

Vaccination schedules

The Summary of Product Characteristics (SPC), a publicly available document produced following the authorisation of a veterinary vaccine, provides information on the authorised use of the product and should be referenced by the veterinary surgeon when prescribing the product. The SPCs for authorised veterinary medicines in the UK are publicly available via the VMD's product database: www.vmd.gov.uk/ProductInformationDatabase/

High quality scientific data are available to support the primary and re-vaccination (booster) schedules. These data have been assessed by the VMD to ensure that the vaccine provides the required onset and duration of immunity claimed by the manufacturer. Veterinary surgeons will take account of these recommendations and any warnings on the SPC alongside any specific factors for the individual animal, for example the level of maternally derived antibodies, or the local disease situation when devising the optimum vaccination schedule for each animal.

Re-vaccination intervals

The VMD is aware of the debate regarding over-vaccination and that the number of vaccinations administered should be optimised, based on a benefit/risk analysis for each individual animal. Products providing a proven long duration of immunity will have this indicated in their SPC. Re-vaccination intervals specified on the SPC are supported by data from duration of immunity studies that confirm the vaccine is effective for the minimum period defined.

Many factors influence the effectiveness of vaccines and the need for re-vaccination. A vaccination programme for an individual animal should be discussed and agreed between the veterinary surgeon and client. A veterinary surgeon is empowered to make a clinical benefit/risk judgement based on many factors including the age, health, vaccination history, breeding status, home environment, likely exposure to other animals, travel plans, lifestyle and disease prevalence in the local area. Where a veterinary surgeon decides to use either a shorter or longer re-vaccination period as compared to the SPC this constitutes off-label use and the veterinary surgeon takes responsibility for this decision and is recommended to agree their course of action with the animal owner.

Serological testing as an alternative to vaccination has been reviewed by several notable experts in the field of veterinary diagnostics. Serology provides some useful additional information on the immune status of an animal but should be used alongside other factors and not as the sole determinant of vaccination frequency. Antibody titre testing to determine if the animal needs re-vaccination is available for canine adenovirus, distemper virus, and parvovirus and for feline calicivirus, herpesvirus and panleukopenia virus. Owners should seek veterinary advice when deciding between serological testing and re-vaccination.

Adverse events following vaccination

As with any medicinal product, adverse events can be associated with the use of veterinary vaccines. The potential for these to occur is carefully evaluated by the VMD at the time the product is assessed and before it can be marketed in the UK. Adverse events to veterinary products are monitored by the Suspected Adverse Reaction Surveillance Scheme (SARSS) which undertakes veterinary pharmacovigilance in the UK. The scheme is run by a team of specialists at the VMD. The benefits of the vaccine must strongly outweigh any potential risk involved with its use both at authorisation and continually thereafter.

Reported serious adverse events involving authorised veterinary medicines are rare. Companies who market animal medicines are required to report to the VMD all adverse events they are informed about and must do so within 15 days if the reaction is serious (i.e. is life-threatening or results in death or significant disability).

Veterinary surgeons are in a unique position to observe adverse reactions and have a key role in the reporting system. Diligent reporting of adverse reactions can provide useful information related to the side effects of any veterinary medicinal product. Advice on the reporting of adverse events can be found on the VMD website and adverse events can be reported using the online report form available on the VMD website (www.vmd.gov.uk).

Veterinary surgeons are provided with feedback on adverse events through the SARSS Report which is published annually in The Veterinary Record. This report identifies any trends which emerged during the year. Quarterly summaries of individual adverse reactions reported to the VMD are published on the VMD website www.vmd.gov.uk/SARQuartSummaries/default.htm

Homeopathic 'vaccines'

Nosodes and sarcodes (homeopathic remedies derived from unwell or healthy animals respectively) on the UK market have not been registered under the Homeopathic (simplified) Registration scheme of the Veterinary Medicines Regulations which is intended to provide assurance that products are produced to good quality standards and are safe.

