

## SUMMARY

### OF CANINE HEALTH CONCERN'S RESPONSE TO THE VETERINARY MEDICINES DIRECTORATE'S POSITION PAPER ON AUTHORISED VACCINATION SCHEDULES FOR DOGS

#### Summary points:

1. The Scientific Principle
2. The VMD is conflicted: industry ties
3. Government and the pharmaceutical industry
4. Veterinary vaccines are Big Business
5. The supporting science
6. Questions
7. Conclusions

#### 1. THE SCIENTIFIC PRINCIPLE: WE MUST STOP OVER-VACCINATING PETS

“When an annual booster vaccination with a modified live virus vaccine (i.e., distemper, parvovirus or feline distemper) is given to a previously vaccinated adult animal, no added protection is provided. Modified live virus vaccines depend on the replication of the virus for a response. Antibodies from previous vaccines do not allow the new virus to replicate. Antibody titers are not boosted significantly, memory cell populations are not expanded. **No additional protection is provided.**”

“Vaccines are not harmless. Unnecessary side effects and adverse events can be minimised by avoiding unnecessary vaccinations.”

*American Veterinary Medical Association  
Council on Biologic and Therapeutic Agents*

#### 2. THE VETERINARY MEDICINES DIRECTORATE IS CONFLICTED

In February 2010, Canine Health Concern and over one hundred veterinarians and pet owners wrote to the Veterinary Medicines Directorate, part of Defra – a government department - calling for the VMD to withdraw one-year live virus vaccines from the market. This was the culmination of sixteen years of appealing to successive governments to call a halt to unnecessary and damaging annual vaccinations for pets.

The VMD's response was disappointing and wholly inadequate, and merely reflected the status quo. Nothing changes.

- The VMD acknowledges that adverse events (life-threatening vaccine reactions) are under reported, calls this 'insignificant', and brushes

under-reporting off in an attempt to claim that infection poses a greater risk than vaccination. However, the VMD also acknowledges that it has no data to quantify disease prevalence in the UK.

- How can the VMD possibly quantify risk versus benefit when the rate of adverse events is unknown, and the rate of disease prevalence in UK dogs is unknown?
- Not only does the VMD's Suspected Adverse Reaction Surveillance Scheme (SARSS) fail to gather a clear picture of the death and disease caused by the over-vaccination of companion animals (as admitted by the VMD in its response), but it actually serves to minimise the known damage and fast-track dangerous biologics to market. The SARSS scheme is a red herring.
- The VMD employs doublespeak to imply one thing but mean another. The World Small Animal Veterinary Association says that we should vaccinate no more often than every three years, but adds that initial vaccines should provide protection for the animal's lifetime. The VMD claims to be in accord with the World Small Animal Veterinary Association, whilst saying that we should vaccinate at least every three years. These statements are diametrically opposed, but are passed off by the VMD as concordant.
- Whilst acknowledging worldwide veterinary opinion with regards to long duration of immunity to canine viral disease, the VMD subsequently sent a letter to the veterinary press, stating: "It is important for veterinary surgeons to understand that, when departing from the SPC, they do so under their own responsibility". This implies that if a vet chooses to follow the known science regarding long duration of immunity, they are acting against the VMD's instructions, and will be unsupported in law.
- In a letter to CHC members from Jeff Rooker in 2008, then Minister for Sustainable Farming and Food, and Animal Welfare (who was advised by the VMD), we are told: "If a veterinary product is used other than in accordance with the authorised manufacturer's instructions a veterinary surgeon administering the product does so at his own risk and may be held accountable for any adverse events". This, in effect, makes it impossible for a vet to advise clients that vaccines which have only been licensed for one year need not be boosted annually – even though the science shows that once immune, dogs and cats are immune for years or life.
- Licenses are granted by the Veterinary Medicines Directorate which stipulates the requirements. The VMD's requirements are illogical and ensure that our pets are over-vaccinated.
- The VMD hides behind European legislation, even though the head of the VMD acted as Chair for the European regulatory body.

