

Report of the Virtual Meeting of the WOAH *ad hoc* Group on the Revamping of the Register of Diagnostic Kits

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Executive Summary:

The second virtual meeting of the *ad hoc* Group on the Revamp of WOAH's Register of Diagnostic Kits was held on 26 January 2026. The meeting reviewed findings from the survey agreed during the first meeting of the *ad hoc* Group, aiming at getting member's proposals on the value, feasibility and framework of a new registration system for diagnostic kits, as well as the feasibility, sustainability and added value of potential future approaches for WOAH in relation to diagnostic kits.

The survey confirmed the need to improve access to reliable information on veterinary diagnostic kits, with no clear consensus on re-establishing a formal WOAH register of diagnostic kits. Discussions therefore focused on identifying realistic and achievable options for WOAH, including the discussion around a minimum viable approach proposed by the Secretariat. Discussions led to the following directions for further consideration by the *ad hoc* Group:

1. moving away from the concept of a 'registration' system, suggesting the use of terms like 'certification' or 'qualification' of diagnostic kits;
2. defining a limited number of priority diseases for which such 'certification' approach could be pursued;
3. development of a standardised validation summary template for diagnostic kits aligned with WOAH standards;
4. including in the workstream a mechanism to facilitate the harmonisation of regulatory systems for diagnostic kits;
 - a. the consideration of indicative minimum requirements which could be used by authorities as guideline criteria to validate diagnostic kits to be registered in places where poor or no regulation exists;
 - b. the exploration of a high-level, non-regulatory framework to clarify the status of diagnostic kits already authorised in different jurisdictions, based on alignment with WOAH standards as suggested by a member of the *ad hoc* Group;
5. further refinement of other elements from the minimum viable scenario presented, to determine which components offer clear added value and are feasible for WOAH to implement;

The outputs of this meeting will inform discussions with the Biological Standards Commission (BSC) at its meeting on 5 February 2026 and guide the next phases of work of the *ad hoc* Group.

1. Opening of the meeting

The meeting was opened by the Secretariat, who welcomed participants to the second virtual meeting of the *ad hoc* Group (hereby referred as 'the Group') on the revamp of WOAH's Register of Diagnostic Kits and thanked members for their full participation in the recent survey. The Secretariat outlined the objective of the meeting: to reflect on survey findings and identify what is realistic, sustainable and achievable for WOAH to take forward.

2. Survey Findings and Presentation of a Minimum Viable Scenario

2.1. Survey Findings

The Secretariat presented the key findings of the survey conducted among members of the *ad hoc* Group. The survey achieved a 100% response rate.

Six of the eleven respondents supported WOAH maintaining a register for diagnostic kits, particularly those with expertise in diagnostic validation, quality control and reference laboratories. Five respondents expressed reservations and suggested alternative approaches for WOAH, and these have expertise in regulation and diagnostic validation and kit manufacturing.

Overall, there was no consensus on establishing a formal WOAH register of diagnostic kits. However, there was broad recognition of the need to improve access for WOAH Members to reliable information on diagnostic kits.

Concerns highlighted in the survey included:

- The need for standardized presentation of validation evidence, with clear links to WOAH Manuals
- Risk of creating a complex or burdensome process with limited added value for manufacturers and Members.

However, the registration process described by the Group represents an idealised model, reflecting expectations for a fully harmonised, reliable and globally recognised system for the registration of diagnostic kits. But, discussions on the financial implications were limited, and the proposed cost-recovery options such as modest, proportional fees supplemented by donor or Member support were not considered viable at this stage. As a result, implementation of this model would likely face significant practical and resource constraints in the short to medium term.

2.2. Minimum Viable Scenario

Based on the survey analysis, internal discussions and feedback, the Secretariat presented a proposed minimum viable scenario as a pragmatic first step for the Group to explore. This scenario aimed to focus discussions on achievable actions, rather than an ideal but potentially unfeasible model.

