FMD VACCINE REGISTRATION -ASEAN PROCESS

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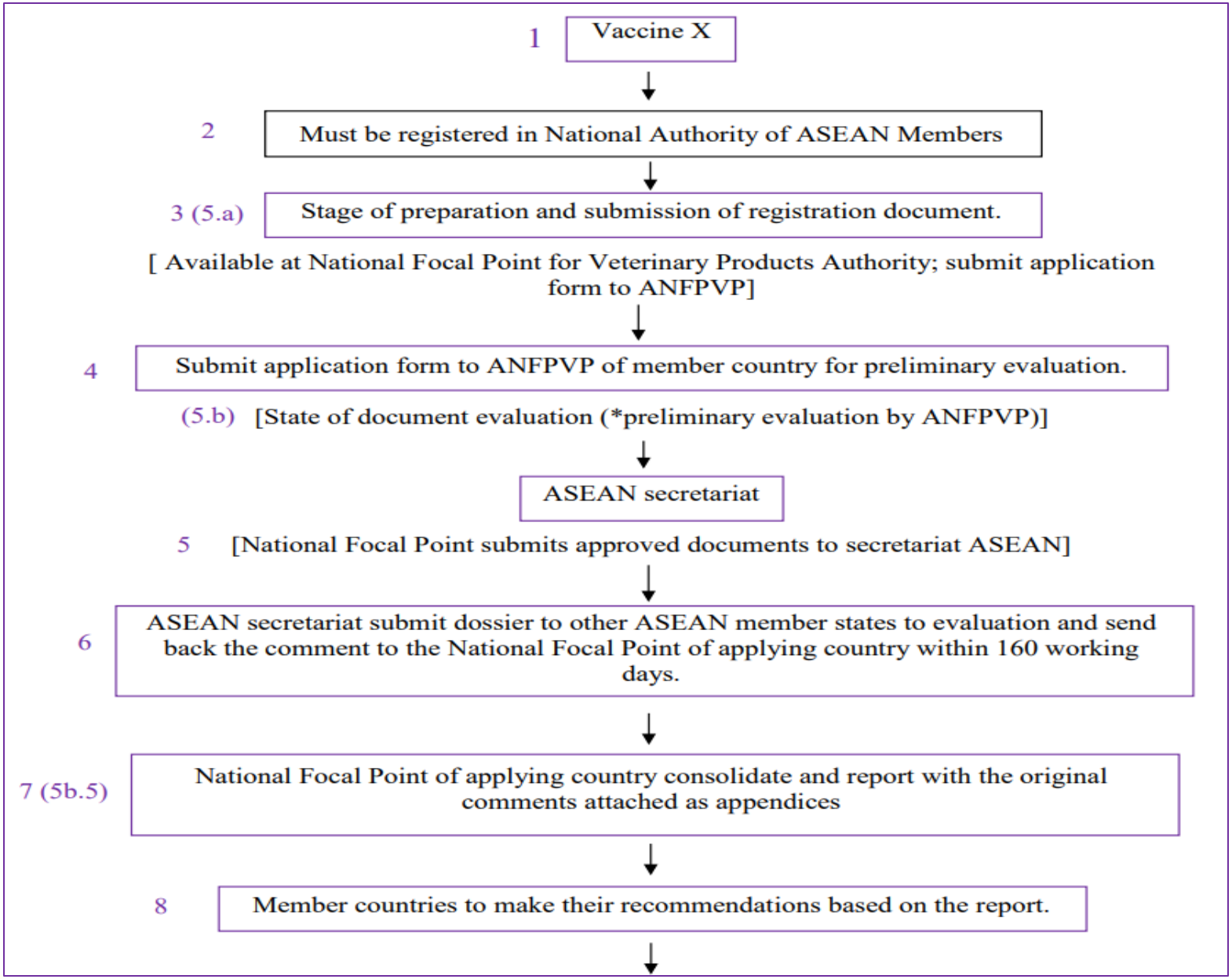
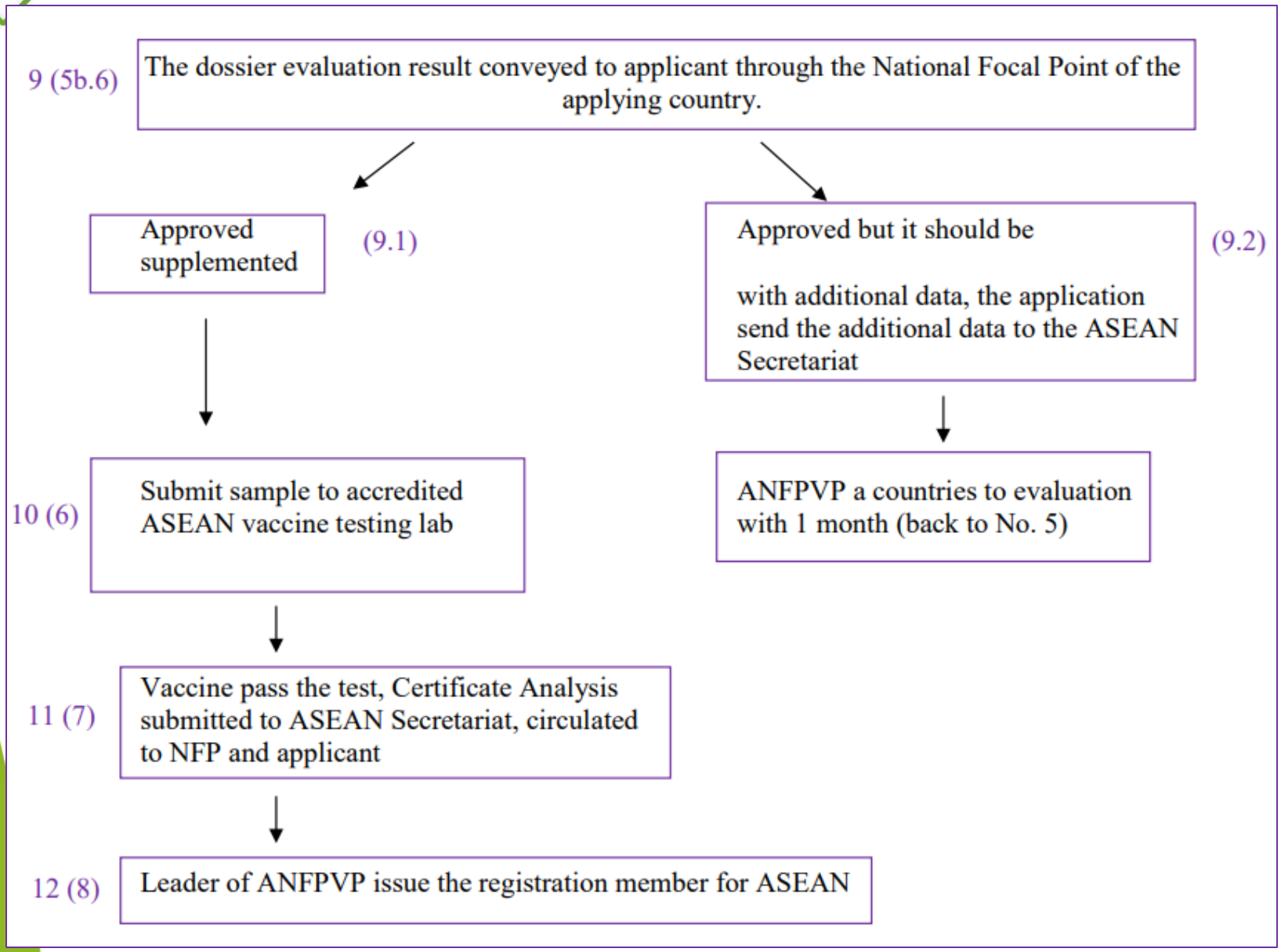
Procedures For Preliminary Review Among ASEAN Member States

