CHAPTER 4.X.

VACCINATION

Article 4.X.1.

Introduction and objectives

In general, Vaccination is intended to prevent and control the occurrence of a disease and reduce the transmission of the pathogenic agent. For the purpose of disease control, ideally, vaccines should induce immunity that, ideally, prevents infection. However, some vaccines may only prevent clinical signs, or reduce multiplication and shedding of the pathogenic agent.

Vaccination may contribute to improvement of animal and human health, animal welfare, agricultural sustainability and to reduction of the use of antimicrobial agents in animals.

The objective of this chapter is to provide guidance to Veterinary Services Authorities for the successful use of vaccination in support of disease prevention and control programmes. The recommendations in this chapter may be refined by the specific approaches described in the listed disease-specific chapters of the Terrestrial Code. Furthermore, the recommendations in this chapter may also be used for any diseases for which a vaccine exists.

The vaccination strategy applied depends on biological, technical and policy considerations, available resources and the feasibility of implementation. The recommendations in this chapter are intended for all diseases for which a vaccine exists.

In addition to other disease control measures, vaccination may be a component of a disease control programme.

The prerequisites to enable a Member Country to successfully implement vaccination include compliance with:

1) the recommendations on surveillance in Chapter 1.4.;
2) the relevant provisions in Chapters 3.1. and 3.4.;
3) the recommendations on vaccination in the listed disease-specific chapters of the Terrestrial Code;
4) in vaccine-producing countries, the relevant general and specific recommendations for principles of veterinary vaccine production and quality control in Chapter 1.1.8. of the Terrestrial Manual.

The objective of this chapter is to provide guidance to Member Countries for successful implementation of vaccination in support of disease control programmes. The recommendations in this chapter may be refined by the specific approaches described in the disease-specific chapters of the Terrestrial Code.

Standards for vaccines are described in the Terrestrial Manual.

Article 4.X.2.

Definitions

For the purposes of this chapter:

Vaccination programme: means a plan to apply vaccination to an epidemiologically appropriate proportion of the susceptible animal population for the purpose of disease prevention or control.

Emergency vaccination: means a vaccination programme applied in immediate response to an outbreak or increased risk of introduction or emergence of a disease.

Systematic vaccination: means an ongoing routine vaccination programme.

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Vaccination coverage: means the proportion of the target population to which vaccine was administered during a specified timeframe.

Population immunity: means the proportion of the target population effectively immunised at a specific time.

Article 4.X.3.

Vaccination programmes

The objectives and strategy of a vaccination programme should be defined by the Veterinary Authority before the implementation of the vaccination, taking into account the epidemiology of the disease, its impact and zoonotic potential, the species affected and their distribution.

If these factors indicate that the programme should be expanded beyond national boundaries, the Veterinary Authority should liaise with the Veterinary Authorities of neighbouring countries. When appropriate, a regional approach to harmonise vaccination programmes is recommended.

Veterinary Authorities should liaise, as relevant, with public health authorities when developing and implementing vaccination programmes against zoonoses.

Vaccination programmes may include systematic vaccination and emergency vaccination.

1) Systematic vaccination in infected countries aims to reduce the incidence, prevalence or impact of a disease with the objective of prevention, control and possible eradication. In disease-free countries or zones, the objective of systematic vaccination is to prevent the introduction of a pathogenic agent from an infected neighbouring country or zone, or to limit the impact in the case of an the introduction of that disease pathogenic agent disease.

2) Emergency vaccination provides an adjunct to the application of other essential biosecurity and disease control measures and may be applied to control outbreaks. Emergency vaccination may be used in response to:

   a) an outbreak in a free country or zone;

   b) an outbreak in a country or zone that applies systematic vaccination, but when vaccines are revaccination is applied to boost existing immunity;

   c) an outbreak in a country or zone that applies systematic vaccination, but when the vaccine employed does not provide protection against the strain of the pathogenic agent involved in the outbreak;

   d) a change in the risk of introduction of a pathogenic agent or emergence of a disease in a free country or zone.

Vaccination programmes should consider other be integrated with other ongoing animal health related activities involving the target population. This can improve the efficiency of the programme and reduce the cost by sharing optimisation of resources.

Article 4.X.4.

Launching a vaccination programme

When deciding whether to initiate a vaccination programme the Veterinary Authority should consider, among others, the following:

1) the epidemiology of the disease infection;

1bis) the probability that the disease cannot be rapidly contained by means other than vaccination;

2) the increased incidence and prevalence of an existing disease, if present.

