of the major infections in dogs and cats and, although adverse reactions occasionally occur, the risk/benefit analysis strongly supports their continued use. There has been no significant shift in the information available on this issue and, therefore, there is no reason to ask the VPC to look again at this issue.

The VMD has operated a Suspected Adverse Reaction Surveillance Scheme for many years (since 1985) and has invested in the further development and expansion of this scheme. It is acknowledged that any pharmacovigilance system is primarily reactive and under-reporting is an inevitable feature. However, under-reporting will apply equally to all products and while changes in the incidence rates of adverse reactions are useful indicators of issues which need to be investigated, it

is the clinical detail in the reports and the trends and patterns of adverse reactions that are a far more important tool in the science of pharmacovigilance. Therefore, under-reporting is not a significant issue.

Immunological science is complex and the regulatory assessment of the data relating to a specific vaccine equally so. To date, as far as we are aware, there are no peer-reviewed publications demonstrating protection by viral challenge of adult dogs that were vaccinated with each specific UK authorised product at the minimum age recommended for puppies. Whilst we accept that serology is correlated with protection for the core-MLV components, there is no universally agreed threshold on the level of antibody that provides complete protection. Furthermore, there are various techniques and methods used to measure antibody titres and care should be exercised when extrapolating titres between methods and between laboratories offering these services. Therefore, titre measurements are useful in the clinical evaluation of a specific patient but they do not necessarily provide the complete picture in determining the level of protection afforded by the vaccine.

Many veterinary surgeons can remember the devastating effects these once common diseases had on our pets, their owners and families and the huge benefit vaccines have had on improving the health and welfare of the canine population should be recognised. These diseases remain an ever-present threat (otherwise vaccination would be unnecessary) and the current veterinary consensus supports a vaccine based solution grounded in sound science and robust data for developing the optimum vaccination schedules for our pets.

In closing this interim response, I would refute the allegation that the VMD is overly concerned with supporting the financial interests of its customers as this allegation is simply without foundation. The VMD will continue to assess veterinary vaccines according to the legal requirements agreed within the EU and using the scientific guidance which represents the agreed view of experts in vaccinology and immunology from around the world.

Yours sincerely

A handwritten signature in black ink, appearing to read 'S. Dean', written in a cursive style.

Professor Steve Dean
Chief Executive