OIE Policy Paper on Vaccine Banks

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OIE Policy Paper on Vaccine Banks

Objective of the Policy Paper

The OIE Policy Paper on Vaccine Banks clarifies the role and positioning of the OIE with regard to its Vaccine Banks. In particular, it defines principles for the implementation of the OIE Vaccine Banks in accordance with the OIE’s mandate, its Strategic Plan, as well as other activities and procedures undertaken by the organisation.

Following a short introduction, this Policy Paper will provide a synoptic description of the Vaccine Bank mechanism put in place by the OIE in 2006. Subsequently, the paper will present five Guiding Principles that drive the management of the OIE Vaccines Banks at present and in the future.

Introduction

- Fighting transboundary animal diseases is at the core of the OIE mandate

The OIE’s Sixth Strategic Plan (2016 – 2020)\(^1\) establishes priorities and activities to contribute to the fulfilment of a global vision expressed as ‘protecting animals; preserving our future’ leading to economic prosperity and social and environmental well-being.

Among the three strategic objectives defined in the Sixth Strategic Plan, Strategic Objective 1 focuses specifically on securing animal health and welfare through appropriate risk management. This objective targets – among others – the control and, when relevant, the eradication of selected transboundary diseases, which is at the heart of the OIE’s mission and strongly aligns with and contributes to the fulfilment of the United Nations Sustainable Development Goals. The positive ripple effects of tackling animal diseases are multiple, widespread and transgenerational; and include, for example, enhanced food security and food safety, a reduction in consequential health costs, increased income and other economic benefits for communities globally, as well as sustainable and safe domestic and international trade.

This Strategic Plan furthermore states that the OIE should assume leadership and coordination of international and regional programmes for the global eradication and/or control of specific diseases of economic and social importance, namely: canine Rabies, Foot and Mouth Disease (FMD) and Peste des Petits Ruminants (PPR). These three diseases each benefit from a harmonized framework and an international strategy, which have been endorsed by the OIE Members.\(^2\)

- Vaccination is an essential component of the control and/or eradication strategy of these transboundary diseases

As stipulated in the international standards contained in the OIE Terrestrial Animal Health Code, epidemiological surveillance, notification, appropriate biosecurity and engagement with human health sector when relevant are - among others - critical for the control and/or eradication of transboundary animal diseases. With regard to the three OIE global strategies mentioned above, vaccination has been identified as a key component to achieve disease control and elimination goals. For each of the three diseases, countries must establish a national vaccination strategy, train teams to implement the vaccination campaigns and conduct epidemiological surveillance as well as post-vaccination monitoring.

The design and implementation of the national disease control plan, including the execution of vaccination campaigns, is a national responsibility. The OIE, in collaboration with its Reference Centres\(^3\) and other relevant partners, provide support to its Members to accompany them in their crucial efforts. In a bid to support its Members while allowing the control and/or eradication efforts to remain country-driven and led, the OIE has developed a Vaccine Bank mechanism to facilitate the purchase of vaccines, when needed and, if possible, thanks to the financial support from several resource partners.

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\(^1\) [http://www.oie.int/fileadmin/Home/eng/About_us/docs/pdf/6thSP_ANG.pdf](http://www.oie.int/fileadmin/Home/eng/About_us/docs/pdf/6thSP_ANG.pdf)

\(^2\) Annex 1 provides more details on the globally agreed frameworks for eradicating and/or controlling canine Rabies, PPR and FMD.

\(^3\) Reference Centres includes Collaborating Centres and Reference Laboratories of the OIE. OIE Collaborating Centres are centres of expertise in a specific designated sphere of competence relating to the management of general questions on animal health issues or other topics related to OIE activities (“specialty”). In its designated specialty, they must provide their expertise internationally. OIE Reference Laboratories are designated to pursue all the scientific and technical problems relating to a named disease.
I. Background

The international standards in Chapter 1.1.10 of the *OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, define Vaccine Banks “as antigen or vaccine reserves, which can be of different types. They may be operated as a bank that holds the antigen component, or a ready-to-use formulated vaccine, or both. The vaccines may be deployed for different purposes ranging from systematic mass vaccinations, to emergency vaccinations, or to strategic interventions. Service contracts are a specific mechanism for accessing antigen or vaccine reserves”.

