
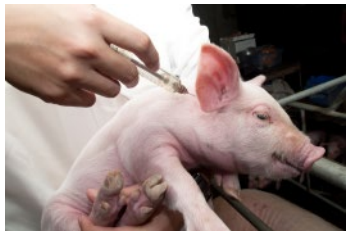



Insight Report - Vietnam:
ASEAN Animal Health Regulatory Benchmarking Survey

Prepared for: Asia Animal Health Association

Report date: 21 September 2018

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Report content

Background & Study Objectives

The 1st ASEAN Animal Health Regulatory Benchmarking Survey…

Background

AAHA (Asia Animal Health Association) is conducting a study to review, track and benchmark the veterinary products' regulation framework and practices across 7 ASEAN countries, namely Thailand, Myanmar, Malaysia, Indonesia, Philippines, Cambodia and Vietnam.

Scope of work

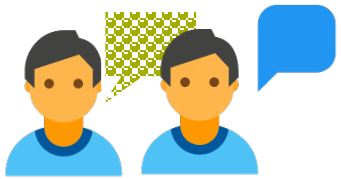
This is the **1st and 2nd phase of a 4-phase project**. In this phase, opinions are derived from business and regulatory managers in animal health (AH) companies. The discussion topics are:

- Assess the impact of regulatory framework that impacted AH industry
- Evaluate the adoption of technology/innovation within the AH regulatory framework
- Gauge the extent of technical harmonization within each country, and across the region
- Evaluate the readiness of the AH regulatory framework for the 21st century

Who do we talk to? How are interviews done? Where we conduct the study?

Total interviews: N=10

Respondent profile	Sample, n=
MNC Business Managers	4
Local Business Managers	1
MNC Regulatory Managers	4
Local Regulatory Managers	1

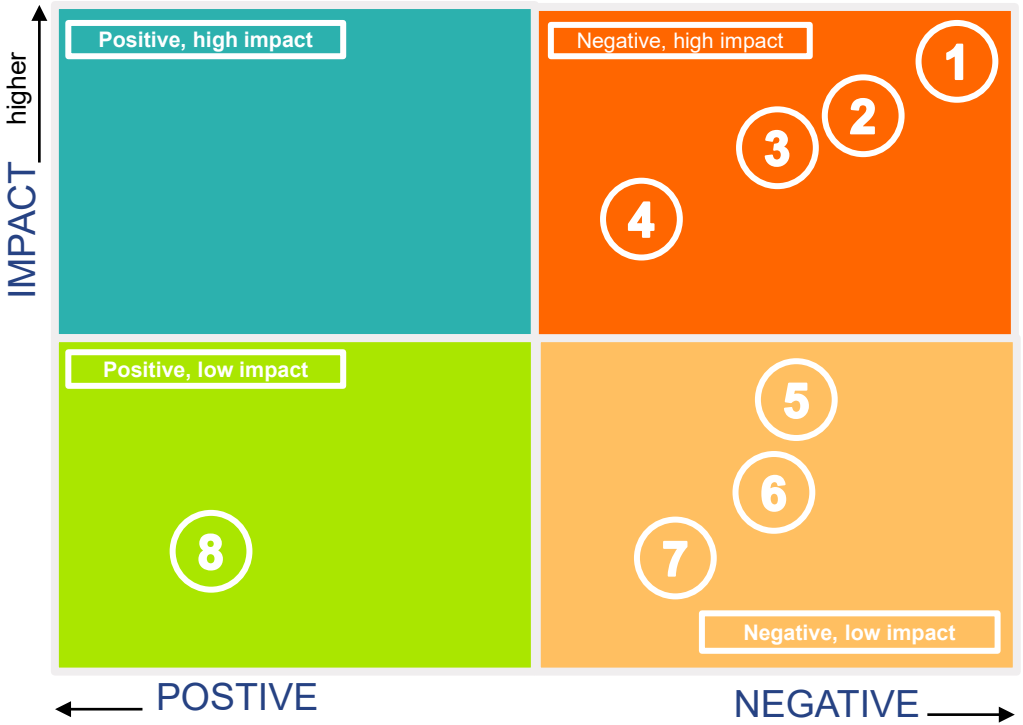


1- 1.5 hours face-to-face / phone interviews with targeted managers

List of respondents are provided by AAHA or free find by Kynetec and approved by AHAA

