

CHAPTER 1.1.10.

VACCINE BANKS

SUMMARY

Vaccine banks provide antigen or vaccine reserves, either of ready-to-use vaccines or of antigenic components that can be quickly formulated into the final product for emergency use or other vaccination campaigns. They may be established for national or international use. For some international banks in particular, it is important to define the drawing rights of the members of the controlling consortium, and to establish clear governance mechanisms. For banks managed by intergovernmental organisations such as WOAAH, appropriate financing should be in place, together with eligibility criteria for access to the bank. Vaccine banks may be deployed by Veterinary Authorities for different purposes ranging from systematic mass vaccinations, to emergency vaccinations, or to strategic interventions.

The major advantage of storing antigen in banks over storing formulated vaccines is the ability to store bulk vaccine antigen as concentrated stocks with prolonged retention of potency in low temperature storage. Appropriate serotypes and strains, alone or in combination, can also be selected from the bank according to the needs at the time of deployment. The disadvantage of antigen banks is the delay between the decision to deploy and the availability of the final formulated vaccine. This delay can, to some extent, be reduced by pre-testing trial batches of vaccine as part of acceptance into the bank, provided that agreement has been reached with the Competent Authority to provide early release certification based on reduced testing in the event of need.

Ready-to-use formulated vaccines can be deployed rapidly and are available for immediate use for the full duration of the shelf life of the vaccine. When not used, a disadvantage is the defined shelf life as this is usually much shorter than for banked antigens stored at low temperature. Also, for pathogenic agents that have several serotypes and/or show extensive strain variation in their antigenic characteristics, the fixed formulation may not sufficiently protect against infection with the strain involved in a given outbreak.

Whether storing antigen or ready-to-use formulated vaccines, plans should be in place to replenish stocks before the end of the shelf life or, where possible, to rotate and replace stock in a timely manner. Vaccines and antigens beyond their approved shelf life are not acceptable for use and must be discarded and destroyed.

Planning for the components of a vaccine bank, and for the quantity of material to be stored, should involve all relevant stakeholders including the Competent Authorities, vaccine bank administrators, vaccine manufacturers and reference laboratories. When combined with recommendations from reference laboratories on matching of field and vaccine strains, information technology (IT) tools involving modelling and epidemiological risk assessment can help in deciding the amounts and strains to include in a bank. Relevant information to inform the planning should include the epidemiology of the disease in question, its geographical occurrence, the nature of the pathogen, patterns of animal production, movement and trade, pre-existing vaccine coverage of the population and the logistics of deployment of the banked vaccine.

The regulatory principles of vaccine production apply equally to vaccine banks and vaccines produced should comply with the requirements of Chapter 1.1.8 Principles of veterinary vaccine production of this Terrestrial Manual and the disease-specific WOAAH standards in Part 3 of this Terrestrial Manual.

A. DEFINITION OF A VACCINE BANK

Vaccine banks are defined as strategic antigen or vaccine reserves. Banks may consist of physical stocks of antigen or vaccine stored in a made-for-purpose facility or may be based on contractual arrangements with manufacturers to supply agreed amounts of one or more defined vaccines within a specific period of time. Hybrid approaches are also possible. Banks may hold the antigen component, or a ready-to-use formulated vaccine, or both. The vaccines may be deployed for different purposes ranging from systematic mass vaccination to emergency vaccinations, or to strategic interventions.

B. TYPES OF BANKS

Vaccine banks can be classified by their geographical coverage as well as by the nature of product stored.

A country may hold its own national bank, or it may be part of a larger group of countries that share a bank, which either have predefined drawing rights, or an *ad hoc* mechanism to determine these drawing rights. Such international consortia are based on shared risk and may share a common geographical region, or have similar disease status and approach to preventing and controlling a given disease. The bank may be held on the territory of one or several of the group members or be retained by the manufacturer(s). Intergovernmental organisations have also recognised the need to set up banks to support and prioritise immediate access to high quality vaccines, in particular by low- to middle-income countries, and thereby avoid the delay associated with conventional procurement procedures. An adequate system of governance should be established for all vaccine banks.

