Adopted 39th AMAF Meeting (28/9/2017)

MECHANISM FOR THE ASEAN REGISTRATION OF ANIMAL VACCINE

MECHANISM FOR THE ASEAN REGISTRATION OF ANIMAL VACCINE

Table of Contents

MECHANISM FOR THE ASEAN REGISTRATION OF ANIMAL VACCINE

1. Introduction and Scope

In principle, the mechanism for the registration of animal vaccines covers several procedures for preliminary review among ASEAN Member States, such as below:

a. The registration procedure,
b. sample supply and testing in the laboratory,
c. Determination of the registration code,
d. Renewal and the revocation of the registration of animal vaccines.

This mechanism will provide only the point of view of each National Animal Vaccine Authority and/or National Policy.

2. Confidentiality agreement and Declaration of Interest

In principle, all parties that be involved in reviewing procedures must be declared the interest to avoid any conflict or bias. Moreover all information that related to applicants and/or products must be secured by the nature.

The ASEAN Secretary shall ensure that each member state has the policy to show the transparency and independency

3. Expense and fee

All expense and fee are under the responsibility of the applicant and managed by the ASEAN Secretariats.
The expense and fee are included but not limited to ;
i. ApplicationFee
ii. Testing Fee
iii. On-site Inspection Fee
iv. Courier cost (if necessary)

The applicant shall bear the relevant expenses and fees to the animal vaccines testing laboratory, including but not limited to the application process, on site inspection, laboratory testing, and courier charges. Such fees should be aligned to the official fees charge by the laboratory for the same amount of work done.

4. Language and Country Specific Requirements

All documents must be written in English.

5. Registration procedure

All animal vaccines that will be distributed in ASEAN countries should be registered. The producer manufacturer or importer shall submit an application form of ASEAN registration of animal vaccines as follows:

a. Preparation and Submission of Registration Documents.

1) Application Forms for the ASEAN registration of animal vaccines are available at the National Focal Point for Animal Vaccines ANFPVP, Animal Vaccine Authority of ASEAN member state or can be downloaded from http//www.asean.org
2) Complete the application forms (Attachments A – L).
3) Submit the application forms and related documents to the National Focal Point for Animal Vaccines ANFPVP of ASEAN member state for the purpose of preliminary evaluation.
4) Vaccines produced by AMS must be registered with theAnimal Vaccine Authority in the country of origin. For imported vaccines must be registered with one of AMS prior to submission.

b. Document Evaluation

1) Preliminary evaluation will be done by ANFPVP of the state of applicant. Complete documents shall be sent to the ASEAN Secretariat to be distributed to ANFPVP of AMS by email within two (2) weeks after received.
2) Comments from National Focal Points for Animal Vaccines ANFPVP should be sent to the National Focal Point for Animal Vaccines ASEAN Secretariat by email within 90 working days.
   Even if there are no comments all National Focal Points for Animal Vaccines should acknowledge receiving both the application forms and registration documents.
3) The recommendation by the ANFPVP of AMS may be as follows:
   a. Approved if the data required are complete and comply with the existing provisions.
   b. Approved with conditions for *[name of country]* if the country has some specific control or regulations.
   c. Approved in principle but it should be supplemented with additional data.
   d. Postponed if lacking important documents, until additional data are submitted.
   e. Rejected due to the presence of prohibited active substance or contrary to the existing provisions.
4) The dossier evaluation result will be conveyed to the Applicant through the ASEAN Secretariat.

4.1 If approved, the Applicant shall submit samples for testing by the accredited ASEAN Animal Vaccine Testing Laboratory or by Accredited Government Laboratory. (ISO 17025)

4.2 If additional information needed the applicant shall send the requested additional data to the ASEAN Secretariat.

The ASEAN Secretariat will distribute the additional data to all National Focal Points for Animal Vaccines ANFPVP of AMS for further evaluation within fourteen working days after received the additional data.

ANFPVP shall submit the evaluation report within 30 working days.

6 Sample supply and testing

6.1 Animal vaccine which has been evaluated and approved must then be tested by an accredited ASEAN Animal Vaccine Testing Laboratory or by Accredited Government Laboratory.

Requirements for the vaccine testing as below;

a. Sample Supply

Animal vaccines for registration must undergo a quality test with satisfactory results and obtain a certificate from an accredited ASEAN Animal Vaccine Testing Laboratory or by Accredited Government Laboratory.

