World Organisation for Animal Health

Track and Report Unsafe Veterinary Products (TRUVET)

Terms of Reference – May 2026

1. Purpose

The purpose of the Track and Report Unsafe Veterinary Products (hereafter called "TRUVET") is to:

- Conduct regular assessment of the status of legislation and tools used by WOAH Members for the detection of substandard and falsified veterinary medicinal products (SFVPs) by Members,
- collect evidence-based data on the scale and distribution of SFVPs at national, global and regional levels,
- alert and inform WOAH Members, partners and public of the presence of SFVPs through standardised risk assessments aligned with WOAH International Standards; and
- support Members in establishing and strengthening collaboration with stakeholders involved in the prevention, detection and response to SFVP within their territories, and facilitate such collaboration upon request.

2. Background

In line with the sixth recommendation of the 2nd OIE Global Conference on AMR and Prudent Use of Antimicrobial Agents in 2018, and with Article 3.4.11.5 – point g of the Terrestrial Animal Health Code of the World Organisation for Animal Health, initiated the VSAFE pilot project. This project aimed to collect notifications of SFVP from its network and to inform and support Members—particularly through alerts—in identifying and removing such products from circulation.

Building on the VSAFE-pilot experience, and in accordance with the sixth recommendation of Resolution 29 adopted at the 92nd General Session, WOAH launched TRUVET at the 93rd General Session in May 2026. TRUVET is the first global, long-term monitoring and surveillance platform dedicated to SFVP. It generates evidence-based insights on their presence at global and regional levels, supports surveillance and risk analysis, and strengthens Members' capacity to detect and eliminate such products.

While grounded in the core principles of VSAFE pilot, TRUVET introduces enhanced functionalities and broader user participation. It provides a more inclusive, non-judgemental and efficient platform for the reporting, analysis and follow-up of SFVP incidents. Beyond incident reporting, TRUVET supports documentation and data analysis, enabling evidence-based policymaking, strengthening post-marketing surveillance systems, and promoting coordinated responses with law enforcement authorities at national, regional and global levels.

3. Scope

- According to the *Terrestrial Animal Health Code* veterinary medicinal product means any product with approved claims to having a prophylactic, therapeutic or diagnostic effect or to alter physiological functions when administered or applied to an animal. **Nevertheless diagnostics are temporary out of the scope for the purpose of TRUVET.** In order to make clear distinction we will refer to the document to veterinary product (VP).
- Substandard and Falsified VPs are within scope. Definitions have been adapted from those adopted by WHO in the absence of definitions in WOAH international standards:
- Substandard VPs are authorised VPs that fail to meet either their quality standards or their specifications, or both.
- Falsified VPs are those that deliberately/fraudulently misrepresent their identity, composition or source.
    - Deliberate/fraudulent misrepresentation refers to any substitution, adulteration or reproduction of an authorised VP or the manufacture of a VP that is not an authorised product.
    - Identity refers to the name, labelling or packaging, or to documents that support the authenticity of an authorised VP.
    - Composition refers to any ingredient or component of the VP that accords with the applicable specifications authorised/recognised by national regulatory authorities.
    - Source refers to the identification, including name and address, of the marketing authorisation holder (MAH), manufacturer, importer, exporter, distributor or retailer, as applicable.

4. Objectives

- Empower Members in implementing WOAH international standards, resolutions guidelines and recommendations, including,
    - Chapter 3.4 of the Terrestrial Animal Health Code ('Veterinary Legislation')
    - Chapter 6.10 of the Terrestrial Animal Health Code ('Responsible and Prudent use of antimicrobials')
    - Chapter 1.1.8 of the Terrestrial Manual for vaccines and diagnostics ('Principles of veterinary vaccine production')
    - Section 2.3 of the Terrestrial Manual for vaccines and diagnostics ('Veterinary vaccines')
    - Resolution 29 (92nd General Session): 'WOAH Members actively report to WOAH incidents of substandard and falsified vaccines encountered in their territories. '
    - Resolution 26 (82nd General Session): 'cooperation with World Customs Organization (WCO), INTERPOL and stakeholders to combat SFVPs.'
- Identify gaps and vulnerabilities in Members' regulatory and technical systems for preventing, detecting, and responding to SFVPs, including in legislation, surveillance, pharmacovigilance, testing, recall, and traceability.

