



**Best-practice framework
for the use of vaccines
in animals**

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INTRODUCTION

EPRUMA promotes the responsible use of medicines in animals (www.epruma.eu) and shares information on best practices to prevent, control and treat animal diseases, supporting animal health and welfare, contributing to food safety, and safeguarding human wellbeing and public health.

Within EPRUMA best practice guidelines, the role of vaccination has always been highlighted. Through this document, EPRUMA partners wish to raise awareness on the benefits of vaccination, and recommend best practices for vaccine use to ensure optimal animal health.

Infectious disease prevention can be achieved through a combination of measures, such as biosecurity, proper hygiene, feeding, husbandry conditions ensuring animal welfare, surveillance for presence of pathogens through animal and environmental testing, and immunisation through vaccination. Vaccination has been an essential tool over the years for preventing a wide range of infectious diseases. For some of these diseases, such as rabies, vaccination still remains the only solution we have to protect animals and people. By helping to eradicate

and control infectious diseases, vaccination improves animal health and reduces the need for treatment, while contributing to food safety and public health.

Nevertheless, the benefits of vaccination have been questioned recently by anti-vaccine pressure groups. A survey conducted among citizens in 2016 showed that 66% of respondents believe pets should be vaccinated, while only 54% think the same applies to farm animals. Over 40% of them replied they didn't know that animal vaccination prevents the transfer of infectious disease from animals to humans. This shows a lack of awareness about the link between vaccination of animals against certain diseases, such as rabies, listeriosis, salmonellosis, etc. and public health, or of the fact that vaccination of farm animals plays an important role in the production of safe food.

ABOUT VACCINES

A vaccine is a biological preparation that provides specific immunity to a particular infectious disease or diseases. A vaccine typically contains an agent that is made from weakened or killed forms of the microbe, or some of its important components¹, leading to immunisation - also called an immune response - in people or animals.

Vaccines stimulate the body's immune system to recognise the agents it contains as foreign. When an infectious or foreign agent (antigen) enters the body, it triggers a response, for example in the form of antibodies. Vaccination mimics the effect of the infectious agent to cause an immune response without causing the disease itself, so that when people or animals are later exposed to the disease - causing microorganism they are vaccinated against, their system is prepared to efficiently fight the corresponding disease.

Veterinary vaccines are medicinal products, known also as immunological veterinary medicinal products. Before they can be used, they need to be licensed or authorised, following an assessment for safety, efficacy and quality. Veterinary vaccines require a **veterinary prescription** before purchase and use.

Vaccines are categorised as:

- Live (or attenuated) vaccines
- Killed (or inactivated) vaccines, including autogenous and sub-unit vaccines
- Recombinant live virus vaccines, including gene-deleted marker vaccines
- DNA vaccines/RNA replicon

Animal vaccination needs to be performed under **veterinary supervision**, and handling of vaccines must follow the instructions given in the product leaflet. For example, vaccines need to be properly stored, i.e. refrigerated and avoiding exposure to light, to maintain their efficacy.

The **mode of administration** of vaccines can vary, depending on the type of vaccine, the type of immunity required, the adjuvants² contained in the vaccine, the animal species, the number of animals, and the easiness of application. Vaccines can be administered through eye drop instillation, air spray, intranasally, orally (e.g. drinking water or baits) or through injection by needle or needle-free. Quality of administration is also critical to the vaccine efficacy.

Transient minor side effects may appear during the first few days following vaccination, such as discomfort and local swelling at the vaccination site, mild fever, decreased appetite and activity, sneezing or mild coughing. These are not critical to the animal's health, and are usually described in the product leaflet.

As with any administration of foreign proteins, a hypersensitivity reaction may occur. In some rare cases - also described in the leaflet - these temporary side effects may be more severe. Supportive treatment by a veterinarian may be required and side effects should be reported to the competent authorities through the pharmacovigilance system, which monitors such incidents.

As the required immunity may not be achieved after the first application, a booster vaccination may be necessary. The veterinarian can advise on the exact time and intervals of the booster vaccination(s) taking into account the species, the age of the animal, the disease or the type of vaccine; these are usually incorporated in the overall health plan.



1 - <http://www.who.int/topics/vaccines/en/>

2 - An adjuvant is a substance that boosts the body's immune system.

ANIMAL VACCINATION AS PART OF AN OVERALL HEALTH STRATEGY, PREVENTION PLANS AND RESPONSIBLE USE

The prevention and control of animal infectious diseases is essential to ensure animal health and welfare, and to safeguard public health.

Dialogue between veterinarians, farmers and animal owners is a key factor in achieving this goal, with support from the scientific community and regulatory authorities.

Healthy farm animals contribute to the production of safe and wholesome food, and healthy pets have a positive impact on people's health and wellbeing.

Veterinary vaccination plays a key role in protecting animals and public health (One Health), as an integral part of overall health plans against infectious disease. Vaccination is also an important part of rapid-response plans to prevent the spread of emerging infectious diseases. Additionally, vaccination can reduce the need to use antibiotics, contributing to the fight against antibiotic resistance.