The first OIE Vaccine Bank, which was in operation between 2006 and 2011, was set up to provide vaccines for avian influenza. At present (2018), the following three OIE Vaccine Banks are operational:

- FMD Antigen/Vaccine Bank (prioritising Asia) established in 2011;
- Rabies Vaccine Bank (prioritising Asia and Africa) established in 2012;
- PPR Vaccine Bank (prioritising Africa) established in 2013.

OIE Vaccine Banks facilitate the procurement of high-quality vaccines, manufactured in accordance with OIE standards, for the benefit and use of OIE Member Countries.

Under existing mechanisms, OIE Vaccine Banks may include ready-to-use, formulated vaccines that can be delivered in a short time frame should an urgent request be received by the OIE from a Member. Moreover, the mechanism also enables the production and delivery on demand of vaccines for planned vaccination campaigns and country requests.

In line with OIE procurement procedures, the OIE Vaccine Banks have been established through the launch of international calls for tender. The competitive selection process allows for the selection of the most suitable and experienced vaccine manufacturer(s), which comply with OIE standards. The most recent calls for tender were launched in 2016 for each of the Vaccine Banks, and concluded by the renewal or the selection of new vaccine manufacturers. The OIE ensures that the competition can be reopened between vaccine manufacturers every four years.

II. Guiding Principles of OIE Vaccine Banks

OIE Vaccine Banks are managed through the application of a set of guiding principles, which ensure efficiency and appropriate response to Member Country requests. These five Guiding Principles should be understood as a coherent whole and should be read, individually and collectively, in terms of their objective to support OIE Members and partners to achieve tangible results towards the control and eradication of selected animal diseases for the benefit of the global community.

The Guiding Principles are:

1) OIE Vaccine Banks support the implementation of disease control strategies adopted by the OIE Membership;
2) OIE Vaccine Banks are established through a transparent selection process and ensure the necessary supply of high-quality vaccines;
3) OIE Vaccine Banks are driven by national needs;
4) OIE Vaccine Banks are flexible and financially secure;
5) The impact of OIE Vaccine Banks is leveraged through partnerships.

The Guiding Principles enable the OIE to:
- Determine whether or not to establish a Vaccine Bank for a particular disease;
- Ensure a high level of transparency, service and quality;
- Grant access to the Vaccine Banks on the basis of a well-argued rationale provided by the country;
- Establish and maintain a business model that is fit-for-purpose and that can maximize use and impact;
- Ensure the full participation of key technical and resource partners.

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4 For the purposes of this paper, the text refers commonly to Vaccine Banks, although for FMD the OIE has set up an Antigen/Vaccine Bank.
1) **OIE Vaccine Banks support the implementation of international disease control strategies adopted by the OIE Membership**

The OIE will only establish a Vaccine Bank for diseases that are supported by an international global control strategy which has been endorsed by the OIE Membership. Recognition of vaccination as a central success determinant is also fundamental. As of 2018, this corresponds to the following three diseases: canine Rabies, PPR and FMD (Annex 1).

On the contrary, the OIE will not establish a Vaccine Bank for diseases for which there is no active global control strategy adopted by the OIE membership.

With regard to Rinderpest, the first and sole eradicated animal disease, a specific decision mechanism and governance has been established through the Global Rinderpest Action Plan (GRAP). The GRAP includes an Operational Framework for the Rinderpest Vaccine Reserve (OF-RVR) which provides a framework to clarify the decision-making process and the role of each stakeholder as well as represents a tool to trigger production and access to vaccines in case of an outbreak. In view of the aforementioned, the OIE will not establish a vaccine bank on Rinderpest. The OIE will continue to be actively engaged and provide global leadership, in partnership with FAO, throughout the post-eradication phase.

2) **OIE Vaccine Banks are established through a transparent selection process and ensure the necessary supply of high-quality vaccines**

The supply of high-quality vaccines is an uncompromising condition of the OIE Vaccine Bank mechanism. Only vaccines manufactured in compliance with OIE standards are eligible to supply beneficiary countries through OIE Vaccine Banks.

In accordance with OIE procurement procedures, the OIE undertakes an international call for tender to select the most suitable and experienced vaccine manufacturers to provide vaccines to OIE Vaccine Banks. All vaccine manufacturers can respond to the international call for tender without restriction.