Challenges faced with regulatory bodies/regulation : Bringing products to market

In Vietnam, the main challenges in stringent product registration, yet with limitation in testing centers with good facilities and innovative testing protocols



IMPACT refers to the impact of this development/topic/change to the AH industry

POSITIVE refers positive development/topic/change, whilst NEGATIVE refers to negative development/topic/change

1. Capability and capacity for the import checks of AH products
2. Unable to meet the predictable timeline
3. Lack of testing centre for innovative vaccines registration
4. Difficulty in field efficacy trial for innovative vaccines
5. Loose enforcement on the regulation
6. Lack of e-technology in product registration
7. Slow in upgrading the regulation to match innovative products
8. Prioritize innovation for swine, poultry and shrimp

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The lack of lab facilities caused delay in product registration, hence innovative vaccine products are not available in market in a timely manner

Negative, high impact

Lack of testing centre for innovative vaccines registration

>> Majority professed that the national testing centre is not able to test high technology vaccines because:

- Lack of manpower and lab facilities

  The national testing centre is handling test for both product registration and shipment release at the same time. Moreover, there is only two testing centres available.

- Not having the right / scientific protocol to test innovative vaccines due to lack of knowledgable resources, materials, equipment, machines.

When they do testing, they do their way of testing, which is not actually the right way to test our product in term of efficacy. They take longer time because they don't know the protocol. – MNC

Not only test kit, some substances like serum, antigen, we've to bring from other country to Vietnam. Some company which do not have legal entity to import this kind of substance or test kit to Vietnam, they need to go with the third market, it's very complicated and takes time for the registration. - MNC

Lack of commercial farms for product field efficacy trials and uncertainty in product registration time also are highlighted as major challenges in product registration

Negative, high impact

Difficulty in field efficacy trial for innovative vaccines

>> New veterinary drug must ‘go through’ field efficacy trials except for pharmaceuticals manufactured by priority countries such as US, Australia, Canada, Japan, etc. Both MNCs and local companies said field efficacy trials is difficult because….

- Difficult to find commercial farm for trial and need wait for approval from authority to start trial activities. Some MNCs have concern that testing in commercial farms might not given an accurate result as the animal and environment are not controlled.
- Long process to get the result (1 to 2 years)

Unable to meet the predictable timeline

>> Regulatory bodies generally cannot meet the timeline set in the guideline (time allocated for product registration). This causes loss of business opportunities for AH companies.

For pharma product, generic/me-too-products will take 1.5 to 2 years (time on the guideline is set for 3.5 months).

For vaccines, products will need 3 to 4 years for registration (time on the guideline is set for 1.4 years).

For innovative products, registration can be 3 to 5 years.

There is still complaints on poor enforcement on regulation. Additionally, regulatory bodies are also slow in updating their regulations to match the benefits of innovative products.

Negative, low impact

Loose enforcement on the regulation

>> Both MNCs and local companies claimed that some companies are not following the registration guideline set by the authority. They pay under-the-table for easier (less documents) and faster registration.

- *Actually it is quite difficult for MNC because we cannot do anything illegal. But for local companies or some companies, they do not care much on corruption or bribery, they can be flexible. I think that it is unfair because we have to commit with USA regulation. – MNC*
- *If you want it to be faster, you have to pay, and you need to know how to pay. - Local*

Slow in upgrading the regulation to match innovative products

>> Few managers said that the regulatory bodies are welcoming innovative products but lack of regulation to support the usage of innovative products.

