

**Conclusions and Recommendations of the OIE Workshop on  
Vaccine Quality and GLP in ASEAN countries  
Bandung, Indonesia, 13-16 January 2009**

Considering that

1. Animal vaccines have been used for successful operation of animal health programmes as primary means of control of many animal diseases and share the significant functions of animal disease prevention and control; and in some cases, vaccines are used for national disease control and eradication programmes.
2. Animal vaccines should be considered for use when they have been manufactured in compliance with OIE standards and other relevant international standards such as for safety, efficacy and stability; and also when properly stored, handled and used in an effective way.
3. In the ASEAN region, Member Countries produce some kinds of animal vaccines locally, while many of them import animal vaccines from other countries. The requirements of registration for those animal vaccines differ in some cases from country to country. National veterinary services need to be further strengthened for effective mechanisms of animal vaccine registration and quality control, either locally produced or imported.
4. Regional Standards for registration and quality control of animal vaccines have been developed in ASEAN countries, which include (1) Manual of ASEAN Standards for Animal Vaccines, (2) Manual of ASEAN Rules and Procedures for the Registration of Animal Vaccines, (3) Manual of ASEAN Standards for Good Manufacturing Practices (GMP) for Animal Vaccines, (4) Manual of ASEAN Accreditation Criteria for Animal Vaccines Testing Laboratories, (5) Manual of ASEAN Code of Practices for the Commercial Storage, Transportation and Handling of Animal Vaccines, to ensure that only vaccines which meet OIE standards and other relevant international standards are utilized. It is recognized that some of these documents need to be reviewed, to be in line with the regular updates of the OIE standards and other relevant international standards.
5. The World Organisation for Animal Health (OIE) provides the international standards on animal health, in the OIE Codes and Manuals, including guidance in the production of veterinary vaccines. The OIE Standards should serve as reference documents in the revision and development of ASEAN Standards.

The workshop recommends the following:

1. The Manual of ASEAN Standards for GMP for Animal Vaccines should be reviewed and revised in accordance with the OIE standards and other relevant international standards. The revisions made to the existing Manual for ASEAN Standards for GMP for Animal Vaccines which was discussed during the OIE Workshop in Indonesia should be sent to ASEAN Member Countries for comments by the end of January 2009. ASEAN Member Countries should submit their comments to Indonesia as the ASEAN Focal Point for Animal Vaccines by the end of February 2009. The comments will be collated and tabled for discussions at the next Meeting of National Focal Points for Animal Vaccines which will be held in Indonesia, tentatively in April 2009.
2. The Manual of ASEAN Accreditation Criteria for Animal Vaccine Testing Laboratories should be reviewed and revised in accordance with the OIE standards and other relevant international standards. This issue should be included as an agenda item at the next Meeting of National Focal Points for Animal Vaccines which will be held in Indonesia, tentatively in April 2009.
3. A Task Force should be established for the review of Manual of ASEAN Accreditation Criteria for Animal Vaccine Testing Laboratories; as well as for the proposal of the job scope and the criteria for selection and nomination of technical assessors of ASEAN Animal Vaccine Testing Laboratories. The Task Force would explore the feasibility and implementation of an ASEAN Certifying Body for technical assessors. The Task Force to be chaired by Thailand should prepare the draft for discussion at the next Meeting of National Focal Points for Animal Vaccines which will be held in Indonesia, tentatively in April 2009.
4. Indonesia, as the ASEAN Focal Point for Animal Vaccines, should send an official letter including the selection criteria and job scope to all ASEAN Member Countries for the official appointment of National Focal Points for Animal Vaccines.  
The criteria for the selection should include
  - (1) Appropriate qualification such as a degree in veterinary science or equivalent
  - (2) Preferably at least 5 years experience in animal vaccine quality control or in charge of animal vaccine regulation

5. ASEAN Member Countries should continue to collaborate within the Region and to continue cooperation with international organizations in order to establish the harmonization of ASEAN Standards for Animal Vaccines. Twinning projects between ASEAN laboratories and OIE Reference Laboratories and Collaborating Centres should be encouraged to improve capacity and expertise for the region. In particular, the ASEAN Animal Vaccine Testing Laboratories should explore the possibility of developing a proposal for an OIE Certified Laboratory Twinning Project.
  
6. Malaysia be nominated as the venue for the next workshop, preferably in October-November 2009, with the topic of "Risk Analysis for import, distribution and handling of animal vaccines".