- The VMD claims that veterinary vaccines are “manufactured to a consistent and acceptable quality using high grade materials and are uncontaminated with potentially harmful infectious agents or other toxic substances”. Yet as recently as April this year, an important study showed that UK dog and cat vaccines are contaminated with a retrovirus that is associated with cancer, and that sensitive screening techniques used for human vaccines are not required for animal vaccines. The VMD did not disclose this in its Position Paper on Canine Vaccination Schedules.
- In view of the fact that veterinary vaccines in the UK have recently been shown, by independent review, to be contaminated with a retrovirus, the VMD cannot make the claim that the licensing procedure, and the quality and safety measures, are beyond reproach. Neither can the VMD legitimately claim that errors and failings do not occur.
- **This fact in isolation illustrates the need to revaccinate as infrequently as possible, thereby minimising the vaccine risk.**
- **Vaccine safety is not assured at the point of license.**
- The VMD claimed in its position paper that it “seeks to ensure that vaccines are safe to be administered to young and older animals where relevant, and pose no risk to the owner, their families or other animals and persons coming in contact with vaccinated animals”. The VMD has failed in this aim, since some vaccines certainly do pose a disease risk to other animals and humans. However, there is no mechanism for disclosure of this information to the pet owning public.
- The VMD suggests that pet owners, in consultation with their vets, should make the decision regarding frequency of vaccination. This is disingenuous as it would require ordinary pet owners to be more knowledgeable than their vets, most of whom in the UK vaccinate annually as a matter of established practice – irrespective of the known science. The VMD abdicates responsibility, effectively keeping annual vaccination as the norm. There is no mechanism for informing pet owners of the known science regarding duration of immunity, or the risks associated with pet vaccination.
- The VMD, on behalf of the government, commissioned four people to participate in a working group looking into canine and feline vaccines, and quotes this report widely. Of the four, two were industry consultants in receipt of research and/or consultancy funds from the veterinary vaccine industry. A third was a member of the Veterinary Defence Society Limited. Nevertheless, the VMD maintains that this was an ‘independent’ working group.

- With respect, we need a new Working Group. One that is comprised of individuals who have no financial ties to the veterinary vaccine industry – or, indeed, the wider pharmaceutical industry.
- The VMD constantly uses the POOCH survey to back up current vaccine practice and to trivialise adverse events. The VMD calls this survey ‘independent’. It was funded by the veterinary vaccine industry and conducted by an organisation that describes itself, in its report and accounts, as a vaccine developer. What business does a government department have in quoting and endorsing industry data in support of vaccines that are not needed?
- The VMD also quotes vaccine industry vox pops, commissioned to aid a sales campaign, to justify current vaccine practice.
- The VMD, at the same time, claims that independent duration of immunity studies are not scientifically rigorous enough for them to call a halt to over-vaccination, despite their publication in numerous peer review journals, and despite their adoption by veterinary bodies around the world.
- One veterinary vaccine manufacturer – Intervet – mounts an annual ‘National Vaccination Month’ / ‘Vaccine Amnesty’ marketing campaign which is confusing and infers that pets need boosting against a whole range of diseases to which they are already immune. This is unacceptable to those who understand the known science, but acceptable to the VMD.
- **The VMD is not concerned with the safety of the pet population, or the interests of the pet owning public. How can it be when it advocates and facilitates the sale and use of vaccines that are not required; under-plays adverse reaction rates; and promotes industry marketing material assembled in defence of unnecessary annual vaccination?**

### 3. GOVERNMENT AND THE PHARMACEUTICAL INDUSTRY

- Before coming to office, our Prime Minister, David Cameron, predicted that political lobbying was the “next big scandal waiting to happen” and was one that had “tainted our politics for too long, an issue that exposes the far-too-cosy relationship between politics, government, business and money”.
- Civil servants are not immune to industry lobbying. For example, companies are paying up to £11,000 a year to a Mayfair-based private members’ club that offers introductions to top civil servants. Civil servants do not pay to attend, but corporate members pay a £1,500 joining fee and an annual charge of £9,500 for access to a series of networking events. (*Sunday Times*, June 13<sup>th</sup> 2010)

