

Pilot Phase 2 for refining the future WOAH Global Information & Alert System for Substandard & Falsified Veterinary Products (SFVPs)

Terms of Reference

Purpose

The purpose of the Pilot Phase 2 is to understand the in-country situation of the legislation and tools in place for detecting substandard & falsified veterinary products (hereafter, the acronym “SFVPs” is used), and to collect the technical specifications required for the development of a fit-for-purpose digital platform for the veterinary domain, similar to the one successfully used by [World Health Organisation \(WHO\) for SF medical products](#) in human health.

Background

In line with the 6th recommendation of the [2nd OIE Global Conference on AMR and Prudent Use of Antimicrobial Agents in 2018](#), the World Organisation for Animal Health (WOAH, founded as OIE) is working on the development of a Global Information & Alert System for SFVPs. It aims to receive notifications of SFVPs from its network and to subsequently inform all Members through alerts to facilitate their identification and eventual removal from circulation.

In 2022, WOAH conducted an initial pilot experience among fourteen voluntary WOAH Members, representing all geographical regions. Based on its learnings, we aim at expanding this pilot period to forty voluntary participants in order to better understand Member’s needs and develop the specifications such system will require.

Objectives

- To understand the in-country situation of the legislation, veterinary products availability, monitoring and surveillance, sampling and laboratory testing, recall of veterinary products and traceability systems available for detecting SFVPs. This information will be pivotal for prioritising the type of Guidelines needed by the participants for the efficient detections and removal of SFVPs in their territories. These Guidelines intend to cover areas such as monitoring and surveillance (active and passive surveillance), traceability, good manufacturing and distribution practises, recalls, pharmacovigilance between others.
- To have better knowledge of the current situation of the presence of SFVPs in the different territories so that WOAH can inform their participants by alert notifications. These alerts will be the basis for providing recommendations by WOAH and for deciding the actions to put in place by our Members.
- To give support to participants in case there is a suspicion of SFVPs in their territories by analysing the incident on a case-by-case basis and by interlinking related incidents that could be present in the region. This can be facilitated by having access to a repository which includes public database of registered veterinary products worldwide, access to pictures of SFVPs provided by participants and collaborators.
- To create a digital platform that can be used by participants as the main tool for reporting SFVP circulating in their territory, consulting any alerts of related /unrelated SFVPs present in the region and for contacting WOAH SFVP Team (herein after ‘the Team’) for queries and assistance in relation to SFVPs.
- To strengthen links with other international organisations such as WHO, World Customs Organisation (WCO) and Interpol by having access to alerts issued by these organisations and *vice versa*. This collaboration will be subject

to participant's consent for sharing information in relation to SFVPs, having assurance that Members will not be negatively impacted upon other due to this collaboration.

- To analyse the presence and trends of incidents of SFVPs at regional and global level, as well as to facilitate, upon participant's request, their own data for the Member's own analysis. This information can be used by participants as basis for assessing their own performance and gap analysis as well as for policy/decision making when preparing new National Action Plans.
- To bring awareness to the different civil societies and general public of the importance of reporting suspected SFVPs to the Veterinary Authorities.

Deliverables

- A preliminary SharePoint Portal accessible to WOAHA Members participating in this pilot only. Access to this Portal will be granted to the Delegate, the Focal Point for Veterinary Products and one additional contact nominated by the Delegate. Upon request of the Delegate, another contact can be replaced by the Focal Point of Veterinary Products if the Delegate considers that the suggested contact is in a better position for reporting SFVPs incidents to WOAHA. This Portal will contain the following:
 - Terms of Reference.
 - Access for submitting the WOAHA Baseline Reporting Form for SFVPs.
 - Access for submitting the WOAHA Immediate Notification Form for SFVPs.
 - Access for submitting the WOAHA Monthly Declaration Form for the Absence of SFVPs.
 - Access to the list of Alerts of Incidents of SFVPs reported, as a minimum, at regional level.
 - Form Requesting Historic Data of Incidents of SFVP reported by the requester.
 - Access to repository including public database of registered veterinary products.
 - Access to best practice guides on post-marketing surveillance available from international agencies and developed based on the experience gained with this project.
 - Open forum for participants to share and discuss aspects of SFVPs.
 - Form for submitting feedback for improving the project in short and long term.
 - Calendar of upcoming events related to SFVPs in the context of this pilot.
- Annual public report summarizing the in-country situation of the presence of SFVPs, as well as the nature of incidents of SFVPs reported at regional and global level. The level of detail included in the report will be based on the participant's response to their consent to share the data. In all cases, information will be summarised at Regional level and not at country level (unless otherwise specified by Members) as indicated at the end of the section 'Data sharing and Confidentiality'.

