

Regulatory Authority Perspective on Veterinary Medicinal Products Harmonization in ASEAN

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6th Cycle Regional Training Seminar for OIE Focal
Points for Veterinary Products

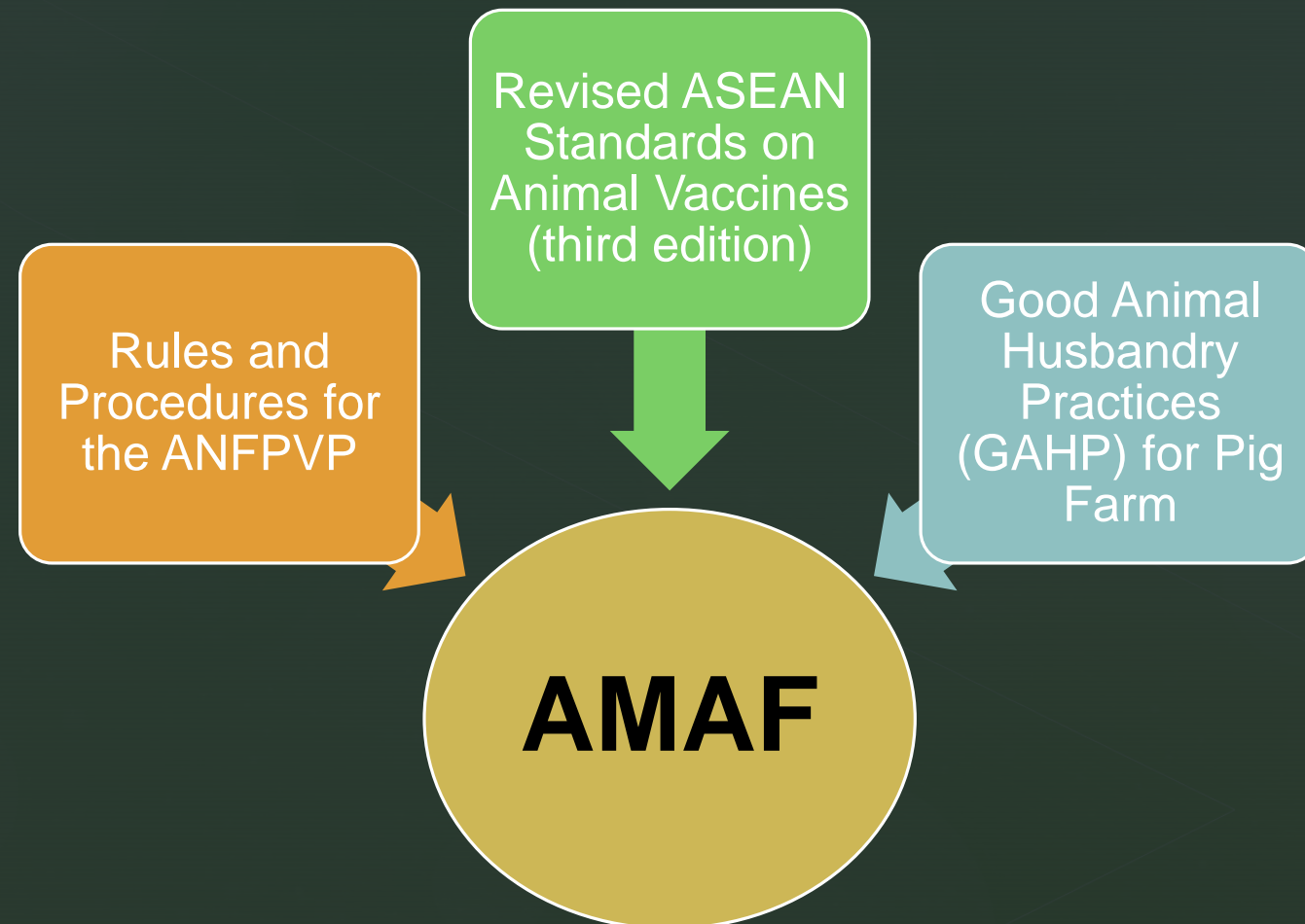
14 -16 February 2020 – Kuala Lumpur, Malaysia