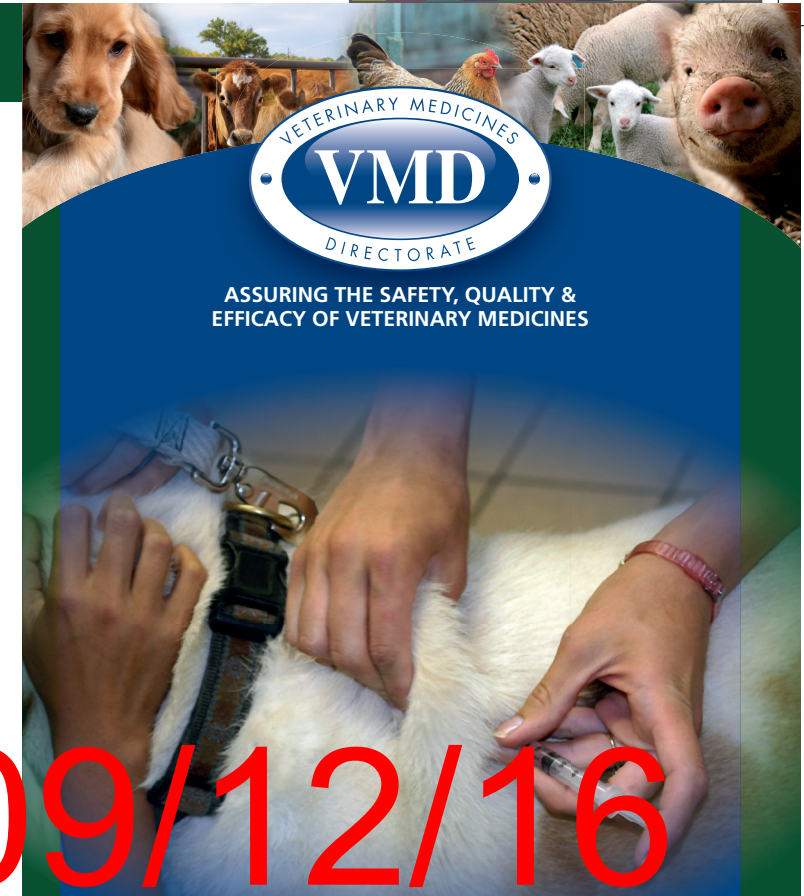
Nosodes and sarcodes have the potential to contain virulent pathogenic organisms from their source material which may pose a serious disease risk to the pet concerned, or even to human health. Homeopathic remedies have not been assessed to see if they provide any protection to the animal. Without evidence of effectiveness, homeopathic nosodes and sarcodes may pose greater risk to pets by leaving them susceptible to disease.

To report an adverse reaction to any medication used please contact:

Veterinary Medicines Directorate
FREEPOST KT4503
Woodham Lane
New Haw
Addlestone
Midlothian KT15 3BR
Tel: 01932 338127
E-mail: sarss@vmd.defra.gov.uk

You can also phone the VMD on 01932 336911 for any additional assistance about veterinary medicines.

Information correct at time of writing September 2010



ASSURING THE SAFETY, QUALITY & EFFICACY OF VETERINARY MEDICINES

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Vaccines for Dogs and Cats – Advice for Veterinary Surgeons



The Veterinary Medicines Directorate is an Executive Agency of the Department for Environment, Food & Rural Affairs

www.vmd.gov.uk

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Regulation of veterinary vaccines in the UK

The Veterinary Medicines Directorate (VMD), an Executive Agency of Defra, is responsible for the authorisation of veterinary medicinal products (VMPs) and for monitoring their safety and efficacy following authorisation. Before a veterinary medicine, including a vaccine can be placed on the UK market a large package of quality, safety and efficacy data undergoes a rigorous independent scientific assessment to ensure the product meets the required EU standards.

1) Quality

The data on quality have to provide proof of consistency and safety of ingredients from which the product is made. Rigorous assessment of data on quality and subsequent manufacturing site inspections ensure that all batches of the product are manufactured consistently to high quality standards. Quality is the foundation of any assessment for safe use and efficacy.

2) Safety

The vaccine must be shown to be safe to use by not causing unacceptable side effects or harm for the animal being treated, the person administering the vaccine or the environment. Where necessary specific warnings are added to the product literature which, when followed, will minimise the risk of any known potential adverse reactions following administration of the product.

3) Efficacy

Vaccines should perform as manufacturers claim they do when the instructions on the label are followed.

The rigorous controls applied to the manufacture, distribution and supply of veterinary vaccines ensure that the products are used correctly, remain at a high level of quality throughout their shelf life and potential risks to the animal, their owners and the environment are minimised.

Detailed instructions for the correct use of authorised VMPs can be found in the products' SPC (Summary of Product Characteristics). SPCs for all UK authorised VMPs are available through the VMD's product information database: www.vmd.gov.uk/ProductInformationDatabase/

The VMD also publishes public assessment reports which provide information on the manufacture of the vaccine and the scientific studies that were assessed to support the safety and effectiveness of the product. Public assessment reports are available for all

vaccines authorised after October 2005 and can also be accessed through the product information database.

Who can supply vaccines for dogs and cats?

All vaccines intended for the immunisation of cats or dogs are categorised as POM-V and may only be prescribed by a veterinary surgeon following a clinical assessment of an animal or group of animals.