The Terms of Reference, annexed to the international call for tender, are developed in collaboration with OIE Reference Centres and other relevant partners and consider, when pertinent, the most recent information on the epidemiology of the disease (e.g. strains).

The selection process to evaluate tenders received in response to the international call for tender is composed of the following two committees:

- A tender opening Committee: this Committee is responsible for verifying that the tenders received comply with the procedures outlined in the international call for tender documents concerning submission requirements (two envelope system, date of receipt, etc.). This Committee develops a list identifying all tenders deemed eligible and the tenderers which did not comply with the requirements.

- An international tender selection committee: this Committee is composed of representatives from OIE Reference Laboratories, OIE staff, other relevant external experts, and donor representatives (as observers and upon request). For international calls for tender to supply rabies vaccines, a WHO representative participates in the selection committee meeting. This committee verifies the tenderers' technical and financial qualifications to ensure that tenderers have the capacity to meet the specific needs of the proposed contract.

For each international call for tender, the OIE may select one or more vaccine manufacturers, ensuring a diversified supply of vaccines in case large quantities are requested. Following the selection of the vaccine manufacturer(s), the OIE signs a contract with the awarded tenderers that stipulates the conditions which will govern the supply of services and vaccines including, among others, the vaccine strains, price, delays or quantities.

OIE Vaccine Banks only supply vaccines that were selected through an OIE international call for tender. As a result, some vaccine formulations or strains\(^\text{5}\), presentations (size of vials, labels) may not be available through OIE Vaccine Banks.

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\(^5\) The members of the Committees are validated by the Director General of the OIE. Moreover, experts participating in such Committees must sign declarations and statements to confirm that they will comply with the *OIE Policy on Conflict of Interests* and the *OIE Policy on the Protection of Legitimate Confidentiality*.

\(^6\) Relevant for FMD.
Vaccines are delivered to the main international airport in the country that has requested the vaccines. The transportation is organised by the vaccine manufacturer, ensuring that the cold chain has been maintained throughout the journey. The transfer of ownership of the vaccines and responsibility for maintaining the cold chain occurs upon arrival at the international airport when the vaccines are collected by the benefitting Member. Members must formally confirm, prior to the receipt of the vaccines, that they will ensure maintenance of the cold chain. The OIE also requests Members benefitting from an OIE Vaccine Bank to provide feedback and information on the use of the vaccines. Country reports received by the OIE upon completion of the vaccination programme should provide information on post vaccination monitoring as well as other relevant information. In the case that the OIE receives information that a Member has poorly managed or used vaccines received through the OIE Vaccine Banks and which resulted in the misuse/loss of important quantities of vaccines, the OIE may refuse future provision of vaccines to the country.

The OIE launches new calls for tender every four years or as required, depending on the availability of funding to maintain these mechanisms, to reopen the competition among manufacturers and to ensure that the most pertinent vaccines are available in the OIE Vaccine Banks.

Vaccines delivered to OIE Members through the OIE Vaccine Bank mechanism are only provided by the awarded manufacturers selected through the OIE international calls for tender. The OIE does not manage donations from vaccine manufacturers or from OIE Members (Members can manage this bilaterally). Lastly, the OIE does not develop nor publish a list of eligible vaccines/manufacturers or prequalified products. The OIE recognises that vaccine manufacturers which do not supply OIE Vaccine Banks may also provide high-quality vaccines that comply with OIE standards.

3) OIE Vaccine Banks are driven by national needs

All OIE Member Countries may be granted access to OIE mechanisms and services. However, priority will be given to developing countries engaged in relevant disease control programmes that have no immediate access to vaccines (e.g. where there are no national production facilities or complexities in putting into place the necessary procurement procedures).

For developed countries, access shall be considered on a case-by-case basis (emergencies, special circumstances, etc.) and direct payment to the vaccine manufacturer by the country is favoured when possible.

It should be noted that a financial limitation to this principle exists. All OIE Vaccine Bank have been established in line with donor-funded projects managed by the OIE. Such projects provide earmarked financial support, which may be specific to a disease and/or countries/regions⁷. However, and in an effort to expand the geographical scope, some flexibility has been introduced to respond to requests coming from non-prioritised countries.