Certain vaccine antigens can be stored as concentrated stocks and retain potency for several years at temperatures below -70°C , depending on the stability of the antigen. Such antigens have to be formulated into vaccines before deployment. Using this approach, the vaccine composition, including choice of strains and potency, can be adjusted according to need, provided that such flexibility has been built into the approval process of the vaccine concerned (usually termed multi-strain vaccine approval). Formulation of antigens for use may be done either by the manufacturer of the antigen or in a dedicated facility maintained by the bank members. In the latter case, the facility needs an appropriate license to formulate the final product in compliance with the principles of Good Manufacturing Practice (GMP) or other manufacturing standards that apply in the country concerned. In these situations, the antigen bank itself assumes the responsibilities of the holder of the product licence for the vaccine released (also termed marketing authorisation or product registration). Vaccine manufacture and release need to be approved by the national regulatory authority where the vaccine is produced. If used in a different country, import and use of the vaccine need to be approved by the country in which it is deployed. Depending on the country concerned, licensing authorities may require that vaccines released from vaccine banks meet the same standards as the commercial vaccines used in food-producing animals or may apply less demanding standards, in particular where vaccinated animals are not intended to enter the food chain (i.e. vaccination and subsequent stamping out). Approval from the national Competent Authority will also cover aspects such as product labelling and literature, such as the product leaflet, in line with the approved conditions for use as detailed in a Summary of Product Characteristics (SPC), or equivalent documents.

In addition to ensuring appropriate approvals for manufacture, formulation and storage, the arrangements for vaccine banks need to clearly define all the essential requirements including: time between receiving an order and delivery, import permits, customs clearance, transportation, and maintenance of the cold chain. In the case of an antigen bank, specific arrangements are recommended to ensure that the contract for the supply of the antigen(s) includes a requirement for the associated supply of control samples (see Sections D. *Quantities of vaccine required in a bank* and F. *Acquisition of antigens or vaccines for a bank*). Contractual arrangements with manufacturers should include storage, formulation, availability of reagents and suitably sized vials, and the supply of formulated vaccines.

The main advantages of vaccine banks holding antigens are the speed that antigens can be turned into the final licensed vaccine when compared with vaccine production beginning from the working seed, the long shelf life of the antigen, and the option for a flexible combination of antigens to address different vaccination strategies. However, there is always a necessary time delay between giving the order for formulation and the availability of the ready-to-use formulated vaccine, which may not be suitable for rapid vaccination in emergency situations. Where appropriate approvals have been received from the Competent Authority responsible for batch release, frequently referred to as early release certification, this delay can be reduced. Early release is possible in an emergency situation (for example an outbreak of foot and mouth disease [FMD] in a country previously free of that disease as

foreseen in Chapter 3.1.8. *Foot and mouth disease [infection with foot and mouth disease virus]*), in a quality controlled manufacturing system in accordance with WOAH standards (WOAH *Terrestrial Manual* Chapter 1.1.8 *Principles of veterinary vaccine production*). Reduced testing might be acceptable at the time of release provided that full finished product testing has previously been performed on a batch of vaccine that is representative of the product to be released, particularly in terms of the method of production and the type and amount of antigen.

Ready-to-use formulated vaccines can be deployed rapidly and have a pre-determined formulation with a finite shelf life that is indicated in the product registration and has been validated by appropriate testing. The approved shelf life will depend on the characteristics of the vaccines when stored in appropriate temperature-controlled facilities as described in the product literature.

The main advantage of ready-to-use formulated vaccines is their immediate availability for use, though this should be balanced with what remains of the ready-to-use formulated vaccines' approved shelf-life when accessed, as it could lead to a very restrictive period of application compared with vaccines formulated on request from banked antigen stocks. Another inconvenience of ready-to-use formulated vaccines for pathogenic agents that have several serotypes and/or exhibit extensive strain variation in their antigenic characteristics is that the fixed formulation may not sufficiently protect against the strain involved in a given outbreak.