Importing vaccines

Where there is no suitable authorised product in the UK and when the health situation so requires, a veterinary surgeon may apply for an import certificate to obtain a vaccine authorised in another EU Member State or exceptionally from outside the EU. Before allowing the importation of the vaccine, the VMD must have sufficient information available on the quality, manufacture and safety of the product to be reassured that no major safety risk will arise.

Special Import Certificates (SICs) allow veterinary surgeons to import and use veterinary medicinal products from other EU Member States and are often available on-line (www.vmd.gov.uk/sic). Special Treatment Certificates (STCs) allow veterinary surgeons to import and use veterinary medicinal products from outside the EU, and human products from outside the UK. Further guidance on the special imports scheme and SIC/STC application forms can be found on the VMD website: www.vmd.gov.uk/General/AppsPage/Forms.htm

What types of vaccine are available in the UK?

There are several main types of vaccines currently available in the UK:

- 1) Modified Live** (attenuated) – contain a live form of the organism that is able to replicate but, by modification, has been made incapable of causing overt disease i.e. it is a weak pathogen.
- 2) Inactivated/Killed** – contain organisms which are dead and cannot reproduce in the animal so they are not capable of causing disease. These vaccines usually contain an 'adjuvant' – an ingredient that is combined with the killed organism to help stimulate an immune response.

There are 2 main forms of killed vaccines:

- a) Inactivated/Killed 'whole organism'** – these contain the entire organism (virus, bacterium)
- b) Inactivated/Killed 'subunit'** – these contain only specific proteins extracted from the organism. These proteins are chosen because they induce a protective immune response.

Multivalent Vaccines – Many dog and cat vaccines are presented as multi-component (multivalent) antigen mixtures. This allows a single injection to stimulate immunity against a number of diseases. Many are blended combinations of live and inactivated components and the safety and efficacy of these multivalent formulations has been established.

Recombinant vaccines – Recently, vaccines have become available where specific proteins (antigens) from the pathogenic organism are inserted onto a harmless carrier virus that does not cause disease. These vaccines have a similar safety to the killed vaccines but may have some of the advantages of live vaccines in terms of their ability to stimulate the immune system.

Importance of dog and cat vaccines in the UK

Vaccination plays an important role in maintaining the health of dogs and cats in the UK and when travelling to Europe under the Pet Travel Scheme (PETS). Vaccines that protect pet animals from severe, life-threatening or debilitating diseases that have a worldwide distribution are generally referred to as **core vaccines**. These diseases have been kept under control in the UK pet populations by the widespread use of vaccination.

The World Small Animal Veterinary Association (WSAVA) recommends that core vaccines should be **administered to all dogs and cats throughout the world**. Continued control of the core diseases in the UK depends on a high proportion of the dog and cat populations maintaining appropriate levels of immunity, to prevent wildlife reservoirs or other sources of infection resulting in widespread recurrence of infection.

Non-core vaccines are required by animals placed at risk of contracting specific infections due to their geographical location, local environment or lifestyle and should be tailored to the individual animal.

WSAVA defined core and non-core vaccines for dogs and cats in the UK

	DOGS	CATS
CORE	Canine adenovirus Canine distemper virus Canine parvovirus	Feline calicivirus Feline herpesvirus Feline panleukopenia virus
NON-CORE	<i>Babesia canis</i> <i>Bordetella bronchiseptica</i> Canine coronavirus Canine herpesvirus Canine leptospires* Canine parainfluenza virus Clostridium tetani Rabies virus**	<i>Chlamydophila felis</i> (<i>C psittaci</i>) Feline leukaemia virus Rabies virus**

* Vaccines against canine leptospires are considered as core vaccines in the UK.

** Vaccines against rabies virus are considered as core vaccines for animals travelling outside the UK.

Vaccines should be administered under the clinical judgement of the veterinary surgeon. The VMD is aware of concern in both the public domain and in the scientific community about possible health risks related to the unnecessary annual re-vaccination of cats and dogs with the core viral vaccines.

In response, the Veterinary Products Committee (VPC), an **independent** scientific advisory committee to the VMD, reviewed feline and canine vaccination in the UK between 1999 and 2002. The VPC concluded that vaccination plays a very valuable role in the prevention and control of the major infectious diseases in cats and dogs in the UK. Although adverse reactions to vaccination, including lack of efficacy, do occasionally occur the VPC concluded that the overall benefit/risk analysis strongly supports their continued use. Nevertheless, veterinary surgeons should be aware of the recommended re-vaccination schedules for the brands they are using and comply with these unless a clinical situation justifies a deviation from these schedules. In considering vaccination schedules for individual pet animals a veterinary surgeon should be aware of the WSAVA guidance on vaccination and should discuss their recommendations with the animal's owner (www.wsava.org/PDF/Misc/VaccinationGuidelines2010.pdf)