Key elements of the proposed minimum viable scenario included:

- Development of standardised validation summary templates aligned with the Terrestrial and Aquatic Manuals;
- Greater use of existing evaluations and data generated by WOAH Reference Laboratories and other competent laboratories to reduce duplication and costs;
- Building on existing databases (e.g. Diagnostics for Animals) by defining baseline quality and validation criteria;
- Consideration of a non-certifying information listing of diagnostic kits, clearly separated from any formal certification process;
- Introduction of a simple, periodic review cycle to maintain accuracy of information rather than re-evaluating all kits.

3. Group Discussion on Feasibility, Sustainability and Added Value of Working towards the Delivery of the Possible Minimum Scenario

3.1. Terminology and Scope

The Group strongly agreed that the term 'registration' should not be used for any future WOAH mechanism for diagnostic kits, as registration is the mandate of national or regional regulatory authorities. Instead, any

WOAH-led system should focus on certification or qualification of diagnostic kits against WOAHS standards, without encroaching on national regulatory responsibilities.

3.2. Standardised Validation Summary Template

There was broad consensus that development of a standardised validation summary template would be a feasible and valuable output. Such a template would:

- Clarify minimum expectations for validation data;
- Support manufacturers, laboratories and regulators;
- Align validation evidence with WOAHS standards;
- Serve as a foundational tool for any future certification or information-sharing mechanism.

3.3. Role of Reference and Other Competent Laboratories

The Group recognised that substantial validation data already exist within WOAHS Reference Laboratories, regional laboratories and accredited national laboratories. Members noted that:

- Reference laboratories should play a coordinating role where appropriate;
- Other competent laboratories could also contribute data, provided minimum quality criteria are defined;
- Resource constraints, conflicts of interest and availability of reference materials must be carefully considered.

The Group emphasised that WOAHS should not aim to re-evaluate all kits centrally, but rather leverage existing data where possible.

3.4. Prioritisation of Diseases

Given the large number of diagnostic kits on the global market, the Group agreed that any certification or qualification approach should initially focus on a limited number of priority diseases of high global or regional importance. This phased approach would allow testing and refinement of the system before any potential expansion.

3.5. Information-Sharing and Existing Tools

The Group highlighted the value of existing networks and publicly available guidance (e.g. disease-specific networks such as the ASF network and Rabies network producing validation summaries for point-of-care tests). The Group agreed that:

- WOAHS has a role in facilitating access to reliable information;
- Existing tools and databases should be strengthened rather than duplicated;
- Clear distinction must be maintained between information provision and certification.

3.6. Sustainability and Added Value

Discussions confirmed that lack of clear added value and limited impact on market access were key reasons for low uptake of the previous WOAHS register. Any future approach must therefore:

- Deliver tangible value to Members;
- Be proportionate in terms of cost and complexity, in particular to ensure the participation and engagement of diagnostic kit manufacturers in the process;
- Avoid creating unrealistic expectations regarding market authorisation.

4. Way Forward and Next Steps

4.1. Key Takeaways

The Group broadly agreed on the following directions:

- Discontinue use of the term 'register' and instead explore a WOHAI certification or qualification concept;
- Prioritise development of a standardised validation summary template as an immediate, achievable output;
- If certification is pursued, limit initial scope to a small number of priority diseases;
- Further refine and assess the other elements of the minimum viable scenario to determine which components deliver clear added value and are feasible for WOHAI to implement.
- Explore if WOHAI could develop a high-level, non-regulatory framework to clarify the status of diagnostic kits already in different jurisdictions through indicative categorization based on alignment with WOHAI standards as suggested by a member of the Group.
- Address regulatory harmonisation, including minimum dossier expectations, as a related but separate workstream.
- Consider if WOHAI could define indicative minimum benchmarks for diagnostic kit registration, as part of the broader regulatory harmonisation effort, to support more consistent evaluation and future WOHAI processes.