For all banks, whether storing antigen or ready-to-use formulated vaccines, there is the need to renew the stocks at the end of the approved shelf life of the antigen or formulated vaccine, respectively. Antigens or formulated vaccines that are beyond their approved shelf life should not be used and must be discarded and destroyed in appropriate specialised facilities (Lombard & Füssel, 2007) unless suitable studies have been carried out and regulatory approval obtained for extending the shelf life. Renewal orders and managing the period between the expiry date of the current stock and the arrival of new stock should be considered in a timely manner. Alternatively, stocks of antigen or ready-to-use formulated vaccines could be rotated and replenished to ensure there is a continuous supply of product within shelf life. Rotation of stock is relatively easily achieved by manufacturers where a market exists for the vaccine concerned. Rotation requires more forethought in the case of banks intended for emergency use, but some banks make antigen or vaccine available to non-member countries in cases of emergency or to low- to middle-income countries in a timely manner to assure its use before the scheduled expiry date.

Authorities responsible for disease control may set up contractual arrangements for long-term supply with one or more manufacturers rather than setting up physical vaccine banks. This approach avoids the substantial capital costs of setting up and maintaining the complex facilities that are needed for storage and production of vaccine. Furthermore, the responsibility for gaining and maintaining regulatory approvals rests with the manufacturer rather than the vaccine bank holder. The costs of maintaining facilities, and of carrying out the trials necessary to demonstrate quality, safety and efficacy in line with at least the minimum standards defined in the WOAH *Terrestrial Manual* have increased substantially as requirements have developed over the years. Commercial manufacturers have the necessary facilities and operate to these standards routinely whilst it can be challenging for non-commercial vaccine manufacturers to meet the required standards. This is particularly the case when countries require full regulatory approval before permitting use of the vaccine in animals of food-producing species, even under exceptional circumstances. In such long-term arrangements, a contract is concluded whereby manufacturers agree to supply defined amounts of one or more vaccines that meet agreed technical specifications within a specified time period of receiving an order. In this way the risks and benefits are shared between the contractor and the manufacturer. Contractors benefit by assuring the availability of an appropriate vaccine in the event of need and manufacturers benefit from a predictable source of funding to maintain their facilities, licenses and stocks even when vaccines are not used to control an outbreak.

C. SELECTION OF VACCINES FOR A BANK

Depending on the disease targeted and the likely contingency requirements, a range of vaccine strains may be required. Competent Authorities in consultation with the vaccine bank administrators and relevant reference laboratories must decide which vaccine strains should be held and whether they should be stored as a separate antigen component for subsequent formulation, or as a ready-to-use formulated vaccine. The value of any vaccine bank is dependent upon the appropriateness of what it holds for field application, particularly in respect of pathogenic agents that have several serotypes and/or exhibit extensive strain variation in their antigenic characteristics.

The potential for an outbreak not adequately covered by a banked vaccine must be alleviated by continual monitoring of the global disease situation, taking into account animal health information systems such as WOAH's WAHIS¹ and disease-specific updates in the periodic reports by international reference laboratory networks, and supported by laboratory genetic and antigenic characterisation facilitated by reference and other suitable laboratories. Additional vaccine strains may need to be included in the banks' portfolio or, where no suitable vaccine strain is available, developed as quickly as possible for subsequent inclusion in the bank. Close cooperation is therefore required between reference laboratories, manufacturers, international animal health organisations and bank managers to ensure that newly emerging strains are rapidly identified and made available to manufacturers for evaluation as potential new vaccine seed strains.

The world is an interdependent community that encompasses rapid and extensive movement of people, animals and animal products, and the increasing awareness of deliberate release of a pathogen through bioterrorism, heightens the risk of disease incursion and makes prediction of a specific threat difficult. Increased cooperation and collaboration between different international, regional and national reference laboratories, vaccine banks, and national, regional, international authorities or organisations should be encouraged as well as mechanisms for consultation with vaccine manufacturers. Structured risk assessment, preferably conducted at a country or regional level, should be used to determine the antigen or vaccine to be stored with a suitable priority level. In the case of FMD, a specific tool (Pragmatist) has been made available for this purpose. Effective risk management of FMD is only possible on the basis of knowledge of what strains are actively circulating and the extent of antigenic match between these strains and the virus antigens stored in the vaccine bank. This, in turn, relies on the continual submission of outbreak strains to reference laboratories for vaccine matching studies. Authorities are encouraged to share as much information as possible between themselves for the purpose of effective risk assessment and risk management whilst recognising that there may be a need to restrict the amount of information relating to the storage of antigens or vaccines that is made publicly available on the basis of both national security and, in some cases, commercial confidentiality.