Prerequisites

- Email confirmation from interested Members stating acceptance of the participation to the 2nd pilot phase. For those Members that were involved in the first pilot phase, they are enrolled to the 2nd pilot phase directly unless otherwise stated by email.

- Participants agree upon their availability to respond any queries from the Team and to participate to any virtual meeting scheduled in relation to this project.
- Participants accept to follow the instructions stated under the section 'working plan' and the terms under the section 'Data sharing and Confidentiality'.

Working plan from participants

Participants are asked to:

- Complete a 5-10 min WOAH Baseline Reporting Form for SFVPs once a year, which should be submitted between 15th January and 31st March 2023.
- Submit a 10-15 min WOAH Immediate Notification Form for SFVPs, every time you are aware of a suspected/confirmed incident of SFVPs and as soon as possible (even if all the information is not available). As a minimum each incident should contain
 - Name of the product and Registration Number as stated in the packaging,
 - Manufacturer as stated in the packaging,
 - Batch number as stated in the packaging,
 - Date and site of discovery.

An open text box is available at the beginning of the Immediate Notification Report to allow participants to write a description of the remaining information relevant of every incident (i.e., quantities, reasons of suspicious, lab testing conducted, adverse reactions detected, etc.) to facilitate reporting in case of lack of resources or time.

- Following receipt of an incident by the Team, an email including the reference number will be provided. The reference number can be used in case you would like to update the information provided in the incident before, or to follow up.
- If no incidents are received in a calendar month, participants must complete the 1-min WOAH Monthly Declaration Form for the Absence of SFVPs. This must be submitted within 7 days after the end of the calendar month.
- Provide feedback on the data collection tools on, at least, a biannual basis for their refinement, their improvement, and for indicating any other issues that should be tackled in this project.
- When the Team receives any communication related to the presence of SFVPs by other international organisations or Civil Societies, the Team will contact the FPVP so that the incident can be forwarded to the respective Veterinary Authority and reported in accordance with the country's legislation. **It is not the responsibility of the Team the follow-up, monitoring, notification and removal of SFVPs at national level.** The Team collects this information to reflect the situation of SFVPs accurately, and will be shared only subject to receive participant's consent as indicated under the section 'Data sharing and Confidentiality'.

Working plan from the Team

- The Team will send a well receipt of the submission of any of the Forms indicated under the section 'Working plan from participants' within 2 business days. If no response is provided, participants can contact the Team to follow-up.

- The Team will contact the participant requesting any clarification needed from any of the Forms indicated under the section 'Working plan from participants'.
- The Team will assess every SFVP incident reported, assessment will be prioritized on a safety-risk basis. Alert notifications will be available via SharePoint and by email within 15 business days (for non-urgent notifications) or within 3 business days (for urgent notifications).

Data sharing and Confidentiality

- For each WOA Immediate Notification Form and WOA Monthly Declaration Form for the Absence of SFVPs completed, participants will be asked whether there is any reason that the information provided cannot be shared. The following options are available:
 - If there is NO reason (that means a response 'NO' under Question 10), it means that participants accept that all information can be shared to the rest of the WOA Member (not only in the SharePoint Portal but also as part of the annual report on the current situation of SFVPs written by WOA) and to other collaborators international organisations such as World Customs Organisation and Interpol.
 - If there is a reason (that means a response 'YES' under Question 10), participants will have the opportunity to explain the reasons that this information cannot be shared, and to extend their response as to whether the incident can be partially:
 - shared with other international organisations (such as World Customs Organisation and Interpol) and with WOA participants at regional level without disclosing the name of the Member reporting the incident.
 - shared with WOA participants only, without disclosing the name of the Member reporting the incident but indicating the region affected.
 - shared with WOA participants only, disclosing the name of the Member reporting the incident.

Whilst it is highly encouraged to share information totally so that accurate alert notifications can be delivered and effective measures put in place by participants, the Team will always act in accordance with the participant's consent response as this is not mandatory.

In all instances, participants consent that the information be shared anonymously, for writing the annual public report describing the presence of SFVPs regionally and globally.

Timelines

From January to December 2023, with the option to continue participation from 2024 onwards.