OIE Members should engage in an iterative process with their OIE Regional and Sub-Regional Representatives to discuss the development and the implementation of their disease control strategies, to scope opportunities to benefit from OIE Vaccines Banks as part of their strategies, and develop a structured and complete request to submit to the OIE. Requests for vaccines will be assessed by the OIE only if an official request has been issued by the National Delegate to the OIE or by a national Minister. All requests for vaccines should demonstrate the existence of a national control strategy and clearly outline how the vaccines will contribute and support the national strategy.

<table>
<thead>
<tr>
<th>Requirements for a Member requesting vaccines through the OIE Vaccine Banks:</th>
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<tbody>
<tr>
<td>- A letter from the national Delegate to the Director General of the OIE</td>
</tr>
<tr>
<td>- A one-page summarising the national control strategy</td>
</tr>
<tr>
<td>- An outline of what will be implemented with the requested vaccines (Why? Where? Who vaccinates?)</td>
</tr>
<tr>
<td>- Sustainability and ownership strategy (this could include reference to a procurement strategy further and beyond the OIE’s support)</td>
</tr>
<tr>
<td>- A report upon use of the vaccines, signalling what was achieved</td>
</tr>
</tbody>
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⁷ Currently, the PPR Vaccine Bank gives priority to the 6 Sahelian countries: Burkina-Faso, Chad, Mali, Mauritania, Niger, and Senegal. The Rabies Vaccine Bank gives priority to Africa and Asia. The FMD Vaccine Bank gives priority to South-East Asia and China Foot and Mouth Disease (SEACFMD) Member Countries.
To stimulate the implementation of the national strategy for a short period of time

In general, the provision of vaccines to OIE Members through OIE Vaccine Banks is to stimulate the implementation of the national strategy for a short period of time. For example, this could correspond to providing vaccines to an OIE Member Country to support the implementation of one or two vaccination campaigns during the first year of the control strategy (indicatively not more than two years), and which would be continued afterwards through national funding.

OIE Member Countries benefitting from the OIE Vaccine Banks should envisage an exit plan, which would include a sustainable strategy describing how to continue the implementation of the vaccination campaigns without benefitting from vaccines made available through the OIE Vaccine Bank for procurement.

OIE Vaccine Banks should not replace national procurement procedures and should rather be seen as a complementary tool for OIE Members to have fixed term access to high-quality vaccines in order to stimulate national buy-in and commitment to controlling animal diseases.

Details on the use of vaccines as well as on the vaccination campaigns implemented should be reported back to the OIE by Members. This is important for the OIE to monitor use of the vaccines, to report on potential results and progress and to share with other countries best practices and lessons learnt. This report should be submitted to the OIE within six months of having used the vaccines.

To contribute to an already structured and well-recognised disease control programme

Some requests to benefit from an OIE Vaccine Bank form part of an already structured and well-recognised disease control programme, implemented in the context of a project being overseen or implemented by the country in collaboration with the OIE and funding partners. In this context, the OIE can provide the beneficiary country with access to OIE Vaccine Banks during the lifespan of the project. In this case, the process to request vaccines from the OIE Vaccine Bank is streamlined, with the OIE Member only having to submit an official letter requesting vaccines and making appropriate reference to the project.

To provide punctual responses to emergency outbreaks

The OIE can also respond positively to address an emergency outbreak, even in the absence of a specific national strategy or structured programme. As with other requests, the National Delegate to the OIE should issue an official letter to the Director General of the OIE requesting access to the OIE Vaccine Bank for the procurement of vaccines.

In this case, the OIE will endeavour to ensure a fast and efficient response, liaising with the vaccine manufacturer to ensure that the delivery is prioritised. For FMD, availability of vaccines will only be for the strains present in (or available from) the OIE Antigen Banks.

When deemed necessary, the OIE will convene an Advisory Committee to provide consultative recommendations to the Director General of the OIE to inform decision-making. This Committee could be convened only for specific cases, for example, when there is no structured control programme in place, or in the case of emergency disease outbreaks. The members of the Advisory Committee would be dependent on the disease for which the vaccines are being requested, and would foresee the participation of internal and external experts. Consultations would occur by conference call or via email.

