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# Section 1: General information on WOAH Rabies Vaccine bank mechanism and its targeted beneficiaries

#### 1. What is the WOAH Rabies Vaccine Bank?

The WOAH Rabies Vaccine Bank is a mechanism to support Member efforts in combatting rabies. It operates on a voluntary basis, offering its services to Members who opt to utilise this resource. Since 2012, WOAH has established contractual arrangements with two vaccine manufacturers for providing anti-rabies vaccines to dogs. It's important to note that WOAH is not a vaccine manufacturer nor a direct supplier of vaccines. Additionally, vaccine stocks are not stored at WOAH's premises. This setup has led to the term "virtual bank" being used to describe the WOAH Rabies Vaccine Bank.

#### 2. What is the main objective of the WOAH Rabies Vaccine Bank?

The WOAH Rabies Vaccine Bank mechanism is an initial platform for discussions between WOAH and its Members regarding rabies control. It acts as a catalyst for the Member to carry out rabies prevention and control activities. It demonstrates WOAH's commitment to supporting Members in their rabies control efforts, thereby contributing to 'Zero by 30: The Global Strategic Plan to eliminate human deaths from dog-mediated rabies by 2030' (Zero by 30).

Accessing the WOAH Rabies Vaccine Bank should mark the primary step in engaging relevant national authorities in controlling rabies. It catalyses the Member to progress further in its national dog-mediated rabies elimination strategy, continue advancing independently and establish a national budgetary line for vaccine procurement.

### 3. What does the WOAH Rabies Vaccine Bank offer to Members?

The WOAH Rabies Vaccine Bank facilitates WOAH Members with the procurement of high-quality dog vaccines (parenteral injectable rabies vaccines for dogs) with optimal shelf life. Vaccines are available in 1 ml and 10 ml vials.

Members may request the longest possible shelf life that the manufacturer can offer to be in line with the vaccination schedule.

It also allows the delivery of vaccines with limited red tape, considering that WOAH has already conducted an international call for tender. All the administrative processes to choose the manufacturer and ensure the quality have already been done following WOAH international procurement procedures.

The WOAH Rabies Vaccine Bank also ensures a timely procurement to support rapid response to rabies outbreaks, with flexible quantities delivered over time. It can also be a fast track and complementary option to the national procurement process.

The WOAH Rabies Vaccine Bank is one of the key ways WOAH supports its Members to achieve 'Zero by 30'.

#### 4. How are vaccine manufacturers selected?

The WOAH Rabies Vaccine Bank has been established through international calls for tender in accordance with WOAH procurement procedures. This competitive selection process ensured the selection of the most suitable vaccine manufacturers who adhere to WOAH standards.

Since the inception of the Vaccine Bank mechanism, three calls for tenders have already been initiated for four years of collaboration with vaccine suppliers. Currently, WOAH is in Phase III, which commenced in January 2022 following the launch of the tender in February 2021. This phase will continue until 2025.

There are no routine assessments conducted on the manufacturers. Instead, WOAH operates under the conditions of quality and responsibility outlined in the contract signed for the four-year collaboration period.

#### 5. How was the selection process conducted?

WOAH issued a <u>call for tenders</u> for WOAH Rabies Vaccine Bank from 19th February 2021 to 19th April 2021. An Opening Committee, comprising members nominated by the WOAH Director General, oversaw the opening of tenders received for this call within the designated timeframe. This committee ensured that all submissions adhered to the stipulated procedures outlined in the tender call and compiled a list of eligible tenders for further assessment.

Subsequently, the WOAH Director General established and nominated a tender selection committee. This committee included WOAH staff members and international external experts from the Department of the Control of Neglected Tropical Diseases (WHO), WOAH rabies reference laboratories from India and USA. The committee assessed both the technical and financial aspects of the offers, evaluating them based on criteria outlined in the tender rules, such as the company's capacity to deliver and sustain, vaccine quality, the adequacy of the proposed vaccine service, the cost of the vaccines and the ability to provide complimentary technical support to the Members.

Following the assessment, Zoetis and MSD Animal Health were selected for contract negotiation with WOAH to become providers for the WOAH Rabies Vaccine Bank.

Before finalising the contracts, WOAH published an ex-ante notice (intention to conclude) on its website to inform the public of the tender call results and its intention to enter contracts with the selected tenderers.

#### 6. Who are the current manufacturers WOAH is working with?

Two vaccine providers, Zoetis and MSD, won the last call for tender and are the only providers that are contracted to supply the WOAH Rabies Vaccine Bank.

#### 7. Who can request access to the bank?

The WOAH Rabies Vaccine Bank was initially created to prioritise rabies-endemic countries. It can support Members who formally send a request to the WOAH Director General.