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.

Flow Chart Registration Process



Flow Chart Registration Process



Confidentiality Agreement and Declaration of Interest

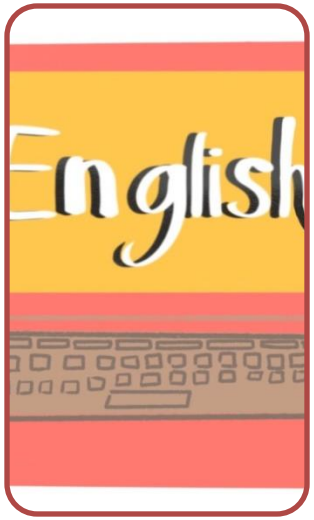
- In principle, **all parties** that be involved in **reviewing procedures** must be declared the interest to **avoid** any **conflict or bias**. Moreover all information that related to applicants and/or products must be secured by the nature.
- The ASEAN Secretary shall ensure that each member state has the policy to show the **transparency** and **independency**

Expense and Fee

a. **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. Application Fee
    ii. Testing Fee
    iii. On-site Inspection Fee
    iv. Courier cost (if necessary)

b. 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.

Language and Country Specific Requirements



All documents must be **written** in **English**

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.

b. Document **Evaluation**

Preparation and Submission of Registration Documents

Application Forms (Attachments A – L)

- A Composition
- B Manufacturing Process
- C Finished Products Examination
- D Raw Material Examination
- E Stability Testing
- F Pharmacology Strength
- G Clinical Trial Publication
- H Packaging
- I Sealing
- J Labels and brochures
- K Finished Product Sample
- L Documents Certification

Document Evaluation

ANFPVP shall submit the evaluation report within 30 working days

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.

Sample Supply And Testing

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 :

- Sample **Supply**
- Sample **Delivery**
- Sample **Testing**
- **On-Site** Inspection
- **Final** Report

Assignment of Registration Number

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

Assignment	Validation
• A Registration Number shall be assigned to an animal vaccine that has met all the requirements.	• 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.**


Thank you!