There was a biochemical product used for castration in boar. However, the product did not perform well in the market as pigs that were injected with this product is still considered non-castration pig, hence Grade B (not Grade A).
(According to the law in Vietnam, the carcass grade was claimed to be Grade B if the testis is not removed).

Vietnam is lacking behind other ASEAN countries in terms of e-registration system. This created additional work for companies.

Negative, low impact

Lack of e-technology in product registration

>> Some managers are not satisfied with the current registration system as it is not online and not transparent.

They have to travel to the Department of Veterinary to submit documents and make payment.

There is no tracking system for the registration documents or progress.

Slow email replies from the regulators for any queries.

Swine, poultry and shrimp production sectors has higher demand on innovative products as Vietnam is one of the major country producing products for these species.

Positive, low impact

Prioritize innovation for swine, poultry and shrimp **

>> One MNC believed that innovation for AH products for swine, poultry and shrimp are prioritised by the authority as Vietnam is one of the top country producing products for these species, thus high market demand.

Moreover, authority is not very demanding in term of registration requirements, so when there is any innovative products for swine, poultry and shrimp that are available in EU / US, authority will approve the registration.

Most innovative products for these species are available in Vietnam.

The drawback is low capability and capacity of authority to conduct product quality test and/or field efficacy test which delay the approval timeline.

** This is considered low impact as it is mentioned only 1 respondent. Potentially this could be high impact to help Vietnam to be leader in meat protein producing country. O Other managers commented this is just expected, so did not considered this to be a major topic for discussion.

Currently, the most expensive and challenging aspect is field efficacy trial followed by product quality test.

Most expensive

- **Field efficacy trial** requested by DAH.

  AH companies have to bear the cost for buying animals (poultry or swine), feed, transportation and fees to AH experts to run the trials. The cost is around 10 to 20 thousands US Dollar.
- Local managers said that product quality test for vaccines is most expensive…

  To test a vaccine with 1 antigen is around 50-70 million VND. It costs 150-200 million VND to test a vaccine with 2 to 3 antigens!
- Few MNCs said the registration in Vietnam is very cheap!

Most challenging

- The most challenging aspect in **product registration** is - - **field efficacy trial**

  Difficult to find farm and materials to run trial, wait for approval to start trial, not appropriate trial conditions (animals and environment), long process to get result.
- Few managers mentioned product quality test for vaccines…

  Different protocol (from what were used by the manufacturer) were used to test the product, thus not able to reflect (real) product efficacy.

  Lack of manpower and facilities – takes about 6 months for vaccine

Majority think that the challenge will remain the same in next 5 years as the regulators will not afford to set up trial farms / experimental station / more labs.

AH companies complained about the intense pressure of quality control by regulators in Vietnam and how these inspections impacted labelling and marketing activities.

Negative development

Capability and capacity for the import checks of AH products

In 2016, regulatory bodies started to have stricter control on quality of imported products. All AH products are checked. Please refer to pg.32 and 33 for more details on requirements and frequency of shipment tests.

Everyone professed that the shipment testing greatly impact their business due to several issues.

- Too frequent and repetitive. Some managers think that the shipment test is not necessary because products were tested during product registration and there are also post-marketing inspections carry out in the market.
- Very time consuming (takes 2 to 4 months for vaccines to be released) due to lack of facility (lab) and manpower. This caused delay in bringing vaccines into the market and ultimately influence the vaccination program in farms.
- Shortened shelf life (because vaccines is in storage waiting for testing), forced to lower selling price for some products.
- Inventory cost has increased and cost for testing is not cheap (about 1% to 2% of the shipment).

Suggestion from one MNC is - - is that the test centres should instruct and allow the importer to send the sample directly, no need for officers to choose and re-seal the sample. It would be help much to accelerate the testing timeline.

