



Elizabeth Hart <eliz.hart25@gmail.com>

Re: Your participation in the session on pet vaccination at the BSAVA conference today

Elizabeth Hart <eliz.hart25@gmail.com>

Sun, May 15, 2011 at 10:31 PM

To: "Brady, Anna-Maria" <a.brady@vmd.defra>

Cc: "Dean, Steve" <s.dean@vmd.defra>, "m.j.day" <M.J.Day@bristol>, Ron Schultz <schultzr@svm>, richard.squires@jcu, atsuji@mail.ecc.u-tokyo, roger.bunvet@, jollenl@, davidfwadsworth@, Walt Ingwersen <wjic.ingwersen@>, info@rcvs.org.uk, registrar@rcvs.org.uk, bvahq@bva.co.uk, administration@bsava.com, "Catherine O'Driscoll (chc)" <catherine@canine-health-concern>, jlnw2@cam, "r.m.gaskell" <r.m.gaskell@liverpool>, Mark Holmes <mah1@cam>, Bea Mies <flyballbea@>, Pauline <major1@>, Sally <sally@>, rbford@ncsu, Jason Merrihew <jason.merrihew@aahanet>, Rick.E.Hill@aphis.usda, "Dr. Lynne White-Shim" <LWhite@avma>, "BENNET-JENKINS, Eva" <Eva.Bennet-Jenkins@apvma>, "SUTER, James" <James.Suter@apvma>, jennimack2@, Heather Yeatman <hyeatman@uow>, "BRYCE, Allen" <allen.bryce@apvma>, "REEVES, Phil" <phil.reeves@apvma>, president@ava, David Imrie <execasava@ava>, "Cristina Sacco (ASAVA)" <asava@ava>, david@adelaidevet, mark.kelman@virbac, Marcia Balzer <communications@ava.com.au>, ted.whitem@unimelb, glenfb@unimelb, Mark Lawrie <mlawrie@ava>, Julie Strous <eo@avbc>, Peter Charles Doherty <pcd@unimelb>, "Atkinson, Jackie" <j.atkinson@vmd.defra>, "Green, Paul" <p.green@vmd.defra>, "Woodland, Ralph" <r.woodland@vmd.defra>

For the attention of:

Dr Anna-Maria Brady
Biologicals and Administration
Veterinary Medicines Directorate

Your Ref: #323746

Dr Brady

Thank you for your letter dated 11 May 2011 in response to my email dated 1 April 2011.

I am currently considering the content of your letter.

Re your statement:

"You question the scientific basis for the statement on the SPC of Nobivac DHP recommending a single booster dose every three years. Primary vaccination enables the immune system to establish an "immunological memory" and to respond more rapidly and strongly to a subsequent antigenic challenge than on first exposure. This property is sometimes referred to more technically as an anamnestic response. **The manufacturer will provide data to demonstrate that a single "booster" vaccination will stimulate an anamnestic response of sufficient magnitude to equal the protection afforded by the primary vaccination scheme. To maintain this protection after the duration of the primary vaccination has lapsed, it will be necessary to stimulate the immunological memory by a single vaccination,**

hence in the case of Nobivac DHP, the recommendation for a single booster after three years, as this is the proven duration of immunity for this individual product.” (My emphasis.)

The SPC for Nobivac DHP states **“Duration of immunity: three years”** and **“To maintain protection a single booster dose is recommended every three years.”** (Refer to copy of SPC attached.)

The SPC provides no reference in the published scientific literature to support these statements, in particular the inference that duration of immunity is limited to three years and boosters are required to maintain protection.

(Note: I have discovered a paper titled “Three-Year Duration of Immunity in Dogs Following Vaccination Against Canine Adenovirus Type-1, Canine Parvovirus, and Canine Distemper Virus”. [Gore T. et al. Veterinary Therapeutics. Spring 2005, Vol. 6, No. 1.] The paper refers to Intervet’s Continuum DAPP vaccine, but this [US Intervet website](#) notes that the three year Nobivac vaccines were formerly known as Continuum. Can you please advise if this paper is pertinent to Nobivac DHP, or otherwise provide me with the correct reference?)

I suggest that three years is the **minimum** duration of immunity for Nobivac DHP, and **no endpoint to duration of immunity has been demonstrated**. I suggest this is the evidence-based information that should be included in the SPC.

Dr Brady, I am confused by your statement that it is necessary to stimulate the immunological memory every three years to maintain protection, i.e.:

“To maintain this protection after the duration of the primary vaccination has lapsed, it will be necessary to stimulate the immunological memory by a single vaccination, hence in the case of Nobivac DHP, the recommendation for a single booster after three years, as this is the proven **duration of immunity** for this individual product.” (My emphasis.)

Can you please provide me with a reference in the published scientific literature that supports your statement?

I have some further queries about your response which I will forward in due course.

In the meantime, I appreciate your offer to put our correspondence on the VMD website to provide transparency in this process.

Yours sincerely
Elizabeth Hart

Att: SPC_168930 Nobivac DHP

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