#### 8. Can WOAH project partners purchase vaccines through the WOAH Rabies Vaccine Bank?

The Terms of Reference of the WOAH Rabies Vaccine Bank indicate that the mechanism will allow direct purchase by international organisations (such as WHO) and implementing partners, (e.g. NGOs, academic and research institutions). This will be done under a "Third Party Clause".

The implementing partners acting as a funding entity ("Third Party") may approach WOAH and request to access vaccines through the WOAH Rabies Vaccine Bank. In this circumstance, WOAH and the relevant manufacturer will approve such Third Parties in writing before placing an order. In some cases, the manufacturer and the Third Party will sign an undertaking previously predetermined in the WOAH Rabies Vaccine Bank contract. In case of frequent collaboration, a formal process and signing of documents may be needed between WOAH and its partner to use the WOAH Vaccine Bank frequently.

If the Third Party is approved, the Third Party will benefit from the terms and conditions of WOAH Rabies Vaccine Bank agreement. However, all parties must agree to delivery timelines and terms of payment (except price per dose). All the corresponding invoices for the vaccine delivery will be paid directly to the manufacturer by the third party.

#### 9. What are the technical specifications of proposed vaccines?

The vaccines available in the WOAH Rabies Vaccine Bank provide a minimum of 36 months of immunity to dogs vaccinated with a single injection of 1 ml. Protective immunity has been demonstrated in vaccinated animals for up to 3 years post-vaccination in dogs.

Both manufacturers guarantee that all vaccines and packaging will be manufactured, tested, and stored according to the conditions previously indicated and agreed upon in the WOAH Rabies Vaccine Bank contract.

The manufacturer provides the vaccine's label and 'Directions for Use' in either English/Spanish or English/French, as specified in the production & delivery order.

All vaccines adhere to good manufacturing practices (GMPs), and their packing and labelling comply with the Technical Specifications and requirements outlined in the WOAH Rabies Vaccine Bank contract.

# Section 2: Application procedure to the WOAH Rabies Vaccine Bank

#### 10. When should you apply to access to the WOAH Rabies Vaccine Bank?

WOAH Members that are planning mass dog vaccination, have a dog vaccination strategy, and have identified funding for implementing dog vaccination programmes but require support to procure dog rabies vaccines can apply for assistance with the WOAH Rabies Vaccine Bank.

Accessing the WOAH Rabies Vaccine Bank should be seen as a step to strengthen internal and external support by the national authorities in eliminating dog-mediated rabies and as a step forward in implementing its national rabies elimination strategy.

### 11. How can a WOAH Member access the WOAH Rabies Vaccine Bank?

To access the WOAH Rabies Vaccine Bank, the Member's Veterinary Authority must endorse all the planned activities. The WOAH Delegate should send an official vaccine request to the WOAH Director General

The procedure to request access begins with discussions between the interested Member and WOAH (specifically the relevant Regional or Subregional Office) to understand the Member's situation and request and clarify the funding source. The steps are as follows:

- 1. Preliminary discussion between the Member and the relevant WOAH Regional or Subregional Office.
- 2. Identification of funding source.
- 3. If funds are available, the Member should provide WOAH with a completed <u>justification</u> form.
- 4. Once WOAH validates the justification form, the Member can send an <u>official request</u> to the Director General. This request must come from the WOAH Delegate (regardless of whether this is a request for a WOAH donation or a Third-party clause, see question 12).
- 5. Once the Delegate receives official acceptance from the Director General, WOAH will organise the delivery to the Member.

## 12. What are the possible sources of funding for WOAH Members?

There are two primary sources of funding available:

**WOAH donation:** Members can access funding by meeting the requirements set out in a donor project and fulfilling the associated conditions.

Third-party clause: vaccines purchased either through:

- Directly by the Member by utilising its national budget or funds from a partner project budget) or,
- Directly by a donor/partner supporting the Member on its rabies elimination programme.

## 13. Will the WOAH Rabies Vaccine Bank overlap with the national procurement process?

The WOAH Rabies Vaccine Bank was created to serve as a rapid and supplementary option alongside the national procurement process. This is not intended to replace the Member's national procurement mechanism but provides an expedited and complementary avenue for vaccine acquisition. The national procurement mechanism remains vital for ensuring minimal engagement from Members in implementing effective disease control measures for dogmediated rabies.

## 14. What is the timeframe from the initial application to the formal donation of vaccines from the WOAH Rabies Vaccine Bank?

The application process can progress relatively quickly, typically two to eight weeks after WOAH receives the official request letter from the WOAH Member. However, this timeline can fluctuate depending on two primary factors:

The duration it takes for the WOAH Member to provide all logistical details, including selecting their preferred manufacturer, specifying vial preferences, determining expected shelf life, and submitting necessary documentation such as import permits for customs clearance facilitation. The availability of vaccine stocks to meet the Member's request.

# 15. Should the Member engage in preliminary discussions with its WOAH Regional and Subregional Office before formally submitting the request to the WOAH Director General?