D. QUANTITIES OF VACCINE REQUIRED IN A BANK

The decision as to how many doses of vaccine are required is complex, embracing questions of epidemiology, vaccinology, logistics and resources (human, technical and financial).

Factors bearing on the decision include:

- i) the nature of the disease in question (serotypes, strains, pathogenesis, routes and rapidity of spread, presence and competence of vectors, etc.);
- ii) the characteristics of the available vaccines (serotypes, strains, monovalent or polyvalent types of formulation), compatibility with DIVA strategies (DIVA: differentiation of infected from vaccinated animals), potency of the vaccines and the antigenic match between field and vaccine strains;
- iii) the number, species, location and density of the animals to be protected;
- iv) the types of emergency vaccination likely to be applied, and the number of doses in the vaccination regime;
- v) logistical requirements (the availability of trained personnel, storage facilities, maintenance of the cold chain, transport, vaccination equipment, consumables, etc.);
- vi) the current and predicted global, regional and national epidemiology of the disease;
- vii) patterns of animal production, movement and trade;
- viii) analysis of the risk of the introduction and spread of the disease in question (which may include epidemiological modelling);
- ix) application of contingency planning (including risk–benefit and cost–benefit analysis and the construction of decision trees, awareness and acceptance by stakeholders).

Decisions on the quantity of the product inevitably involve a compromise between the potential economic impact of the disease, fixed cost of the maintenance of the vaccine bank, cost of purchase, storage and replacement, cold

1 <https://wahis.woah.org/#/home>

chain capacities of the beneficiaries and the likely number of doses required. The post-vaccination disease control and surveillance strategy further impacts the decision on the number of vaccine doses required.

The minimum vaccine requirement should be based on a country's planned vaccination strategy as detailed in its contingency plan. In the case of FMD, a modelling tool (VADEMOS) has been developed to estimate current and future vaccine dose demand at national, regional and global levels. The procurement of additional supplies of vaccine, either from other banks or from commercial sources, is likely to take considerable time. It would be beneficial in terms of cost, time and volume, for different national or regional vaccine banks to cooperate, or to consider setting up regional or international vaccine banks.

When relevant, vaccine banks may adopt a balanced approach combining a proportion of stored antigens (core strains and optional strains), with a proportion of ready-to-use formulated vaccines (for rapid deliveries).

E. REGULATORY CONSIDERATIONS

The manufacture of a vaccine, including vaccines intended to be exported for inclusion in a vaccine bank in a third country, requires approval by the national Competent Authority of the country in which the vaccine is produced, usually in the form of a manufacturing licence. Likewise, the deployment and use of a vaccine requires approval by the national Competent Authority of the country in which it is used. National Competent Authorities in WOAHP Members should ensure that vaccines comply with at least the minimum standards defined in the relevant general chapters (e.g. chapter 1.1.8 and the relevant chapters in Section 2.3 *Veterinary vaccines*) and disease-specific chapters of this WOAHP *Terrestrial Manual* (such as 3.1.8 *Foot and mouth disease*). National Competent Authorities may apply WOAHP standards or may apply more stringent requirements as specified in national legislation. In addition to licensing products in compliance with full regulatory requirements in inter-epidemic periods, most countries also have systems in place to approve products more rapidly and with reduced data requirements in emergency situations or where there is no prospect of generating a full data package. In the event of disease emergencies, countries may also approve the use of unauthorised products or products authorised in another country, relying on existing data for the product concerned and placing specific controls on its import and use. In view of the different approaches adopted by different countries and for different diseases, those intending to use antigen and/or ready-to-use vaccines procured from a vaccine bank need to ensure that they are aware of the regulatory requirements for the production, regulatory approval, and use of vaccines produced from the bank and how these requirements will be met.

For vaccine banks the following additional considerations apply, with more detail developed throughout this chapter, as relevant:

- i) storage conditions:
 - a) facilities,
 - b) containment of stored antigen or vaccine,
 - c) labelling of stored antigen or vaccine;
- ii) monitoring of stored concentrated antigen;
- iii) transport to storage facilities;
- iv) transport for deployment:
 - a) transport of antigen for reformulation,
 - b) transport of vaccines for use.