Animals which are in good health always have a better response to vaccination. With this in mind, the veterinarian will define the most appropriate vaccination programme

after checking the health status of the animal(s) under his/her care, and considering the species/category or health risk. Immunomodulators³, particularly immunostimulants⁴, are able to non-specifically enhance the innate immune function and to improve the host's resistance to diseases.

The benefits of proper animal vaccination include helping to:

► Prevent and eradicate infectious diseases

Vaccination has been used for over a hundred years with outstanding results in both human and animal health. Vaccines provide excellent immunity against disease, and, for example, enable the differentiation between naturally infected and vaccinated animals when using a marker-vaccine (DIVA). Fatal infectious diseases such as smallpox (in humans) and rinderpest (livestock) have been eradicated thanks to a proper implementation of vaccination schemes. For many others, such as foot-and-mouth disease or rabies, vaccination still remains the only tool to prevent and control disease outbreaks.

Rabies vaccination in companion animals and in wildlife (through vaccine-loaded bait distribution) as part of overall national plans has led to the elimination of the disease in many European countries.

The implementation of proper vaccination programmes in farm animals is in line with sustainable agriculture practices leading to better animal health and welfare and, therefore, to higher production and a sustained income for farmers.

3 - Immunomodulators are substances that modulate the activity of the immune system.

4 - Immunostimulants, also known as immunostimulators, are substances that stimulate the immune system of an organism by inducing activation or increasing activity of any of its components. Non-specific immunostimulants act irrespective of antigenic specificity to augment immune response of other antigen or stimulate components of the immune system without antigenic specificity, such as adjuvants and non-specific immunostimulators.



➤ **Stop the spread of emerging infectious diseases**

(emergency vaccination)

Vaccination has been successfully used in Europe and many other places around the globe to halt the spread of diseases, such as bluetongue and lumpy skin disease.

➤ **Reduce the need to use antibiotics**

Antibiotic resistance is a major challenge worldwide. Vaccination is a valuable strategy to prevent the use of antibiotics in animals. A concrete example of the implementation of this practice with outstanding results was the introduction of oil-based bacterial vaccines in the early 1990s, which led to the elimination of the need to use antibiotics in salmon farming. Immunising animals through vaccination against bacterial diseases is seen as a solution to protect them from bacterial infections and, therefore, to reduce the need to use antibiotics.

Protection from viral diseases also prevents the occurrence of secondary bacterial infections and may reduce the need for antibiotic treatments.

➤ **Ensure public health**

The link between animal and human health is no longer disputed and is described within the “One Health Concept”. Animal vaccination is a valuable tool to protect people’s health within an overall public health strategy, as 70% of infectious diseases agents affecting people worldwide are either zoonotic, i.e. they originate from direct contact with sick animals (mostly wildlife) or their products (including food borne diseases), or they are transmitted from sick animals to humans via insect bites.

The vaccination of companion and farm animals in Europe has led to the prevention of certain infectious diseases, such as rabies in people and a reduction in human cases of listeriosis, Q fever and salmonellosis. Vaccination is particularly important for food-producing animals, as healthy animals deliver healthy food.

PROPER VACCINATION: RECOMMENDATIONS

EPRUMA has extensively worked on best practices to preserve antibiotic efficacy. Within EPRUMA best practice guidelines, the role of vaccination has always been highlighted, and it is often part of national guidance. Guidelines for vaccination of animals are available in many European countries .

With these best-practice recommendations, EPRUMA aims to complement existing guidelines on vaccination, which are available in many European countries ⁵.

EPRUMA recommendations to users

➤ **Ensure a proper vaccination programme for the animal’s needs through an open dialogue with the veterinarian**

1. Vaccination against certain infectious diseases is obligatory. Each country has established a list of mandatory vaccinations per species, for both farm animals and companion animals. The veterinarian will advise on the proper vaccination programme for each animal or group of animals. The veterinarian will also inform the owner about the vaccinations the animal(s) have to receive before they can travel or can be exported to another country. The veterinarian is also responsible for

preparing all the necessary documents for this purpose, e.g. the animal’s (pet) passport.

2. Vaccination can sometimes minimise the effects of an established disease, either by preventing the disease, or by reducing the clinical signs in the animals at risk. The veterinarian may advise vaccination in such cases of an already established infectious disease found in a group of animals.

3. There are some instances where vaccines do not exist, particularly to protect against some bacterial diseases, or for certain animal species. In that case, especially in farm animals, the veterinarian may inform the animal owner about the possibility of producing and using an autogenous vaccine in line with the applicable legislation. Autogenous vaccines are custom-made inactivated vaccines, associated with targeted treatment of a restricted number of animals in a defined location and over a defined period of time. They can be a useful tool

5 - France, UK (RUMA), Vetresponsable (Spain), AMCRA (Belgium)

where no vaccine exists for the concerned disease, strain of microorganism or the animal species, but their use in a different situation (i.e. for another group of animals, location or species) can be illegal.

► Ensure a correct vaccination

Vaccination requires a good veterinary knowledge of when, where and how to apply it. All instructions for use are laid down in the product leaflet - especially on handling the product before, during and after use – and must be followed thoroughly. This will ensure a successful vaccination, and will prevent an accidental exposure to animals not intended to be vaccinated, as well as to the user of the veterinary medicinal product and to the environment.