- **The businesses regulated by the Veterinary Medicines Directorate do not need such introductions. There is a revolving door between the VMD and the veterinary pharmaceutical / vaccine industry.**
- The VMD was established following the publication, in February 1988, of the *Review of Animal Medicines Licensing* by Mr P.W. Cunliffe CBE, **former Chairman of ICI Pharmaceuticals Division**. It seems that the VMD was formed in consultation with, and to meet the needs of, the pharmaceutical industry.
- Under Margaret Thatcher in the UK and Ronald Reagan in the US, a period of effective deregulation and a pro-business legislation ensured that pharmaceutical companies grew to become immensely profitable.
- The Thatcherite neo-liberalism that dominated UK and international politics in the 1980s continued under New Labour in regard to its treatment and regulation of a number of key sectors, including pharmaceuticals.
- Rather than distancing themselves from pharmaceutical companies, and tightening the regulatory screws on conflict of interests, the links between government agencies and pharmaceutical companies have spread unchecked.
- **The head of the VMD – Steve Dean – was appointed head of the Veterinary Medicines Directorate in March 2002. He had spent 17 years as a marketing manager within the pharmaceutical industry, and later became a pharmaceutical industry consultant. He is an industry man.**
- Professor Dean's appointment merely reflects government policy with regard to the veterinary pharmaceutical industry.
- The VMD considers the pharmaceutical industry to be its customers, for whom it continuously strives to improve service quality (VMD Report and Accounts). The animals and the pet owning public are considered as an afterthought.
- Rather than keeping an arms-length distance from the pharmaceutical industry, Steve Dean - the man charged with the task of "protecting public health, animal health, the environment and promoting animal welfare by assuring the safety, quality and efficacy of all aspects of veterinary medicines in the UK" (which is the stated aim of the VMD) speaks at seminars for the veterinary vaccine industry and helps the industry at its launch events.

- Members of the VMD/VPC have declared interests (research grants, shares, consultancy) with a wide range of pharmaceutical companies, including AstraZeneca, Sanofi Aventis, Pfizer, GlaxoSmithKline, Intervet Schering-Plough, Wyeth, Merial, Novartis, Pfizer, Virbac, Eli Lilly, and Bayer. Declaration of such interests is considered enough to allow these conflicts.
- The VMD regulates the supply of veterinary medicinal products in the United Kingdom. However **it is keen to minimise the burden of this regulation on the industry** (VMD Report and Accounts).
- “The VMD should outline how it is using new forms of technology to **help veterinary medicine manufacturers bring new products to market.**” (Hampton Review)
- The VMD – a government department - is deeply conflicted.
- **The VMD does not have an arms length relationship with the veterinary pharmaceutical industry, which pet owners might have assumed. Rather, its culture is one of facilitation and support for the highly incestuous and powerful pharmaceutical industry.**
- **We call upon this government to remodel the Veterinary Medicines Directorate so that it honours its initial aim of protecting animals and the pet owning public.**
- **We ask the government to put a stop to damaging over-vaccination of companion animals.**

#### 4. VETERINARY VACCINES ARE BIG BUSINESS

- The veterinary vaccines sector accounted for 20% of global animal health product revenues in 2004. Global sales totalled \$3.2 billion and market forecasts predict the sector will grow in excess of \$4 billion by 2009. (Animal Pharm report)
- Six companies account for more than 70% of world veterinary vaccine sales. The market leader is Intervet, with sales of almost \$600 million in 2004. (Animal Pharm report)
- Since 1991, the companion animal market has grown at 6.6 per cent per annum in real terms, which almost matches human health care. (Visiongain report – The Global Veterinary Pharmaceutical Market)
- Although the pet population has increased marginally, the key driver for growth has been the willingness of pet owners to **spend more** on the health of their animals. (Visiongain report)

- **The human-pet bond has a high economic ceiling**, and both veterinarians and the animal health industry have recognised the potential of this market segment. (Visiongain report)
- Veterinary vaccine companies invest heavily to influence vets.
- Veterinary vaccine companies sponsor research and other projects within the veterinary teaching establishments. This arguably influences the curriculum.
- Veterinary vaccine companies sponsor further education for vets.
- Veterinary vaccine companies help fund professional veterinary body seminars and events.
- Veterinary vaccine companies supply marketing material for vets, and engage vets in media campaigns to sell unnecessary boosters.
- Veterinary vaccine companies have been known to provide funds to assist vets in setting up their own practices.
- Veterinary vaccine companies send vets on jaunts overseas. One vet said: "I've been on three skiing holidays with Intervet, but it doesn't influence my buying decisions."
- Veterinary vaccine companies appear to see vets as part of the sales team.
- Veterinary pharmaceutical companies, which include veterinary vaccine companies, fund the Veterinary Medicines Directorate.
- Veterinary vaccine companies hand money to major animal charities, and major animal charities help veterinary vaccine companies with their marketing initiatives to sell unnecessary vaccines.
- Veterinary vaccine companies employ 'confusion marketing' to sell vaccines that are not needed.
- Pet owners are subjected to a barrage of 'expert' opinion, and advertising and PR campaigns to ensure that they vaccinate their pets far more frequently than is necessary. Pet owners then pick up the bill when their animals become sick or die.
- All of this goes unchecked.