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3) the increased likelihood of introduction of a pathogenic agent or emergence of a disease;

3bis) the zoonotic potential of the disease;

4) the density of the exposed susceptible animals population;

5) the an insufficient level of population immunity;

6) the risk of exposure of specific subpopulations of susceptible animals;

7) the suitability of a vaccination programme as an alternative to or an adjunct to other disease control measures such as a stamping-out policy;

7bis) the existence of an animal identification system to differentiate vaccinated from unvaccinated subpopulations;

8) the availability of a safe and effective vaccine resources;

8bis) the availability of human, financial, and material resources;

9) the cost-benefit analysis considerations of the vaccination programme, including the its impact on trade and public health.

Article 4.X.5.

Vaccination strategies

Different vaccination strategies may be applied alone or in combination, taking into account the epidemiological and geographical characteristics of occurrence of the disease. The following strategies may be applied:

1) Blanket vaccination: vaccination of all susceptible animals in an area or an entire country or zone.

2) Ring vaccination: vaccination primarily of all susceptible animals in a delineated area surrounding the location establishments where an outbreak has occurred. To prevent outward spread of disease, vaccination should be applied from the outer boundary of the area inwards.

3) Barrier vaccination: vaccination in an area along the border of an infected country or zone to prevent the spread of disease infection into or from a neighbouring country or zone.

4) Targeted vaccination: vaccination of a subpopulation of susceptible animals defined by a greater likelihood of exposure or severity of the consequences.

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Choice of vaccine

Depending on the disease, several vaccines may be available. To achieve the objectives of the vaccination programme, the choice of a vaccine is a critical element that depends on different several factors including:

1. Availability and cost

   a) availability of the vaccine including marketing authorisation relevant regulatory approvals and in adequate quantities at the time required;

   b) capacity of the providers to supply the vaccine for the duration of the vaccination campaign and to respond to increased needs;

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c) flexibility in the number of doses per vial to match the structure of the target population;

d) a comparison of the costs of vaccines that meet the technical specifications established in the vaccination programme.

2. Vaccine characteristics

a) Physical characteristics

– route and ease of administration;

– volume of dose;

– type of adjuvant and other components.

b) Biological characteristics

– immunity against circulating strains;

– live, inactivated or biotechnology-derived vaccines;

– number of strains and pathogens included in the vaccine;

– potency of the vaccine;

– onset of immunity;

– shelf-life and expiry date;

– thermostability or thermotolerance;

– duration of the effective immunity;

– number of doses required to achieve effective immunity;

– ability to be monitored for vaccine-induced immunity;

– effect on the ability for vaccinated animals to be differentiated from infected from-vaccinated animals, at the individual or group level;

– suitability of vaccine formulation for species and age of animals in the target population;

– safety for the users, the consumers and the environment.

c) Side effects

– adverse reactions;

– unintentional transmission of live vaccine strains;

– reversion of attenuated strains to virulence.

When a single vaccine only is available, the same factors listed above should be considered in deciding whether or not to launch a vaccination programme.

Other critical elements of a vaccination programme

In addition to the choice of vaccine, the vaccination programme should include the following other critical elements, and the vaccination programme should be communicated to all stakeholders.

1. **Legal basis**

   There should be a legal basis for the vaccination programme, including for possible compulsory compliance and for possible compensation of animal owners for possible adverse reactions in their animals.

2. **Target population**

   The vaccination programme should define the animal population to be vaccinated and the geographical area where the target population is located.

   The target population may include the entire susceptible population or an epidemiologically relevant *subpopulation* depending on the likelihood of exposure, the consequences of the disease, the role of the different *subpopulations* in the epidemiology of the *disease infection* and the resources available. The target population may include *wildlife*.

   Factors to consider in determining the target population may include species, age, health status, maternal immunity, sex, production types, geographical distribution as well as the number of animals and herds. These factors should be reviewed and updated regularly.

32. **Vaccination coverage**

   In practical terms, it may be difficult to immunise the entire target population. The vaccination programme should define the minimum vaccination coverage necessary to achieve the minimum a *sufficient population immunity required to achieve to fulfil the objectives of the programme*. The minimum population immunity required will vary according to the epidemiology of the disease, density of susceptible animals, efficacy of the vaccine and geographical factors.

   Measuring population immunity during the monitoring of the vaccination programme may assist in identifying subsets of the target population that have not been adequately immunised.

43. **Stakeholder involvement**

   **Veterinary Services.** The vaccination programme should demonstrate good governance of the vaccination programme by the Veterinary Services and by clearly identifying the involvement of different stakeholders including other government agencies, governmental organisations, farmers, animal owners, farmer organisations, private sector veterinarians, non-governmental organisations, veterinary paraprofessionals, local government authorities and vaccine suppliers. Stakeholder acceptance of vaccination is crucial for the success of the vaccination programme. Different stakeholders should preferably be involved in the planning and implementation of vaccination, the awareness campaigns, the monitoring of vaccination, the production and delivery of vaccines and the financing of the vaccination programme.