Additional comments on the capability and capacity for the import checks of AH products

Recent feedback from MNCs

- Timeline for clearance set by regulators is 30 days since declaration date. If the shipment cannot be cleared on time, the importer will be penalized and not allowed to transfer shipment to their own warehouse for 6 months and it is non-negotiable to custom officers!
- Shipment cannot be cleared on time due to lack of manpower for sampling and testing, lack of resources and infrastructure for drug testing, complicated documentation and clearance process.

Open discussion between regulatory bodies and AH companies to solve issues

- Both MNCs and local companies agreed that the regulatory bodies in Vietnam are open to receive inputs from AH companies and willing to solve issues.
- For instance, MNCs had raised the issues regarding the Circular 13 (shipment test) and regulators held a meeting/discussion with all AH companies to debate and discuss on this topic.
- Currently, the revised of the Circular 13 is in discussion with highlight items:

Sampling	➢ Exempt sampling for imported item with small amount (unit net weight under 100g, total weight of 1 shipment under 1kg) ➢ Take sample of 1 batch of 1 product for each shipment (for shipment contains many batch).
Frequency of testing	➢ The special vaccines PRRS, FMD, Rabies, Flu (avian) vaccines will be sampled with the frequency same as normal vaccines (1 per 5 shipments).
Testing	➢ Exempt testing for product still has no testing methodology in appointed testing centres.

AH companies complained about the intense pressure of quality control by regulators in Vietnam and how these inspections impacted labelling and marketing activities.

Negative development | Positive development

Post-marketing surveillance

Issues raised by managers are - - If the retailers /distributors did not store the product well and affect the product content / quality…and during inspection, if the product did not deliver on the specified quality, the product might be deem to be fake and manufacturer will be fined (5 to 10 million VND).

Product labelling

Local managers claimed that inspection is done (too) frequently, and there are constant request for them to update/add more information into the label.

Sometimes the companies failed to follow the requirement because the vaccine package is too small (to add more information) or the old label was printed in large amount, they do not want to waste the printed labels!!

Strict quality control on AH products

Few MNCs commented that testing and inspection required by regulators help to screen out cheap and low quality products especially products from local companies.

Advantage to MNCs as the number of competitors reduced.

AH companies complained about the intense pressure of quality control by regulators in Vietnam and how these inspections impacted labelling and marketing activities.

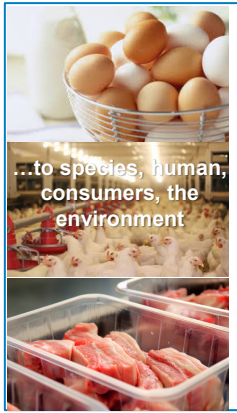
Restriction in marketing (promotional activity)

Feedback from MNCs - - to organize a promotional program, they have to propose and get approval from authority (about one month).

The price discount / free goods are not allowed to more than 50% (of actual price)

Assessment on: safety, manufacture/quality, efficacy & R& D activities

All managers believe their products are safe to use. In term of manufacture/quality, the only challenge is retailers are not storing the product well.



Safety

- MNCs claimed their products are manufactured with very high safety standard, thus product safety is guaranteed.
- Some managers complained about quality of illegal products circulating in the market and how this 'incident' could potentially impacted the reputation of AH products in Vietnam!

"We utilized the safety study from USA, so FDA or USDA set a very high safety standard and we followed this." (MNC)

Manufacture/Quality

- None of the MNCs faced any issue with product quality.
- The challenge for local manufacturers is storage condition in retail stores. Inappropriate storage condition will impact the product quality!

"Substances such as vitamin, after manufacturing, the product is under the sun a day, the content decreases. Then, provincial inspector takes the sample in stores, they test and send a document, which say that the content is under 65%, they post our product is fake online." (Local)

By and large, all companies claimed they did not faced issue with efficacy (from their customers' feedbacks), but efficacy test done by regulators can be concerning due to unsuitable protocol(s) used. Intervention from regulators do dampen R&D activities

Efficacy

- Both MNCs and local companies claimed no issue in term of product efficacy.
- However, majority of the managers struggled with the way their products are tested by the regulators – no using / adoption the right protocol and hence, impacted the efficacy results in the trials/test.