- Strengthen understanding of the occurrence of SFVPs across territories, enabling WOAH to issue alert notifications, develop recommendations, and support Members in determining appropriate response measures.
- Train Members in the use of TRUVET as the primary tool for reporting SFVP and for accessing alerts on related or unrelated incidents in their regions.
- Analyse regional and global trends in SFVP and, upon request, support Members in analysing their own data to inform performance assessment, gap analysis and evidence-based policymaking, including the development of National Action Plans.
- Support Members in the investigation and management of SFVPs through case-by-case analysis, identification of regional linkages between incidents, and access to a centralised repository of registered products, incident data and supporting evidence.
- Strengthen the effectiveness of WOAH's mandate by systematically sharing analyses, risk assessments and impact information on SFVPs across relevant WOAH departments, including emergencies, official status, WAHIS, and the PVS Pathway.
- Enhance collaboration and information exchange with international organisations, the private sector and civil society through controlled access to alerts, based on participant consent and appropriate safeguards.
- Strengthen collaboration with the World Health Organization (WHO) using a One Health approach to address substandard and falsified medical and veterinary products, in accordance with Members' needs and consent; and
- Raise awareness among civil society and the public of the importance of reporting suspected SFVP to Veterinary Authorities.

5. Access to TRUVET

- Access to TRUVET is available to different groups of accounts and users, who can access different services and functions.
- **WOAH Member account:** Each WOAH Member account is automatically granted to two WOAH Member users: WOAH Delegate and the respective WOAH Focal Point for VPs (hereafter WOAH-FPVP).

  Delegates may also request access for additional users within their WOAH Member account. These may include personnel from Veterinary Services and other regulatory authorities responsible for the registration and surveillance of veterinary medicinal products. Requests must be submitted to the WOAH SFVP Team (sfvp@woah.org) and include full name; affiliation, email address, and justification for access. It is expected additional users commit to report SFVPs.

  Users within the same WOAH Member account will have access to:

  - A dedicated Member portal, including a Member-specific dashboard;
  - The Baseline Report module on the management of veterinary medicinal products quality;

- The SFVP database, presenting aggregated regional data;
- A list of authorised users within their Member account; and
- Member-specific data on reported products.

- **External Partners account (EPA):** This group may include:
  - Private sector entities, including pharmaceutical manufacturers and MAHs for VPs;
  - WOAH Collaborating Centres (WOAH-CC) and Reference Centres (WOAH-RC);
  - Nongovernmental International organisations with formal agreements with WOAH, including WHO, INTERPOL and WCO.

  EPA from WOAH-CC and WPOAH-RC are automatically created. EPAs from private sector and nongovernmental organisations may be granted subject to a request submitted to the WOAH SFVP Team (sfvp@woah.org) and subsequent evaluation.

  Only one external partner user (EPU) per EPA shall be authorised. EPUs shall have access to TRUVET for submitting suspected or confirmed SFVP cases, or for access to reports only in instances described in section 'Data sharing and Confidentiality'.

- **The Public** shall have access only to a dedicated public portal and public alerts issued by WOAH in consultation with relevant parties.

6. Prerequisites for Access

- All WOAH Member users previously enrolled in the VSAFE pilot shall be granted automatic access to TRUVET, subject to acceptance of the terms and conditions at first login.
- WOAH Member accounts not previously enrolled in VSAFE pilot shall be established accounts for Delegates and WOAH-FPVPs.
- WOAH Member users agree to comply with the provisions set out under "Regular Tasks for WOAH Member Users" and "Data Sharing and Confidentiality".
- EPUs agree to comply with the provisions set out under "Tasks and Conditions for External Partner Users" and "Data Sharing and Confidentiality".
- All user types must accept the terms and conditions upon their first login.