1. An assessment of the health of the animal or of the herd/ flock by a veterinarian prior to their vaccination is critical to ensure that only healthy animals are vaccinated. This assessment will be based on clinical signs and/or diagnostic testing results. Animals in good health have a better response to the vaccine. The veterinarian will ensure that contraindications are respected as, for example, certain vaccines are not recommended for animals which are too young, pregnant animals, animals in lactation or egg-laying birds.
2. Vaccines must be properly stored until the time of vaccination, as they are often sensitive to direct light and temperature. They need to be stored in strict accordance with leaflet instructions, In most cases, unlit and at a temperature of 2 to 8°C. It is therefore very important to ensure that the fridge (or freezer) where vaccines are kept is continuously monitored to detect any changes in temperature, e.g. by using monitoring thermometers.
3. Precautions to avoid any contamination or inactivation of the veterinary medicinal product must be taken. These include always using material and protocols to ensure sterile injections, and using chlorine-free water in the case of vaccination via drinking water.
4. Any equipment needed should be clean and calibrated to deliver the correct dose.
In the case of vaccination of a group of animals by injection, the veterinarian will make sure that a sufficient amount of sterile needles are available to replace them regularly. Needles should have the appropriate size and should remain clean and sharp.
5. Appropriate handling of the animal(s) is very important to ensure proper administration of the biological veterinary medicinal product and minimise stress during the process. Stress may cause transient immunodepression, and therefore compromise the success of the vaccination.
6. Vaccine containers must be checked before use, making sure they are sealed (sterile) and within the limits of the expiration date.
7. The administration route or injection site for vaccination must be in accordance with the leaflet instructions.
8. The veterinarian has to ensure that all the animals in the group are vaccinated. The dose, dilution rate and all precautions must be carefully checked before vaccination. Vaccinated animals must be marked properly to avoid an accidental duplication of vaccination, or an omission of some animals in the group.
9. All booster vaccinations recommended (as per leaflet specifications) by the veterinarian have to be administered. As immunity against a vaccine's antigen may decline over time, one or more booster doses may be necessary to bring immunity back to protective levels. The veterinarian will inform the animal owner about the time to introduce a booster vaccination depending on the type of vaccine, the strains it contains, the species, age, the country's regulation for some pathogens, etc. She/he will also explain the procedure if a booster dose has been omitted.
10. The disposal of unused/expired vaccines or of empty containers must be done as recommended on the leaflet, in accordance with national legislation.
11. Co-administration (in mix, at the same site or a different sites) with other veterinary medicinal products should only be done when authorised and as per the instructions provided in the leaflet.



When necessary, e.g. for injectable vaccination, the animal should be adequately restrained, and the necessary assistance - i.e. staff or equipment - should be in place or readily available before any vaccine is administered.

12. All vaccinated animals have to be monitored closely, immediately after vaccination and for the next couple of days. If any unusual clinical signs emerge, the veterinarian must be contacted immediately for advice and to report these for pharmacovigilance.

13. For food-producing animals, any applicable withdrawal periods for milk, meat or eggs as mentioned on the product leaflet must be thoroughly respected.

► **Keep detailed records of vaccination, preferably in digital form**

1. Vaccination records for each individual animal (cattle, sheep, pigs, horses) or for each cage/batch (swine, poultry) or tank (aquaculture) should be kept, as recommended by the competent national authority.

2. Vaccination records of companion animals should always be included in the official documents, e.g. in the pet passport.

► **Always monitor animals after vaccination**

1. Monitor animal health immediately after vaccination. If any side-effects are observed, they have to be reported to the authorities as appropriate through the pharmacovigilance system for veterinary medicines.

2. Assess success of vaccination in herds/flocks in which the infectious agent is no longer circulating by using available tools, such as seromonitoring.

CONCLUSION

Vaccination has been an essential tool over the years for preventing, controlling and eradicating infectious diseases, for improving animal health and welfare and reducing the need for treatment, as well as contributing to food safety and public health.

Vaccines are biological veterinary medicinal products that need to be used with great care under veterinary supervision. Not all animal vaccines are identical. The veterinarian has the scientific background to advise the animal owner, and to prescribe the right product for each

species, category of animals, risk or disease condition, based on the directions provided in the products' leaflet.

The veterinarian will assess the health status of the animal(s) or herd/flock before vaccination, by observation of clinical signs and/or use of diagnostic tools, ensuring a proper administration and advise on booster doses to reach a level of immunity that will successfully protect the animal(s).

EPRUMA partners



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The voice of the animal medicines industry



COPA/COGECA

European Farmers and Agri-Cooperatives



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European Group for Generic Veterinary Products



DIAGNOSTICS FOR ANIMALS

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FEFAC

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Federation of Veterinarians of Europe

Associate partners



AMCRA

Centre for Expertise on Antibiotic Consumption and Resistance in Animals (Belgium)



RUMA

Responsible Use of Medicines in Agriculture Alliance (United Kingdom)



SDa

The Netherlands Veterinary Medicines Authority Institute



VETRESPONSABLE

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