In setting up and gaining regulatory approval for manufacture, the vaccine bank will need to demonstrate that these aspects are conducted in line with the relevant chapter in the WOAHP *Terrestrial Manual* and with national requirements.

Countries requesting vaccines from a vaccine bank need to ensure that their contingency plans include arrangements for import permits, customs clearance and maintenance of the cold chain as required.

F. ACQUISITION OF ANTIGENS OR VACCINES FOR A BANK

According to the type of bank and the disease concerned, the acquisition of the appropriate vaccine(s) or antigen(s) will depend on whether they are available from the commercial sector, government institutions or other production facilities. Irrespective of the source, antigens and vaccines need to be produced in facilities approved in line with regulatory requirements for manufacture and need to meet the quality requirement specified in the relevant regulatory approval.

Vaccine banks may use direct procurement or may use international calls for tender to acquire antigens or vaccines. They may wish to seek advice from appropriate official regulatory authorities to ensure that the standards specified in the technical specifications for the procurement are fully aligned with the terms of regulatory approval. Requests for tenders can then ensure not only a competitive price, but also a veterinary medicinal product manufactured to an acceptable level of quality, the standards being at least those set out in this WOAH *Terrestrial Manual*. For diseases where there is official WOAH recognition of that disease status, vaccines used in the Members concerned must comply with the standards in the WOAH *Terrestrial Manual*. It is recommended that the process of selecting suppliers should not focus solely on lowest cost but should also take into consideration technical and quality criteria as well as delivery capacities. This could be achieved by a stepwise process, first assessing the technical proposal responding to the technical specifications, followed by an evaluation of the commercial bid of the eligible candidate suppliers. The technical specification should establish that suppliers can produce the desired vaccines or antigens in the necessary amounts within a specified time period that includes the time required for mandatory tests of compliance such as sterility, safety, and potency.

G. STORAGE OF VACCINES OR ANTIGENS IN A BANK

It is important that the areas of storage for vaccine banks comply with recognised quality standards (e.g. chapter 1.1.8), which also address security of the premises (e.g. restricted access to premises, logbooks, continuity of access to electric power). Storage areas for vaccine banks should be regularly inspected by the Competent Authorities to ensure continual compliance. In the case of a vaccine that has regulatory approval, the storage conditions for both the antigen and for the formulated vaccine that is stored before release form part of the approval. Likewise, the location and operation of storage areas fall within the scope of the certificate of GMP (or other manufacturing standard) approved by the national Competent Authority. Any deviation from the approved conditions or areas for storage therefore requires approval from the relevant regulatory authority. If antigens are stored in one location but formulated and finished in another, both areas need to be covered by the 'GMP envelope' and agreed arrangements must be in place for transfer of material between the two.

If the vaccine bank is co-located with a laboratory or other facility where pathogens are handled, the bank storage facilities should be completely independent and be protected by positive air pressure with high efficiency particulate air (HEPA) filtration at the air inlets. Maintenance and monitoring personnel should, where they have had a possible exposure to relevant infection, obey a quarantine procedure before entering the bank.

Storage of antigens or vaccines in a bank should be appropriate to the product. The antigen may be a chemically inactivated or killed organism, a subunit derived from recombinant technology, or it may be a live vaccine based on an attenuated or recombinant strain. Antigens may be concentrated in frozen liquid form held at temperatures below -70°C in suitable containers that are appropriately labelled (see e.g. Chapter 3.1.8, Section C.6 *Storage and monitoring of concentrated antigens*). Freeze-dried vaccines and their diluents should be stored in accordance with the manufacturer's specification, typically at $+4^{\circ}\text{C}$ or -20°C , or as appropriate. Backup storage, equipment and contingency power supplies should be in place. For all methods of storage it is vitally important that vaccines or antigens are optimally maintained and routinely monitored, and that their storage is properly documented, in order to have assurance that they will be fit for use when needed. Managers of vaccine banks should therefore ensure that the necessary arrangements are in place to monitor their reserves on a routine basis as specified in the product licence and to include, where necessary and at appropriate time intervals, a testing regime to ensure integrity of the antigen component or acceptable potency of the final product. For example, storage facilities should be equipped with continuous temperature recording and alarm systems to detect divergence outside the required range; periodic inspection should also be carried out of the antigen containers for cracks or leakage. In this context, managers may wish to also consider the possibility of independent testing, or of greater reliance on overseeing or auditing of the manufacturer's test procedures.