"They test the product in a different protocol, different test also we cannot find out. Sometimes they cannot find out our product efficacy or protective level, so they blame our company, did not read the standard. But different protocol, different standard." (MNC)

R&D activities

- MNCs have no comment regarding R&D as there is no R&D activities carry out in Vietnam, they just bring in the available products.
- Feedback from (one) local manufacturer - - High frequency of visits by authorities on their manufacturing site inspection restrict innovation. They are wary that any innovative R&D activities are been deem inappropriate!

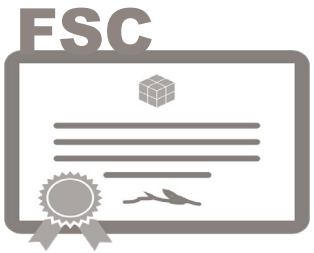
"The companies are allowed to do research but development is inspected too much so we can't develop, we are not dare to expand. My manufacturing site has been overloaded but I don't expand it anymore. " (Local)

In short, challenge in GMP for local manufacturers is the investment cost, whereas MNCs have no issue at all. There's no big challenge in FSC.

Vietnam does not require PIC/S

- Few MNCs commented that the GMP standard in Vietnam is very low compared to GMP standard in US / EU.
- Local manufacturers said they do faced issues with GMP!
  - The GMP requirement is not difficult but the investment cost is tremendous! (Factory cost about 50 to 70 billion VND; land cost about 100 million VND)
  - Small to medium local manufacturers cannot afford to comply with GMP standard.
  - 'Certificate of eligibility for manufacturing veterinary drugs' issued by DAH for local manufacturing site(s) which cannot afford GMP requirements (yet meet some basic standard/condition listed for producing quality drugs)
  - Manufacturing site inspection is very frequent and troublesome. Inspectors will check facilities, equipment, environment, waste disposal, workers, etc. The local manufacturers claimed inspectors are actually trying to get 'bribe' from them….

- For MNCs, there's no major issue in getting FSC as their products are selling in many other countries.
- Only one issue raised - - regulators will reject FSC in some countries like India and China due to different specifications / requirements.



Importance & feasibility of ASEAN technical harmonization

ASEAN technical harmonization are seen to be an advantage for MNC, but problematic to local companies. All however agreed Vietnam is not ready for it as there is shortage of manpower and facilities to implement it

Progress

- Majority are not aware of ASEAN harmonization. Currently, Vietnamese regulatory bodies are improving their regulatory framework by setting up regulations based on global standard, e.g. OIE, FDA or USDA.

Challenges & benefits to the industry

- The current view is that Vietnam is not ready to implement ASEAN harmonization. It lacks facilities (labs, for example), technology and manpower to fulfill ASEAN technical requirements.
- Few MNCs suggested that AH companies should support the regulatory bodies by investing in facilities and technology!
- ASEAN harmonization will benefit MNCs as the template of dossiers is consistent, thus faster and easier registration is expected.
- The concern from local companies is that the small and medium size local companies are not able to compete with imported products if the regulators did not set up regulations to protect them.

AAHA is said to be relatively active in Vietnam, although this view is only voiced by MNCs. Locals will seek support with VVA if there is any issue with regulation/ regulatory bodies.

- MNCs agreed that AAHA plays an important role in Vietnam and agreed AAHA is the right partner to approach and negotiate with regulatory bodies.
- Some suggestions from MNCs are:
  - More dialogs with the regulatory bodies (e.g., find some important/ interesting topics to discuss with them regularly)
  - Advise regulatory bodies in improving regulatory framework
  - Support regulatory bodies in term of knowledge and technology.