7. Regular tasks for WOAH Member users

- WOAH Member users shall:
  - Maintain and regularly update the Baseline Report on SFVP for their respective WOAH Member accounts. TRUVET applies an annual cut-off date for assessing the global situation regarding the quality management of veterinary medicinal products.
  - Submit an Immediate Notification Form as soon as a suspected or confirmed SFVP incident is identified. Where complete information is not available, the minimum required data shall include:

        - Product name and Registration Number (as indicated in the packaging);
        - Manufacturer (as indicated in the packaging);
        - Batch number (as indicated in the packaging); and
        - Date and site of discovery.
    - Where national reporting templates exist (e.g. PIC/S members), users may upload these and complete any additional relevant information within TRUVET.
- Review and update submitted reports as necessary prior to validation. Following validation, amendments may be proposed for review by the WOAH SFVP Team.
- Complete a Declaration of Absence (DOA) if no incidents are reported within a 30-day period. Once submitted, a new DOA will be generated after a further 30 days unless an incident is reported. Reporting an incident resets the 30-day cycle.

8. Task and conditions for EPUs

- EPUs may submit reports of suspected or confirmed SFVP incidents.
- Incidents reported by EPUs will be shared with the relevant WOAH Member to ensure national authorities are informed. This does not replace any legal obligation of EPUs to notify national authorities directly. Responsibility for investigation, follow-up, and removal of SFVP at national level remains with the relevant authorities.
- Information provided by EPUs will be shared with other users only in accordance with the consent provisions outlined under “Data Sharing and Confidentiality”.
- EPUs shall not have access to Member-reported incidents unless explicitly authorised by a WOAH Member account or where their involvement is essential for case assessment.

9. Task of the WOAH SFVP Team

- The TRUVET Team shall:
    - Request clarification on submitted reports through the platform where required;
    - Ensure coordination among users within the same Member account;
    - Resolve discrepancies via the Member Administrator where necessary.
- All incidents shall be assessed on a risk-based priority approach.
- Where alerts are required, the WOAH SFVP Team shall coordinate with relevant stakeholders, including MAHs, to validate and agree on the information prior to dissemination. Alerts shall normally be issued at regional level without identifying specific countries/territories, unless otherwise agreed.
- While unregistered or unlicensed products fall outside the primary scope of TRUVET, their potential risk to animal health and welfare is recognised. Users are therefore not discouraged from reporting such cases. However, these reports may be subject to lower prioritisation in risk assessment and alert dissemination, unless there is clear evidence of significant harm or regulatory concern.

10. Data sharing and Confidentiality

- Data from VSAFE pilot is migrated to TRUVET, maintaining the original confidentiality settings.
- For each new report, users shall indicate whether information may be shared. Options include:
  - if there is NO reason why data cannot be shared, users accept that all information can be shared with the concerned manufacturer/MAHs, with other stakeholders including WOAH-CC or WOAH-RC (only if there is a need for their involvement on the case), and with International Organisations such as WHO, WCO and INTERPOL.
  - if THERE IS a reason why data cannot be shared, users will have the opportunity to explain the reasons, and to extend their response as to whether the incident can be partially:
    - shared only with the concerned manufacturer/MAHs to seek clarification of the case.
    - shared only with WOAH-CC or WOAH-RC for support threat analysis and assessment.
    - shared only with other stakeholders including international organisations (such as WCO, WHO, INTERPOL, etc.),
    - shared with WOAH Member users only, disclosing only the region affected.
- Where necessary, the WOAH SFVP Team may facilitate communication with manufacturers or MAHs, subject to Member notification and consent.
- Where necessary, the WOAH SFVP Team may communicate SFVP incidents across relevant WOAH departments, involved in animal health emergencies, official status recognition, WAHIS, and the PVS.
- While transparency and information sharing are strongly encouraged, all disclosures shall remain subject to Member consent.
- All users agree that:
  - Data may be shared in aggregated form at regional level;
  - Information may be used in WOAH communications and publications without identifying individual Members unless explicit consent is provided; and

11. Timelines

These Terms of Reference shall enter into force upon the launch of TRUVET in May 2026 and shall remain valid until formally revised.

12. Version History

Code	Date	Reason creation
V1.0	January 2024	VSAFE pilot phase
V2.0	May 2026	Launch TRUVET