In the case of antigen-containing banks, there is a need for routine stability testing of stocks. Sufficient smaller volume samples that are representative of the bulk antigen stock are necessary for such purposes and both bulk and samples should be stored side by side.

Where the requirement is to hold antigens or vaccines at a site other than at the principal site of manufacture, Competent Authorities should ensure that appropriate testing is carried out before the antigens are formulated into finished vaccine. Any new antigens should be held in a defined quarantine area until the necessary tests have been performed to formally accept them into the bank.

H. DEPLOYMENT PLANNING

Deployment planning addresses all aspects of the release of antigen for formulation into the final product, and the release and delivery of the ready-to-use formulated vaccine to the destination.

The request to deploy should be made by the Competent Authority(ies) of the requesting country or region, the decision for deployment being taken in agreement with the governance and management of the vaccine bank. The approval issued by the Competent Authority will include the conditions that must be met for release of the vaccine from the control of the manufacturer into the distribution chain. This can take a number of forms, from a simple import license for specific batches of vaccine through to official control authority batch release, depending on the terms of the license and the countries in which the vaccine is to be released and used. Early release may be possible if approved for emergency situations or release may only be possible once all tests are completed and verified. Members of vaccine banks need to ensure that the arrangements for batch release are fully understood and agreed with their respective Competent Authority to avoid delay in the event of need.

For the optimal use of a vaccine bank, the order for deployment should be informed, where appropriate, by results from a diagnostic laboratory (preferably a reference laboratory) with the ability to characterise the agent causing the disease and match the field strain with the available stored antigens or the ready-to-use formulated vaccines. In recent years a greater focus has been placed on the fate of vaccinated animals and the implications of vaccination as set out in the *Terrestrial Code* Chapter 4.18 *Vaccination*. For many diseases, DIVA vaccines have been developed together with companion diagnostic tests to substantiate that vaccinated animals and their products are free from infection. Successful deployment of DIVA vaccines requires the use of an accompanying diagnostic test. An important aspect of licensing vaccines with DIVA claims is to verify that the claims made for the combination of the vaccine and the accompanying test have been verified by the manufacturer to an acceptable standard and in line with general and specific guidance in the *WOAH Terrestrial Manual* (e.g. Chapter 3.1.8. Section C.5.4 *Purity: testing for antibody against NSP* for FMD vaccines). Using vaccines and accompanying tests that have been independently verified as complying with WOA standards is very helpful to countries.

Competent Authorities should have emergency plans to ensure that the stored vaccine is distributed and administered to meet disease control goals. In an outbreak situation, the speed of the implementation of the vaccination programme is critical in reducing the number of infected premises, the duration of the epidemic and, for certain diseases, the number of animals that need to be culled. The Competent Authorities should ensure that the necessary cold-chain facilities for vaccines and diluents, if appropriate, are available, that vaccination protocols are defined in advance, that vaccination teams are established and trained appropriately, that all the other necessary documentation, equipment, reagents and clothing are stored at sufficient levels to support any potential vaccination campaign, and that stakeholders are aware of the need for such a campaign (see *WOAH Terrestrial Code* Chapter 3.5. *Communication*). Performing periodic exercises and simulations should be considered.

I. CONSIDERATIONS FOR VACCINE BANKS MANAGED BY INTERGOVERNMENTAL ORGANISATIONS

Vaccine banks managed by intergovernmental organisations, such as WOA, may rely on specific funds for financing, to achieve prevention and control of specific diseases. Such mechanisms have been used to establish vaccine banks for FMD, peste des petits ruminants, avian influenza, and rabies for dog vaccination, and may be considered for other animal diseases in the future.

With the financial support of donors, in the context of international aid or with the use of other financial mechanisms such as trust funds or complementary funding, an intergovernmental organisation (regional or global) may manage

regional or global vaccine banks that are licensed and retained by the manufacturers selected through specific international calls for tender. Multiple donor funding mechanisms allow for cost sharing (establishment or replenishment), and for the management of donor-specific requirements.