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## 5. THE SUPPORTING SCIENCE

- It has been known since Dr Ronald D Schultz first conducted his independent duration of immunity (DOI) studies in the 1970s, that there is no scientific justification for the current revaccination schedules of dogs and cats.
- All vaccines come with a risk of severe and life-threatening adverse reactions, which are detailed scientifically in CHC's response. It makes sense to administer vaccines as infrequently as absolutely necessary in order to minimise any risks.
- Veterinary bodies around the world have called for an end to annual vaccination. These are the World Small Animal Veterinary Association, the American Animal Hospital Association, the American Veterinary Medical Association, the Australian Veterinary Association, and the VMD-equivalent, the Australian Pesticides and Veterinary Medicines Authority.
- The veterinary bodies listed above have advised that a simple blood (titre) test would confirm circulating antibody, indicating whether or not a pet is immune. This would serve to take the place of annual vaccines which come with diverse unwanted consequences.
- Over-vaccination of companion animals puts pets at unnecessary risk of a wide range of scientifically acknowledged vaccine adverse effects. These include cancer, epilepsy, allergies, arthritis, heart disease, thrombocytopenia, aggression and other behavioural problems, autoimmune haemolytic anaemia, bone marrow failure, immune-mediated blood diseases, haematologic malignancies (lymphoma and leukaemia), dysregulation of humoral and cell-mediated immunity, organ failure (liver, kidney) and autoimmune endocrine disorders – especially of the thyroid gland (thyroiditis), adrenal gland (Addison's disease) and pancreas (diabetes). All of these are referenced in the main body of CHC's response to the VMD.
- Vaccine adverse effects usually come to light **after** they have been approved and placed on the market.
- The vaccine process, itself, is expected to cause adverse effects in a proportion of the vaccinated population – whether human or animal. The balancing act for the veterinary vaccine industry, veterinarians and legislators lies in how many adverse reactions can be expected, and how many are acceptable. Only after adverse effects reach unacceptable limits (in the eyes of manufacturers and legislators), are vaccines withdrawn from the market. However, the VMD is not looking for individual casualties, it is looking for trends.
- It is difficult to understand why, after 16 years of campaigning on the part of Canine Health Concern, the British Veterinary Medicines



Directorate, and the successive Ministers this government department has advised, should fail to reflect and uphold the known science, despite repeated requests, and despite repeated submissions of DOI (duration of immunity) data.

- Dogs and cats are dying and being made ill by unnecessary vaccines.

## 6. QUESTIONS:

- **Why would a British government department (the VMD), charged with the task of protecting animals and consumers from the ill-effects of pharmaceuticals, consistently refuse to uphold the known science, and consistently champion the pharmaceutical industry agenda?**
- **Why would successive government ministers support the VMD's obfuscation and fob pet owners off with claims that vaccines are safe and rigorously tested? Why do they fail to address the actual issue – that we are over-vaccinating our animals?**
- **Why do veterinarians continue to vaccinate animals every year when they do not need to be vaccinated every year?**
- **Why do veterinarians appear to be unaware of the many adverse effects of vaccines?**
- **Why does the VMD not adhere to the EU Precautionary Principle? The burden of proof of harmlessness of any pharmaceutical product is on the proponent NOT on the general public.**

## 7. CONCLUSIONS

- Our pets are being vaccinated when they do not need to be – and risking serious vaccine-associated disease and death – because the veterinary pharmaceutical industry is subjected to lax governance by a government department that puts industry needs before British citizens and their pets.
- The VMD must get out of bed with the veterinary vaccine industry.
- There is no scientific justification for annual vaccination. Pet owners are being coerced into spending money unnecessarily, and pets are dying years before their time. Successive governments have done nothing to stop this, which would indicate that this is government policy.
- Pet owners are not told of the potential adverse effects of vaccines; neither are they told of the independent duration of immunity studies

which show that most pet vaccines are unnecessary. There is no informed consent.

- There needs to be disclosure of the facts. Informed consent sheets – free from vaccine industry spin - need to be given to the public so that they can make informed choices about their pets' vaccine schedules.
- One-year MLV vaccines should be withdrawn.
- Will the current coalition government do anything for the people and their pets? Will David Cameron do something to put an end to the “far-too-cosy relationship between politics, government, business and money”?
- When will the over-vaccination of companion animals end?