For the purpose of conducting field trials, if required, a protocol should be prepared by the applicant and approved by the ANFPVP of AMS.

b. Sample Delivery

1) Samples delivered must be supported by official letter from the Director General of the veterinary competent authority of AMS
2) Animal vaccine samples must be delivered in a suitable condition.
3) The number and other requirements of samples must comply with the requirements of the testing Laboratory.

c. Sample Testing

1) Sample of animal vaccine will be tested according to the ASEAN Standard for Animal Vaccines.
However, the animal vaccines which is not available in ASEAN Standards shall be tested in accordance to the internationally-

accepted standards (Examples: OIE Manual of Diagnostic Reagents and Animal Vaccines, WHO, British Pharmacopoeia, European Pharmacopoeia, Code of Federal Regulation of USDA, United State Pharmacopoeia).

2) Assay fees shall be paid by the Applicant.
   If the vaccine meets the requirements, a Certificate of Analysis will be issued by Testing Laboratory or by Accredited Government Laboratory.
3) If the vaccine does not meet the requirements, it will be declared as “Unsatisfactory Serial”. Applicant is allowed to resubmit the samples with new batch number, but must be completed with the requirements as mentioned in article 6 part b.
4) For vaccines where no ASEAN-accredited laboratory is available to conduct testing, this could be tested in the Government Laboratory and an on-site visit of the manufacturing establishment by an ASEAN team will be conducted to follow-up on the quality control of those vaccines. The inspection will be funded by the Applicant.

d. On-site Inspection
   1) If necessary, an on-site inspection of the manufacturing establishment laboratory shall be conducted by the National Focal Point of applying country and one member of ANPFAV from other country to assess the GMP compliance.
   2) All expenses relative to this activity shall be borne by the applicant.
   3) The report of the on-site visit shall be submitted to ASEAN Secretariat for future reference.

   For GMP assessment for non-domestic manufacturers is based on GMP certificate and/or Certificate of Pharmaceutical Product (CPP) issued by competent national regulatory authorities from country of origin. However, Thai FDA reserves the right to conduct GMP inspection of non-domestic manufacturers in case of any suspicious circumstances.

e. Final Report
   The Certificate of Analysis issued by the ASEAN-accredited Laboratory or by Accredited Government Laboratory. or Government Laboratory shall be submitted to ASEAN Secretariat and circulated to the ANFPVP of AMS for their information.
   1) ASEAN Secretariat shall provide the applicant with the Certificate of Analysis.

7. Assignment of registration number

ASEAN Secretariat shall issue the registration number after all requirements meets.

a. Registration Number
   1) A Registration Number shall be assigned to an animal vaccine that has met all the requirements.
   2) Animal vaccine which has passed the evaluation can be issued a Registration Number which is valid for five (5)years. The validity of the renewal registration number of vaccine is for five (5) years.
   3) The Registration Number shall be composed of the suitable registration codes as follows:

b. Registration Code
   Through a Registration Number, information concerning the said vaccine can be identified as follows:
   1) The status of the registration number: whether it is a permanent “P” or temporary “T” one.
   2) Code of imported product from outside ASEAN country or local product of ASEAN country.
      Any product from outside ASEAN is made code “ I “ (Imported) and local product of ASEAN country is made code “ A “ (ASEAN).
   3) Year and Month of registration
      The first two figures after letter “I” or “A” indicate the year of the registration, while the subsequent two indicate the month issued.
   4) Numerical registration of veterinary drug
      The numbers following the month of registration indicate the numerical registration number.
   5) Specification of veterinary drug
      The first letter at the end of the registration number indicates the category of animal vaccine, that is V for vaccines. The second letter indicate vaccine classification, that is K (Killed Vaccine), L (Live Vaccine), while the third letter indicate the form of final product of vaccine, namely S (Solution), FD (Freeze Dried), or F (Frozen).

      For example, the Registration Number for a live vaccine :
      P-A-0804-0001-V-L-FD
      where,
      P = Permanent
      A = ASEAN
      0804 = Year 2008 Month of April
      0001 = numerical number (first vaccine registered in 2008)
      V = Vaccine
      L = live
      FD = Freeze-dried

8. Renewal of Registration

a. Renewal of application must be done one (1) year before expiry.

b. In principle the process of renewal is as follows:
    1) The Applicant shall submit an application including the PSUR and pharmacovigilance-related Information to the ASEAN Secretariat.
    2) ASEAN Secretariat will distribute and continue as article 5 part b. 2) and 3) until all dossier declare approved for renewal.
    3) The Applicant shall submit samples for testing as described in Para 26: Sample Supply & Testing (a) to (e).
    4) A Renewal of Registration Number will be assigned as described in Para 37 then will be followed Code R and number (Example: P-A-0804-0001-V-L-FD-R1 is meaning the vaccine has been renewal registered for first time).
    5) The old number will be maintained for record purposes.
    6) The evaluation results will be reported at the next ASWGL meeting.

9. Variations or Amendments

After granting the ASEAN registration, the applicant must be accountable for submitting any variation or amendments which related to safety, efficacy, quality, environmental risk and product information including label and package inserts.