ANFPVP JOURNEY



THE MEETING NOTED THAT THE 40TH AMAF MEETING ADOPTED THE FOLLOWING DOCUMENTS



PLAN OF ACTION OF THE ANFPVP (2015 – 2020)

Objective 1

- Enhance Capacity and Capability of ASEAN Member States in Veterinary Products and Vaccines (Indonesia)

Objective 2

- Enhance and Implement ASEAN Standards and Guidelines for Veterinary Products (Indonesia)

Objective 3

- Promote Knowledge and Awareness on Veterinary Products in the Industry through Technical Assistance (Singapore)

Objective 4

- Enhance Cooperation and Collaboration related to Veterinary Products (Philippines)

▶ The progress of the Plan of Action of the ANFPVP Activities(2015 – 2020)

Enhance Capacity and Capability of ASEAN Member States in Veterinary Products and Vaccines

- 1.Training on Veterinary Products Testing and the Workshop on Risk Analysis for Veterinary Products focusing on Rabies Vaccine (AMS's, ASEAN Secretariate).
- 2.Workshop on the Implementation of the Good Manufacturing Practices for Veterinary Medicinal Products including inspection procedures for vaccine manufacturers (AMS's, ASEAN Secretariate)

Enhance and Implement ASEAN Standards and Guidelines for Veterinary Products

- 1.The ASEAN Standard for Animal Vaccine Registration was adopted by the 39th AMAF Meeting
- 2.Indonesia informed that they will conduct internal consultation in regards to the development of ASEAN Mechanism on Veterinary Drug Registration and Approval and will share the draft to the ASEAN Secretariate

Promote Knowledge and Awareness on Veterinary Products in the Industry through Technical Assistance

- The AMR Regional Action Plan for Livestock (Singapore)
- The ASEAN Guidelines on Autogenous Vaccines (use and minimum technical requirements) (Singapore, Thailand, ANFPVP Focal Points and ASEAN Secretariate)

Enhance Cooperation and Collaboration related to Veterinary Products

- On-going progress in enhancing cooperation and collaboration related to veterinary products. Further updates will be provided by Philippines during the 7th ANFPVP Meeting

➤ PROGRESS OF INITIATIVES UNDER THE COOPERATION

A. Regularization of Products and Utilization of Animal Vaccines

▪ Recognition of Animal Vaccine Testing Laboratories :

Re-assessment of Recognition of the Veterinary Biologics Assay and Research Center (VBAC), Pakchong, Nakhon Ratchasima, Thailand

Thailand will reapply for the audit of reassessment of recognition of VBAC and will add the swine vaccines in addition to the chicken vaccines to be covered under the scope of audit.

Re-assessment of Recognition of the National Veterinary Drugs Assay Laboratory, Gunung Sindur, Bogor, Indonesia

Scope of audit : Newcastle Disease Vaccine (live), Newcastle Disease Vaccine (inactivated), Marek's Disease Vaccine (live), Infectious Laryngotracheitis Vaccine (live), Infectious Bronchitis Vaccine (live), Infectious Bronchitis Vaccine (inactivated), Egg Drop Syndrome '76 Vaccine (inactivated), Fowl Cholera Vaccine (inactivated), *Haemophilus paragallinarum* vaccine (inactivated)

PROGRESS OF INITIATIVES UNDER THE COOPERATION

B. ASEAN Standard Requirements for Animal Vaccines

- The ASEAN Register of Animal Vaccines was adopted by the 40th AMAF Meeting. Each AMS will examine their national regulations system for the implementation of ASEAN Register of Animal Vaccines. The gaps on the implementation of the ASEAN Register of Animal Vaccines will be discussed at the 7th ANFPVP Meeting - --- (**Action Line: AMS**)
- AMS agreed to revisit the following adopted documents:
 - 1) Mechanism for the ASEAN registration of Animal Vaccine
 - 2) Protocol for ASEAN Recognition of Reference Animal Testing Laboratories and
 - 3) ASEAN accreditation criteria for vaccine testing laboratories to ensure the consistency of all documents. ----- (**Action Line: Indonesia and Thailand**)