Eligibility criteria are defined for countries that have access to such vaccine banks as well as guidelines on the use of regional and global vaccine banks. Depending on the disease, these banks may include vaccines produced and delivered on demand (planned deliveries), or specific replenishment mechanisms for rolling stocks.

The benefits of regional (or global) vaccine banks are numerous and seek to:

- i) save costs (economies of scale);
- ii) facilitate the delivery of determined quantities of high quality vaccines complying with WOAHS standards;
- iii) deliver more doses at a lower cost with access to more vaccine strains;
- iv) reduce the risks associated with the storage of vaccines;
- v) facilitate the harmonised implementation of regional or global disease control strategies;
- vi) create incentives for the implementation of disease control programmes;
- vii) reduce the number of procurement procedures;
- viii) promote the use of vaccines that comply with WOAHS quality standards for national and international disease control programmes.

Specific financial mechanisms can also allow countries or intergovernmental organisations to purchase directly from such banks.

Collaboration between vaccine banks (including those managed by intergovernmental organisations) and regional organisations is an economical way of increasing the amount of emergency vaccines available. Care is required to ensure that collaborating vaccine banks and regional organisations operate to the same or equivalent standards. Drawing rights should be clearly defined, and regular contact should be maintained between vaccine banks and regional organisations to confirm the quality of the vaccines. In the case of shared banks, regulatory compliance needs to be addressed at an early stage to ensure that vaccine produced from the bank is manufactured to WOAHS quality standards and will therefore be readily accepted for use in recipient countries.

Some vaccine banks also rely on long-term supply arrangements with selected providers that may include replenishment mechanisms, production on demand for non-urgent or planned deliveries, and buy-back schemes. While vaccine banks often hold physical stocks of antigens or vaccines, it is also possible to establish virtual vaccine banks with reduced physical stock. Specific service contracts between the bank holder and the manufacturers operating any of the above solutions should set out clear obligations, pricing specifications, maximum delays for delivery and contractual penalties in case of failure to meet the conditions of the service contract.

FURTHER READING

EUROPEAN MEDICINES AGENCY (2004). Position paper on requirements for vaccines against foot-and-mouth disease, EMA/CVMP/775/02-FINAL 01/12/2004, available at (last accessed on 29 May 2015)

http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/10/WC500004592.pdf

European Medicines Agency (2022). Guideline on data requirements for multi-strain dossiers for inactivated veterinary vaccines, EMA/CVMP/IWP/105506/2007 Rev. 2 available at (last access 10 June 2022)

https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-data-requirements-multi-strain-dossiers-inactivated-veterinary-vaccines-revision-2_en.pdf

FORMAN A.J. & GARLAND A.J.M. (2002). Foot and mouth disease: the future of vaccine banks. *Rev. sci. tech. Off. Int. Epiz.*, **21**, 601–612.

LOMBARD M. & FÜSSEL A.-E. (2007). Antigen and vaccine banks: technical requirements and the role of the European antigen bank in emergency foot and mouth disease vaccination. *Rev. sci. tech. Off. int. Epiz.*, **26**, 117–134.

'Prioritization of Antigen Management with International Surveillance Tool (Pragmatist)'. Available at the website of the European Commission for the Control of Foot-and-Mouth Disease (EuFMD), last accessed 10 June 2022 at <https://www.fao.org/eufmd/resources/pragmatist/en/>

'Vademos, Model for Vaccine Demand'. Available at the website of the European Commission for the Control of Foot-and-Mouth Disease (EuFMD), last accessed 10 June 2022 at <https://www.fao.org/eufmd/resources/vademos-model-for-vaccine-demand/en/>

WORLD ORGANISATION FOR ANIMAL HEALTH (WOAH: FOUNDED AS OIE) (2014). OIE Vaccine Banks. *OIE Bulletin*, No. 3. OIE, Paris, France, pp. 9–11.

*

* *

NB: FIRST ADOPTED IN 2008 AS *GUIDELINES FOR INTERNATIONAL STANDARDS FOR VACCINE BANKS*.
MOST RECENT UPDATES ADOPTED IN 2023.