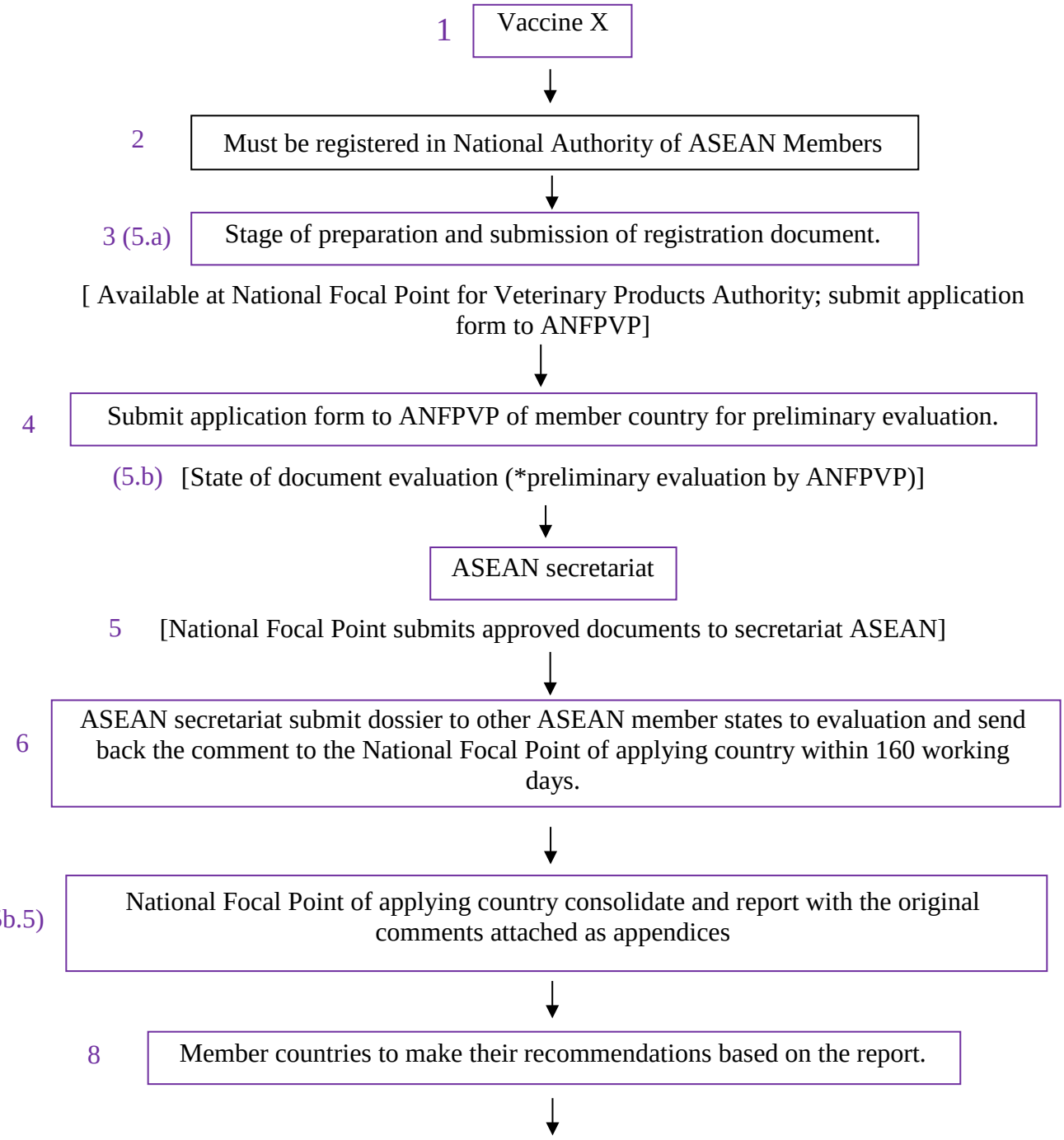
Procedure, criteria and descriptive information for variation will be stated in another ASEAN guideline.