➤ **PROGRESS OF INITIATIVES UNDER THE COOPERATION**

- **ASEAN Guideline on Good Manufacturing Practices (GMP) for Veterinary Medicinal Products**

Indonesia that has developed the ASEAN Guideline on Good Manufacturing Practices (GMP) for Veterinary Medicinal Products as part of the key deliverables for 2018–2019. The draft was circulated before the Meeting and received inputs from the AMS.

Action Line: Indonesia, AMS, and ASEAN Secretariat

FAO COOPERATION

1. Technical support provided to the AMS by the AMU/AMR Technical Advisory Group (TAG) for South-East Asia and the FAO-OIE Regional Network of Collaborating and Reference Centers on AMR in the Asia-Pacific Region.

Action Line: FAO and OIE

2. Considering the success made to deliver a cohesive, region-wide celebration of the World Antibiotic Awareness Week (WAAW) in November 2018, the AMS and relevant technical group, with support from FAO and OIE, to continue to deliver and implement a coordinated and cohesive celebration of the WAAW in 2019 and beyond.

Action Line: AMS, FAO and OIE

3. Appreciation to FAO for its support provided to AMS to combat AMR. Comprehensive activities conducted at country and regional levels with support from FAO to advance the implementation of the ASEAN Regional Action Plan on AMR. To ensure continuing strong cooperation, AMS agreed to develop the ASEAN-FAO AMR workplan, which will bridge complementing activities, connect shared interests, and identify areas for potential synergy between FAO and the ASEAN.

Action Line: Singapore, FAO and OIE

OIE COOPERATION

OIE's initiatives on AMR to support AMSs on the implementation of OIE Strategy on AMR and the Prudent Use of Antimicrobials, focusing on :

- 1) Improving awareness and understanding;
- 2) Strengthening knowledge through surveillance and research;
- 3) Supporting good governance and capacity building; and
- 4) Encouraging implementation of international standards.

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) Workshop

Some noted on the importance of joining the VICH Outreach Forum (VOF):

- To have access to the technical forum composed of regulatory authorities from US, Europe and Japan, as well as experts from the industry;
- To have the opportunity to understand technical requirements for Veterinary Medical Products (VMP) registration in more details;
- To have the opportunity to influence the future work of VICH, e.g. guidelines to be developed, so as to benefit ASEAN regulatory bodies and industry;
- To have the opportunity to join VICH Technical Working Groups for the development of specific guidelines.

AMS agreed to encourage the continuation of VICH trainings in ANFPVP meetings. ASEAN Secretariat support to explore funding support from OIE/FAO or ASEAN Animal Health Trust Fund and to provide information to ANFPVP in due course.

ASEAN Implementation of Regional Animal Vaccines Registration

Each AMS will conduct their internal assessment on the implementation of ASEAN Registration of Animal Vaccines in view of different authorities in each country to register the vaccines. The result of the national assessment will be reported at the 7th ANFPVP Meeting.

ANFPVP ISSUES TO BE FOLLOWED UP

| No | Key Decisions/Issues | Timeline | Follow-up By |
|----|--|---|------------------------|
| 1. | ASEAN Guidelines on Autogenous Vaccines (use and minimum technical requirements) | June 2019 | Singapore and Thailand |
| 2. | ASEAN Standards for Good Manufacturing Practices (GMP) for Veterinary Medicinal Products | June 2019 | Indonesia |
| 3. | The organisation of the VICH Workshop at the 7 th ANFPVP Meeting | Preparation to VICH Workshop shall be convened two months before the 7 th ANFPVP Meeting | ASEAN Secretariat |
| 4. | National assessment on the implementation of ASEAN Registration of Animal Vaccines | Reported at the 7 th ANFPVP Meeting | AMS |

Thank you