- Vietnam Veterinary Association (VVA) is actively in education and providing updated information on the AH industry. Information provided are related to - organizational structure of the AH industry, the policies of animal husbandry, processes diagnosis, about food safety, management and use of veterinary medicines, technical solutions for fighting dangerous diseases.
- This association actively organize scientific seminars to share all animal health related information. It is said to be the main source of information for local AH companies whereas none of the MNC mentioned about this association. From time to time, VVA also act as facilitator to the regulatory (on behalf of the members) if there is any conflict.

Future outlook of ASEAN regulatory framework

Managers agreed that for Vietnamese AH regulatory framework to meet the 21st century there are lots of improvement needed!

Current view

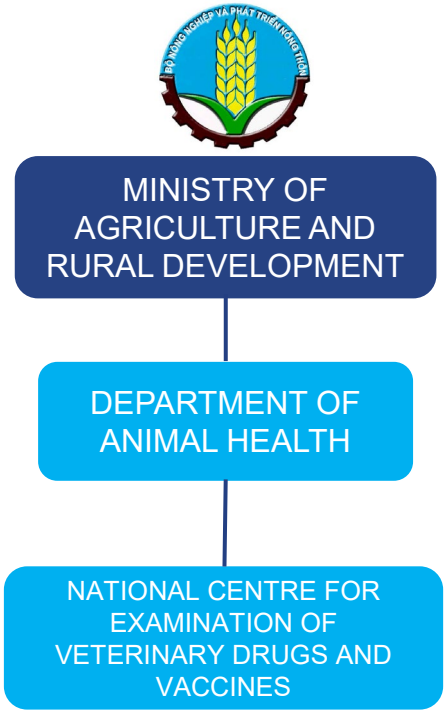
- Most shared the view that current regulatory framework does not 'Fit the 21st Century'. Regulatory bodies set up high requirement but they do not have the capabilities to implement it.
- Mixed views - - some felt that a complete overhaul is necessary to allow the regulatory bodies to review all aspect of framework. These managers suggested using a template from a developed country. Others however said, with some tweaking on the current framework will be sufficient!

Action needed

- Have commitment in timeline for product approval, shipment release and feedback to any queries. If needed - Reduce pressure of quality control – shipment test and market surveillance
- Align product registration requirements with developed countries.
- Exemption of lab test/field trial if the regulators not able to conduct the test in a timely or effective manner.
- More facilities (lab, machines) & manpower – speed up approval & shipment release
- Utilize e-technology for online document submission and progress tracking
- Collaborate with AH companies to set up standard farm for trial

Appendix – desk research

Organization structure of the authority and their roles : 3 regulatory bodies involved in the registration and approval of animal health products



Ministry of Agriculture and Rural Development (MARD)

- Recognize, add products to list of veterinary drugs, list of vaccines, biological products, microorganisms or chemicals used in veterinary medicine

Department of Animal Health (DAH)

- Assessment of registration dossiers for approval
- Post-market surveillance assay (drugs and vaccines)

National Centre for Examination of Veterinary drugs and Vaccines (NCEVDV)

- Analysis of veterinary drugs and imported materials for both registration and quality control
- Supervision and implementing the field trial process of veterinary drug and vaccines