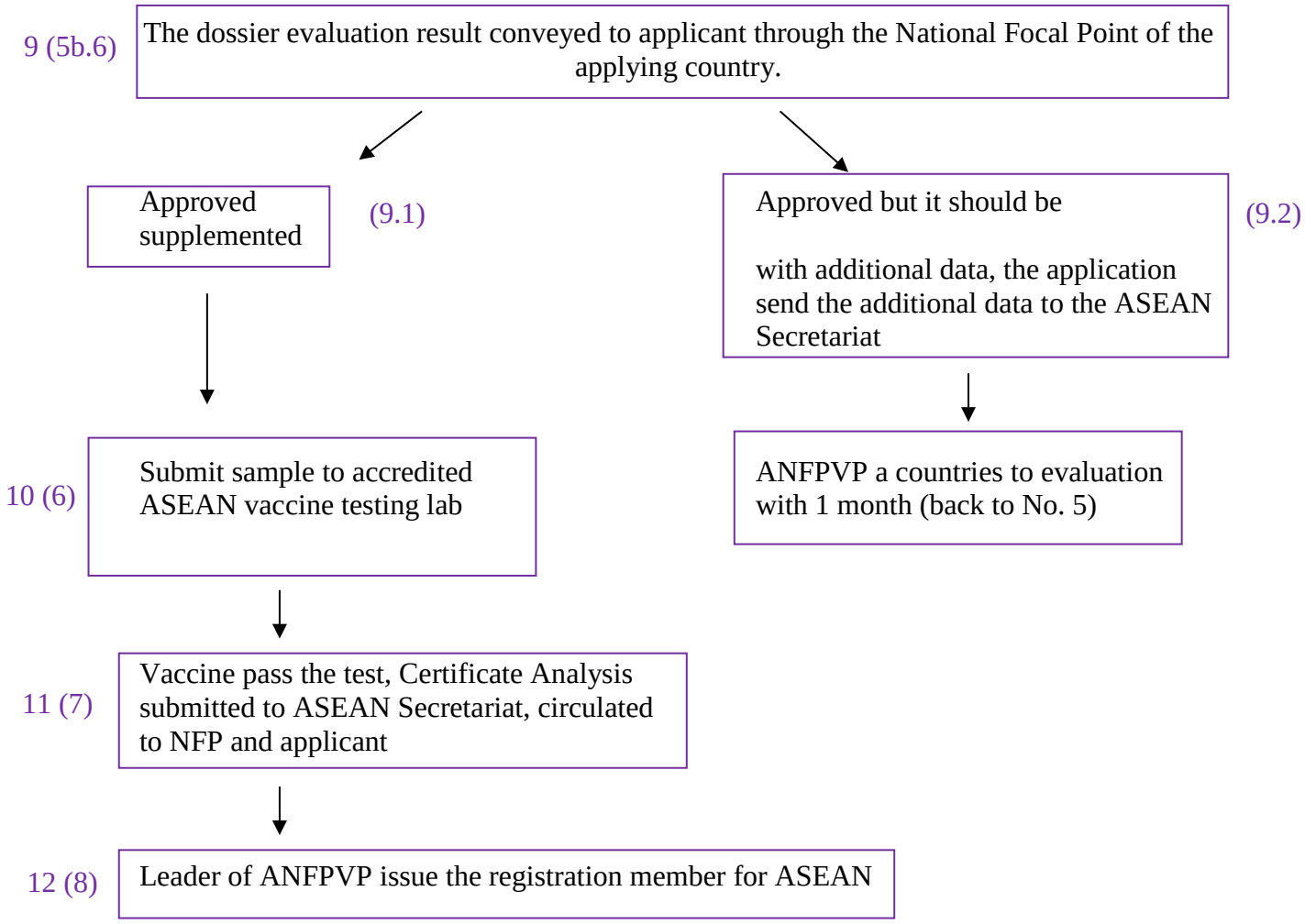
10. Revocation of Registration

If there is any evidence or concern related to safety, efficacy to animal, human or environment, ANFPVP will request the applicant to come into the re-evaluation procedure and continue as article 5 part b. 2) and 3) until all dossier declare approved for re-evaluatedprocedure.

If the applicant does not comply with this re-evaluatedprocedure orthe result is rejected, the registration must be revoked by ANFPVP.

FLOW CHART


1
Vaccine X
2
Must be registered in National Authority of ASEAN Members
3 (5.a)
Stage of preparation and submission of registration document.
[Available at National Focal Point for Veterinary Products Authority; submit application form to ANFPVP]
4
Submit application form to ANFPVP of member country for preliminary evaluation.
(5.b) [State of document evaluation (*preliminary evaluation by ANFPVP)]
ASEAN secretariat
5 [National Focal Point submits approved documents to secretariat ASEAN]
6
ASEAN secretariat submit dossier to other ASEAN member states to evaluation and send back the comment to the National Focal Point of applying country within 160 working days.
7 (5b.5)
National Focal Point of applying country consolidate and report with the original comments attached as appendices
8
Member countries to make their recommendations based on the report.


9 (5b.6)
The dossier evaluation result conveyed to applicant through the National Focal Point of the applying country.
Approved supplemented
(9.1)
Approved but it should be
with additional data, the application send the additional data to the ASEAN Secretariat
(9.2)
10 (6)
Submit sample to accredited ASEAN vaccine testing lab
ANFPVP a countries to evaluation with 1 month (back to No. 5)
11 (7)
Vaccine pass the test, Certificate Analysis submitted to ASEAN Secretariat, circulated to NFP and applicant
12 (8)
Leader of ANFPVP issue the registration member for ASEAN