The Members are encouraged to have preliminary discussions with the WOAH Regional and Subregional office. The WOAH Regional or Subregional Office will offer insights and provide recommendations to Members to efficiently implement their rabies control activities and national strategic plans. It will also explore potential support from WOAH or through the United Against Rabies forum.

The WOAH Regional or Subregional Office will verify if the Members are actively engaged in rabies control activities and assess the mass dog vaccination strategy and sustainability of the programme in the absence of donations. Additionally, the WOAH Regional or Subregional Office will offer insights and provide recommendations if the Members have the necessary

infrastructure for receiving, transporting, and storing the vaccines. For example, the WOAH Regional or Subregional Office will ascertain whether the Member possesses adequate cold chain facilities to maintain the vaccine within the required temperature range of +2°C to +8°C.

## 16. How does WOAH assess the information included in the justification form?

Granting a Member access to the WOAH Rabies Vaccine Bank is aimed at supporting the Member in either initiating or enhancing its rabies elimination programme. When a Member requests access to vaccines, WOAH views this as an opportunity to initiate discussions with the Member to gain insight into their additional needs for advancing their rabies elimination programme. Through the discussions facilitated by the WOAH Rabies Vaccine Bank, WOAH can also establish connections between the Member, the United Against Rabies Forum, WOAH Reference Laboratories and other relevant stakeholders.

WOAH will evaluate whether the vaccine request is supported by a well-planned and established vaccination strategy that contributes to the overall national rabies elimination strategy of the requesting WOAH Member. Additionally, WOAH will evaluate the Member's preparedness to receive, store, and transport the vaccines and its capacity to implement the vaccination campaign and effectively communicate with the public. Furthermore, WOAH will evaluate the Member's capability to implement the vaccination plan post-delivery.

In cases where aspects of the rabies programme and vaccination campaign need improvement, WOAH can offer suggestions and guidance to assist the Members in optimising their efforts.

# 17. What are the key considerations for a Member when requesting vaccines from WOAH, and how are these requests evaluated?

There is no predefined limit on the number of vaccines a Member can request from WOAH. However, reasonable requests must be made based on a clear national strategic plan for rabies elimination and a well-defined vaccination campaign supported by available human and financial resources.

Initial discussions between the Member and the relevant WOAH Regional and Subregional Office are essential to clarify this point and guide the Member in ensuring that their vaccine request aligns with the objectives of the WOAH Rabies Vaccine Bank, the Member's current needs and their implementation capabilities.

This approach applies to both WOAH donations and direct purchases through Third Party. Given that the WOAH Rabies Vaccine Bank provides vaccines of excellent quality at specially negotiated prices, there are minimum requirements to ensure that Members can benefit from them.

In the case of WOAH donations, the number of vaccines allocated will also depend on the availability of funds. Initially, WOAH may recommend a smaller vaccine donation quantity if deemed appropriate.

#### 18. How is the vaccine delivery organised?

WOAH will communicate with the Member to confirm details regarding the requested vaccines, such as the preferred vial size (from the available options in the bank, either 1 or 10 doses per vial), desired shelf life, and expected delivery date.

Additionally, WOAH will ask the Member to choose the manufacturer they wish to collaborate with from the two options available in the WOAH Rabies Vaccine Bank. Members can select their preferred manufacturer, and WOAH will not impose or recommend any specific manufacturer.

In the case of a donation, WOAH will reach out to the manufacturer chosen by the Member and provide all the necessary information. WOAH will verify the manufacturer's availability to fulfil the Member's request, subsequently arrange the purchase order, and coordinate delivery in collaboration with the Member.

### 19. Is it possible for a Member to apply for assistance from the WOAH Rabies Vaccine Bank several times?

Members can submit multiple applications to the WOAH Rabies Vaccine Bank, provided each application adheres to WOAH requirements. Furthermore, certain projects funded by specific donors may include multiple vaccine donations facilitated through the WOAH Rabies Vaccine Bank. In such cases, Members benefiting from these projects do not need to submit new applications when requesting additional vaccine batches, especially if the proposed vaccination aligns with the project's objectives.

### 20. Should Members pay WOAH or the manufacturers for the vaccine?

For WOAH donations, payments are usually directly processed by WOAH to the manufacturer selected by the Member. However, in cases where a Third-party clause is applicable, payment should be made directly by the relevant party (either the Member or the donor/partner) to the manufacturer chosen by the Member or Third Party.

#### **Section 3: Follow-up action after vaccine donation**

## 21. Does WOAH monitor or follow up the use of vaccines donated to members? If yes, how?

After the vaccines are delivered, the Members are expected to report the vaccine utilisation within 6-12 months of the delivery or 3-6 months after finalising the vaccination campaign to the relevant WOAH Regional and Subregional Office. Providing a report of the utilisation of the vaccine donation is especially important if the Member plans to re-access WOAH Rabies Vaccine Bank.