54. **Resources**

   **Vaccination** programmes may often span several years. To achieve the desired objective, human, financial and material resources should be available throughout the estimated duration of the vaccination programme.

65. **Actions and timeline**

   The vaccination programme should describe the responsibilities, expected deliverables and timeline for each activity.
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76. Timing of vaccination campaigns

The vaccination programme should describe the periodicity of the any vaccination campaigns. Depending on the disease and type of vaccine, animals may be vaccinated once or several times during their lifetime.

The objective of the a vaccination campaign is should be to achieve the necessary vaccination coverage necessary to attain or maintain and the minimum population immunity in the target population within a defined timeframe. The vaccination campaign should be implemented in such a manner as to ensure that the majority of the target population is immunised within as short a time as possible. The vaccination programme should include a detailed description of the implementation of the vaccination campaigns, including frequency and starting and ending dates of each campaign.

The frequency, timing and duration of the vaccination campaigns should be determined taking into consideration the following factors:

a) vaccine characteristics and manufacturer’s directions for use;

b) vaccine storage facilities and delivery systems;

b) accessibility of the target population;

c) animal handling facilities;

d) animal body condition and physiological state;

e) geographical factors;

f) climate conditions;

g) vector activity;

h) awareness, acceptance and engagement of stakeholders;

i) types of production systems and animal movement patterns;

j) timing of agricultural, social or cultural activities;

k) availability of resources.

77. Auditing of the vaccination campaigns

The vaccination programme should include periodic auditing of all the participants in any vaccination campaigns. Auditing ensures that all components of the system function and provide verifiable documentation of procedures. Auditing may detect deviations of procedures from those documented in the programme.

Indicators related to auditing of the a vaccination campaign may include:

a) proportion of the targeted population of animals and herds vaccinated within the defined timeframe;

b) number of vaccine doses used compared with number of animals vaccinated;

bbis) number of animals vaccinated compared to census figures for the relevant animal population;

c) number of reports of breaches of the cold chain;

d) performance of vaccinator teams in respect of in complying with the standard operating procedures;

e) timing and length duration of the campaign;
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f) overall cost and cost per individual animal vaccinated.

To enable auditing of the vaccination programme, a recording system should be in place to measure the indicators above.

Article 4.X.8.

Logistics of vaccination

Vaccination campaigns should be planned in detail and well in advance considering the following elements:

1. Procurement of vaccine

The vaccine selected for use in a vaccination programme should have been subjected to the registration relevant regulatory approval procedure of the country, which is congruent with the recommendation of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH).

For systematic vaccination campaigns, the process of procurement of the selected vaccine should be initiated in advance to ensure timely delivery to meet the timeframe of the vaccination campaign.

National disease contingency plans should provide for emergency vaccination. These provisions may allow for simplified procedures to procure vaccine and grant authorisation for temporary use. If vaccination is to be used systematically, definitive relevant regulatory approval registration should be obtained.

Vaccine banks, established in accordance with Chapter 1.1.10 of the Terrestrial Manual, facilitate the timely procurement of vaccines.

2. Procurement of equipment and consumables

In addition to the vaccine itself, the planning of the vaccination campaigns should include the procurement of all necessary equipment and consumables.

2. Implementation of the vaccination programme

In addition to the vaccine itself, the planning of the vaccination campaigns should include the procurement of all necessary equipment and consumables as well as standard operating procedures should be established to:

a) implement the communication plan;

b) establish, maintain and monitor the fixed and mobile components of the cold chain;

c) store, transport and administer the vaccine;

d) clean and disinfect equipment and vehicles, including heat sterilisation of reusable equipment;

e) dispose of waste;

f) determine the disposition of partially used or unused containers of vaccine, such as ampoules, vials, and bottles, etc., of vaccine;

g) implement biosecurity to ensure vaccination teams do not transmit the pathogenic agent between establishments;

f) identify vaccinated animals;

g) ensure the safety and welfare of animals and vaccination teams;
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 gotta ensure the safety of vaccination teams;
 h) record activities of vaccination teams;
 i) document vaccinations.

The availability of appropriate animal handling facilities at the vaccination site is essential to ensure effective vaccination as well as safety and welfare of animals and vaccination teams.

3. Human resources

Vaccination should be conducted by appropriately trained and authorised personnel under the supervision of the Veterinary Services Authority. The vaccination programme should provide for periodic training sessions including updated written standard operating procedures for field use.