4) OIE Vaccine Banks are flexible and financially secure

The OIE is neither a vaccine manufacturer nor a vaccine supplier. The OIE Vaccine Bank is a hybrid mechanism corresponding to a supply agreement between the OIE and vaccine manufacturer(s) to provide vaccines to the OIE Membership. OIE Vaccine Banks are virtual given that the OIE does not keep any physical stock on its premises, but rather calls upon a drawdown mechanism of vaccines from the vaccine supplier. Concerning the FMD Antigen Bank, the current supply agreement with the manufacturer does not entail any leasing costs.

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8 For example, the Regional Sahel Pastoralism Support Project funded by the World Bank Group or the ASEAN Regional, Strengthening Foot and Mouth Disease Control in South-East Asia funded by the New Zealand Ministry of Foreign Affairs and Trade.
The agreements signed with the vaccine manufacturers allow the OIE to immediately solicit the manufacturers to supply vaccines to an OIE Member that has been granted access to the Vaccine Bank. The availability of rolling stocks of vaccines coupled with a fast decision-making process at the OIE guarantee a service that rapidly provides high quality vaccines to OIE Members.

OIE Members can access vaccines through OIE Vaccine Banks via the following three modalities:

1. Purchase of vaccines and transportation costs is paid by the OIE with financial support from OIE resource partners within the framework of a grant managed by the OIE. Monies from the OIE Regular Budget are not used to finance the OIE Vaccine Banks nor to procure and supply vaccines to OIE Member Countries.

2. Purchase of vaccines and transportation costs is provided by an international organisation or an implementing partner. Examples to date of international organisations purchasing vaccines from OIE Vaccine Banks include the FAO, the WHO or the World Bank Group.

3. Purchase of vaccines and transportation costs is paid directly to the vaccine supplier by the OIE Member Country that has been granted access to the OIE Vaccine Bank by the OIE Director General (Direct Purchase).

Regardless of the access modality used, all requests to access to OIE Vaccine Banks must be developed in collaboration with the national Veterinary Services of the beneficiary country.

In addition, from the offset, the OIE has underscored that the establishment and management of the OIE Vaccine Banks cannot result in any financial risk for the organisation. Prior to granting access to an OIE Vaccine Bank, the purchasing modality (whom will pay for the vaccines and their corresponding transportation costs) is confirmed to eliminate all uncertainties be it for the OIE or for the vaccine manufacturer(s). When the payment is not issued by the OIE, but through a third party (international organisation, implementing partner or directly by a Member Country), the vaccine manufacturer has the right to accept or refuse the financial guarantees proposed by the third party. Such clarity is essential for the long-term sustainability and credibility of the mechanism.

To date, purchases from the OIE Vaccine Bank for FMD have all occurred through modality one - purchase of vaccines and transportation costs is paid by the OIE with financial support from OIE resource partners. The following graphics demonstrate the evolution in purchasing modalities from the OIE Vaccine Bank for Rabies and for the OIE Vaccine Bank for PPR. This evolution shows the leverage effect of opening access to the OIE Vaccine Bank mechanism to international organisations and OIE Members (direct purchase).

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9 The OIE would like to acknowledge the following resource partners for the financial support received to set up Vaccines Banks and deliver vaccines between 2006 and 2017: Australia, Canada, China, France, Germany, Japan, Korea, New Zealand, the European Union, and the Bill and Melinda Gates Foundation.

10 In the past, specific circumstances have led to occasional purchases by implementing partners such as donor governmental agencies (which pay for vaccines to a beneficiary country in a framework of a project), research institutes or Non-Governmental Organisations.

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5) **The impact of OIE Vaccine Banks is leveraged through partnerships**

Partnerships are key for the implementation of the OIE’s mandate.

The OIE develops synergies and engages with numerous international institutional and regional partners including - among others - the WHO, FAO, and the World Bank Group. Such partnerships foster and support collaboration in areas of common interest, and the OIE actively explores the development of additional partnerships with other organisations as warranted.

Similarly, and for the OIE Vaccine Banks, the first decade of experience garnered in the management of OIE Vaccine Banks has demonstrated the importance of collaboration with a wide range of international, regional and local partners, to support OIE Member Countries both for delivery of vaccination campaigns in response to emergency outbreaks as well as in relation to national disease control programmes.

