NOAH statement on canine vaccination

Member companies of NOAH who market vaccines for companion animals have received multiple queries from practitioners seeking clarification regarding the messages within the recent publication from WSAVA, *Vaccination Guidelines for New Puppy Owners.*

NOAH welcomes any guidance assisting the veterinary profession in their determination of vaccine protocols and helping to educate the public. The guidance, whilst promoting the benefits of vaccination however appears to be at variance with many of the protocols that practices have adopted and the advice contained within the datasheets/Summary of Product Characteristics (SPC) for the vaccines licensed in the UK. Apparent discrepancies include the advice in the Guidelines document regarding vaccination protocols, the routine use of non-core vaccines (particularly Leptospirosis and Kennel Cough), the role of serology testing to determine vaccination requirements and vaccine safety.

This guidance is written from a global perspective; many countries do not have the developed and educated companion animal market found in the UK. Likewise the vaccines available, their constituents and licensed claims are not universal across the globe and nor are the licensing and regulatory authorities and their requirements.

Vaccine manufacturers must gain and maintain a licence in the UK from the Veterinary Medicines Directorate (VMD), or the European Medicines Agency (EMA) by obtaining a Marketing Authorisation (MA) before the vaccine can be used. In order to obtain an MA, the company must submit a satisfactory data package detailing efficacy, onset of immunity, duration of immunity and justification of the need for the vaccine with regard to disease prevalence/incidence. These data are rigorously assessed by the scientific assessors of the independent regulatory agencies. The licensed claims are part of the MA and are found within the approved written materials. It is of note, that not all countries have licensed claims for extended duration of immunities, and in many countries all vaccines are given on an annual basis. In recent years, in the UK, where it has been possible to do so, companies have extended duration of immunity in the Marketing Authorisation.

We firmly believe that the individual veterinary surgeon is best placed to make a benefit/ risk decision, in consultation with their client, for the individual animal with regards to the most appropriate vaccination protocol. In the majority of cases, these recommendations will fall within the scope of the licensed product; should there be a need to deviate from the licensed claims (i.e. off-label use), the veterinary surgeon is empowered to make a clinical benefit/risk judgement. In such
cases, the veterinary surgeon takes responsibility for this decision and it is recommended that they agree their course of action with the animal owner.

With regards to the issue of whether leptospirosis vaccines are considered core or non-core, again NOAH believes the individual veterinary surgeon is best placed to make that decision in line with WSAVA’s principle; the incidence/prevalence of the disease in the UK and its zoonotic risk means that the majority of the profession in the UK regard it as a core vaccine for animals in the United Kingdom. Any decision not to include it within routine vaccinations, in our opinion, would require informed consent and clinical justification. No licensed leptospirosis vaccine in the UK has duration of immunity beyond 12 months. We are not aware of any evidence that suggests that leptospirosis vaccines are associated with any increased risk of adverse reactions or that toy breeds of dogs require any additional precautions when receiving vaccinations against leptospirosis. However, if vets do suspect an adverse reaction, NOAH encourages them to report this suspicion to the Marketing Authorisation Holder or to the Veterinary Medicines Directorate.

Kennel cough remains a common infectious disease within the UK and whilst rarely fatal, it can have welfare consequences in the more vulnerable animal, cause distress to dog and owner alike, as well as hinder working dogs. It also may require antimicrobial treatment in certain cases. Again the veterinary surgeon should look at the benefit/risk of using the intranasal vaccines in balance with their clinical judgement of the individuals’ risk and use vaccines where they consider appropriate.

Serology is a useful diagnostic test with regards to assessing humoral responses but can have limitations for determining vaccination status in individual animals. Results are not always easy to interpret (Burr, 2006), take no account of cell mediated immunity, and for the owner may set false expectations. This may result in difficult decisions when the results reveal an indeterminate level as well as additional cost of sampling and significant delays whilst awaiting results. The veterinary surgeon must still make clinical decisions with regards to the animal’s health status, environment and likely exposure to infectious disease.

It is inevitable and understandable that as disease incidence falls, more attention turns to the potential adverse reactions from vaccination. We endorse the WSAVA’s comments that the risk is considered small and the benefits of protection far outweigh the risk, and NOAH continues to encourage the profession to report any suspected potential side effects including suspected lack of expected efficacy. All reports are assessed by the regulatory authorities and are integral to maintaining an MA and keeping a vaccine on the market. We also appreciate WSAVA’s intention of continuing to educate the public, but are concerned that oversimplification of potential linked adverse events such as epilepsy and arthritis do need qualification, given the lack of evidence for the association between vaccination and the onset of these diseases. Such statements are open to mis-interpretation and owners may unjustifiably assume spontaneous disease is a result of a vaccine, putting the attending veterinary surgeon in a difficult position.
The UK regulatory agency for veterinary medicines, the VMD considered many of these points in a recent position paper titled ‘VMD Position Paper on Authorised Vaccination Schedules for dogs’ (VMD, 2014). A notable point from this paper was the following quote;

‘...the benefits of vaccination are considered significantly greater than the risks of infection by the ever present canine infectious diseases in the UK.’

In the light of increased movement of pets from mainland Europe and beyond, the continued wide distribution of canine parvovirus and indeed the re-emergence of confirmed cases of canine distemper in a number of locations in the UK, the threat of infectious disease to our pets is ever present and demands that a high level of vaccinal immunity is maintained across the country. It would be unfortunate if in seeking to provide "best practice" advice on the use of vaccines, expert guidance were to lose sight of the need to maintain the confidence of both the pet owning public and indeed the veterinary profession itself in the continued value of the use of vaccines to keep significant infectious disease threats at bay.

In conclusion, we believe the profession within the UK has adopted many of the principles of the WSAVA guidance for some considerable time, such as annual health checks, determining individual requirements and the adoption of extended duration of immunities where appropriate whilst still exercising their duty of care to the individual animal and the wider community by ensuring protection against infectious diseases.

References:

Veterinary Medicines Directorate website (February 2014)