4.2. Next Steps

The Secretariat will:

- Prepare concise meeting notes, including an executive summary, for consideration by the Biological Standards Commission at its meeting on 5 February 2026;
- Incorporate feedback from the BSC into the next phase of work;
- Convene a further virtual meeting after the BSC discussion, either late February or early March 2026, to refine and agree on the final roadmap;
- Launch a poll to identify suitable dates for an in-person meeting, tentatively planned for mid-2026 (June or July 2026).

5. Closing of the Meeting

The Chair thanked participants for their constructive engagement and acknowledged the diverse perspectives shared during the discussion. The meeting was closed with agreement to maintain momentum through a rapid turnaround of outputs and continued collaboration.

6. Virtual meetings

The Group met via video conference on 26 January 2026. The agenda of the on-line meeting and the list of participants are presented in [Annex 1](#), and [Annex 2](#) respectively.

Annex 1. Agenda

2ND MEETING OF THE WOAAH *AD HOC* GROUP ON THE REVAMPING OF THE REGISTER OF DIAGNOSTIC KITS

26 January 2026

1. **Opening of the Meeting (5 min)**
Welcome remarks by the Secretariat (SRDK)
2. **Survey findings and presentation of a possible minimum scenario (20 min)**
 - Key survey findings
 - Presentation of the minimum viable scenario
3. **Group discussion on feasibility, sustainability and added value of working towards the delivery of the minimum viable scenario (50 min)**
 - Clarifications and reactions from Members of the *ad hoc* Group
 - Practical feasibility and sustainability
 - Alignment with WOAAH standards and Member needs
 - Risks and limitations
4. **Way forward and next steps (10 min)**
 - Key takeaway from discussion
 - Areas needing further work or refinement
 - Update members of the BSC at the BSC meeting
 - Proposal of dates for a physical meeting in Paris
5. **Closing (5 min)**

Annex 2. List of participants

2ND MEETING OF THE WOAAH *AD HOC* GROUP ON THE REVAMPING OF THE REGISTER OF DIAGNOSTIC KITS

26 January 2026

MEMBERS OF THE *AD HOC* GROUP

Dr Carrie Batten (Chair)
Head of Non-vesicular Reference
Laboratories, the Pirbright Institute
UNITED KINGDOM

Dr Charles Sanne Bodjo
(Vice Chair)
Acting Director
Pan African Veterinary Vaccine
Center of African Union (AU-
PANVAC)
Debre Zait
ETHIOPIA

Dr Axel Colling
Veterinary Diagnostic Scientist
CSIRO Australian Center for
Disease Preparedness
AUSTRALIA

Dr Pauline Martins da Cunha
Head, Division for the Regulation of
Biological Products
Rio De Janeiro
BRAZIL

Dr Zahide Dilik
Specialist Veterinarian Izmir-
Bornova Veterinary Control Institute
Directorate
REPUBLIC OF TÜRKIYE

Ms Anna Greatrex
Commercial Director
Innovative Diagnostics
IDvet, Grabel
FRANCE

Ms. Tamara Elizabeth Grisard
Global Head of Regulatory Affairs
and Product Compliance
IDEXX Diagnostics
North Carolina
UNITED STATES OF AMERICA

Dr Hassan Ishag
Veterinary molecular microbiology
Expert
Abu Dhabi Agricultural and Food
Authority, Abu Dhabi
UNITED ARAB EMIRATES

Ms Aurore Romey
Head of National Ref Lab for Foot-
and Mouth Disease
ANSES
FRANCE

Prof Chenghuai Yang
Director Department of Veterinary
Culture
China Institute of Veterinary Drug
Control
PEOPLE'S REPUBLIC OF CHINA

OBSERVERS

Prof. Ann Cullinane
Head of Virology Unit
Irish Equine Centre
Naas
IRELAND

Prof Chris Oura
Professor of Veterinary Virology,
The University of the West Indies,
St-Augustine
TRINIDAD AND TOBAGO

WOAH HEADQUARTERS

Dr Javier Yugueros-Marcos
Head of Department
Veterinary Products and Drug
Resistance Department

Dr Agatha Ugboma
Project Officer
Regulatory System for Veterinary
Products
Veterinary Products and Drug
Resistance Department