The OIE would like to highlight that, in the framework of the Tripartite Alliance, a series of collaborations have been implemented with both FAO and WHO. The collaborations with WHO have focused prevalently on supplying large quantities of rabies vaccines for dog vaccination, whereas the OIE has worked closely with FAO on PPR as well as on Rabies. The OIE will continue to build upon these collaborations and scope new opportunities for the future.

Collaborations with other implementing partners have also been successful in the past to capitalise on other existing efforts to support OIE Members in the implementation of their national disease control endeavours. On a case-by-case basis, and when supported by a well-argued rationale, the OIE will consider collaborations with other international organisations, regional organisations and Non-Governmental Organisations, to support the implementation of vaccination campaigns. Crucial to the OIE’s decision to engage will be assurance that the national Veterinary Services are fully involved in the vaccination campaigns which will benefit from the vaccines provided from the OIE Vaccine Bank.

Strong and efficient collaborations with the private sector, and particularly with vaccine manufacturers, will remain essential to the OIE for the management of its Vaccine Banks. The OIE will continue to reinforce this relationship based on transparency, efficiency and sustainability to succeed in the fight against transboundary diseases.

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11 Overall, the following organisations have purchased vaccines through the OIE Vaccine Banks since 2011: WHO, FAO, Swiss Tropical and Public Health Institute, US Centers for Disease Control and Prevention (CDC), World Bank, Four Paws.
Conclusion

Using the Guiding Principles outlined in this Policy Paper as the overarching framework, the OIE will continue to provide its Members with access to OIE Vaccine Banks. Such efforts will continue based on the discretion of the OIE and depending upon resource partner support. In all cases, OIE Vaccine Banks will provide complementary support to the implementation of global animal disease control strategies endorsed by the OIE membership.

Using a fit-for-purpose Vaccine Bank mechanism, based on Member needs, the OIE endeavours to build efficient and sustainable partnerships to effectively control and eliminate transboundary animal diseases.

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Annexes

Annex 1  Description of three international disease control strategies supported by an OIE Vaccine Bank

Annex 2  Flowchart ‘Establishing an OIE Vaccine Bank’

Annex 3  Flowchart ‘Answering a vaccine request’
Annex 1:
Description of three international disease control strategies supported by an OIE Vaccine Bank

Following the recommendations of the first international FMD conference held in Asuncion, Paraguay in 2009, a Global FMD Control Strategy was developed under the FAO/OIE Global Framework for the Progressive Control of Transboundary Animal Diseases (GF-TADs) and released in 2012. The overall objective of the Global FMD Control Strategy is to contribute to poverty alleviation and to improve livelihoods in developing countries, and to protect and further the global and regional trade in animals and animal products.

The PPR Global Control and Eradication Strategy was endorsed in April 2015 during the international conference on PPR held in Abidjan, Côte d’Ivoire, with the vision of global eradication by 2030. The FAO and the OIE, through resolutions from their governing bodies, confirmed their commitment to this initiative. This global action was driven by strong evidence that PPR undermines the important role played by sheep and goats in improving rural livelihoods.

In 2015, the world called for action on rabies and set the goal of zero human dog-mediated rabies deaths worldwide by 2030. In September 2017 the global anti-rabies initiative was launched, and the WHO, the OIE, the FAO and the Global Alliance for Rabies Control (GARC) unveiled an ambitious plan to end human deaths from dog-transmitted rabies by 2030. The plan ‘Zero by 30: The Strategic Plan’ – centres on a One Health approach and addresses the disease in a holistic and cross-sectoral manner while highlighting the important role that veterinary, health and educational services play in rabies prevention and control.

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12 https://www.oie.int/doc/ged/D11886.PDF
14 Resolution N°25 voted at the 84th OIE General Session of the World Assembly of OIE Delegates
Annex 2:
Flowchart ‘Establishing an OIE Vaccine Bank’
Annex 3:
Flowchart ‘Answering a vaccine request’

*In the case of international organisations such as WHO or FAO, direct access to the OIE Vaccine Banks may be granted by the OIE. The international organisation, having been granted access, may place an order directly with the vaccine manufacturer (thus bearing the cost of the vaccines and their transportation).
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