The number of vaccination teams should be sufficient to implement the vaccination campaign within the defined timeframe. The vaccination teams should be adequately equipped and have means of transport to reach the places where vaccination is carried out.

4. Public awareness and communication

The Veterinary Services Authority should develop a communication strategy in accordance with Chapter 3.3, which should be directed at all stakeholders and the public to ensure awareness and acceptability of the vaccination programme, its objectives and potential benefits.

The communication plan may include details on the timing and location of the vaccination, target population and other technical aspects that may be relevant for the public to know.

5. Animal identification

Animal identification allows for the differentiation of vaccinated from non-vaccinated domestic animals and is required for the monitoring and certification of vaccination.

Identification can range from temporary to permanent identifiers and can be individual or group-based. Animal identification should be carried out implemented in accordance with Chapters 4.1 and 4.2.

6. Record keeping and vaccination certificates

Vaccination programmes under the Veterinary Services Authority’s responsibility should provide for maintenance of detailed records of the vaccinated population.

Whenever needed, the Veterinary Services should consider issuing official certificates of the vaccination status of animals or groups of animals.

7. Additional animal health related activities

In addition to vaccination against a specific pathogenic agent, vaccination programmes may include other animal health-related activities such as vaccination against other pathogenic agents, treatments, biosecurity, surveillance, animal identification and communication.

Including additional animal health-related activities may enhance the acceptability of the vaccination programme. These activities should not negatively affect the primary objective of the vaccination programme.

Simultaneous vaccination against multiple pathogenic agents may be conducted, provided that compatibility has been demonstrated and the efficacy of the immune response against each of the pathogenic agents is not compromised.
Evaluation and monitoring of a vaccination programme

The vaccination programme should provide for outcome-based evaluation and monitoring to assess the achievements of the vaccination programme. Evaluation and monitoring should be carried out periodically during the campaign to enable the timely application of corrective measures and to enhance the sustainability of the vaccination programme.

Based on the objectives and targets of the vaccination programme, the following outcomes should be assessed:

1) vaccination coverage stratified by species, age, geographical location and type of production system;
2) population immunity measured by testing, stratified by species, geographical location and type of production system;
3) frequency and severity of adverse reactions;
4) reduction of incidence, or prevalence or impact of the disease.

If the objectives and targets of the vaccination programme are not achieved, the reasons for this should be identified and addressed.

Exit strategy of a vaccination programme

The vaccination programme may provide for an exit strategy to cease vaccination. The cessation of vaccination may apply to the entire target population or to a subset of it, as defined by the risk of exposure and as determined by the Veterinary Authority.

Criteria to cease vaccination may include:

1) eradication of the disease in a country or zone has been achieved;
2) risk analysis demonstrates sufficient reduction of likelihood of introduction of the pathogenic agent or emergence of the disease;
3) reduction of the incidence, or prevalence or impact of the disease to a level where alternative measures such as a stamping-out policy may be sufficient more appropriate to achieve disease control;
4) inability of the programme to meet the desired objectives;
5) adverse public reaction to the vaccination programme;
6) a revised cost-benefit analysis leads to decision to cease the vaccination programme.

When the achievement of disease free status requires the cessation of vaccination, the Veterinary Authority should prohibit vaccination and take appropriate measures to control remaining vaccine stocks as well as vaccine importation.

The cessation of vaccination may require the revision of the contingency plan and enhanced biosecurity, sanitary measures and surveillance for early detection of disease.
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Article 4.X.11.

Impact on disease status and management of vaccinated animals

_Vaccination_ has proved its capacity to help prevent, control and eradicate _several_ diseases in addition to or as alternative to _stamping-out policy_. However, depending on the disease and type of vaccine used, _vaccination_ may mask underlying _infections_, affect _disease surveillance_ and have implications for the movement of vaccinated animals and their products.

When appropriate, _vaccination_ programmes should include provisions for the management of vaccinated animals such as ‘_vaccination to live_’ or ‘_suppressive vaccination_’ policies. _Listed Disease-specific_ chapters of the _Terrestrial Code_ provide additional recommendations on the management and _trade_ of vaccinated animals and their products.

_Disease-free_ countries or zones applying systematic or emergency _vaccination_ in response to an _increase_ in the _risk_ of occurrence _introduction_ of a disease should inform trading partners and the OIE of their _vaccination_ programme, as appropriate. Unless otherwise specified in the relevant _listed disease-specific_ chapter, in the absence of _cases_ and unless otherwise specified in the relevant _listed disease-specific_ chapters, _vaccination_ of animals does not affect the _disease status_ of the country or _zone_, and should not disrupt _trade_.

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