Source: Ministry of Agriculture and Rural Development

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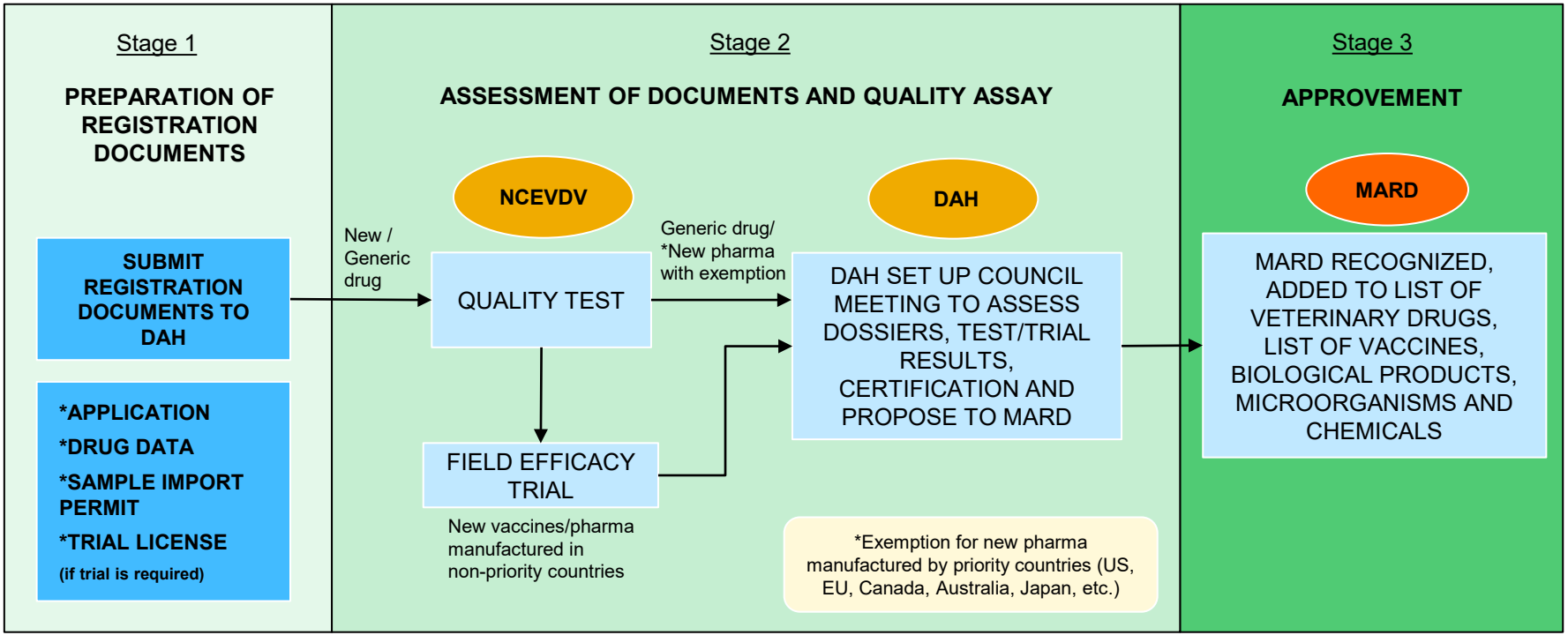
Flow chart of new registration of veterinary drug and number of veterinary drugs permitted for circulation until 2016



Year	No. of Veterinary Product Permitted for Circulation	
	Domestically produced	Imported
2016	6,746	3,318

Source: Ministry of Agriculture and Rural Development

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General requirements of veterinary drug registration

According to Decision No 10/2006/QĐ-BNN of MARD dated 10 February 2006, registration of all veterinary products as follow:

1. The production plant must firstly be registered and certificated.
2. Prepare registration dossier, complete with the application form for sample permit should be submitted to the DAH.
3. Samples of products should be sent to the NCEVDV for analysis.
   a. For locally manufactured products, when the results of this analysis are known and the dossier assessed, then consideration can be made for approval.
   b. For foreign manufacturers, the Committee of Science and Technology under the DAH deals with registration matters in general and with specific points on individual products. Criteria for approval:
   - ✓ Quality
   - ✓ Safety
   - ✓ Efficacy
   - ✓ Stable of product
4. Once issued a registration is valid for two years and the certificate of re-registration is valid for five years.

Source: Ministry of Agriculture and Rural Development

Future trend - Vietnam to ban antibiotics in livestock farming

News reported by Vietnamnet.vn…

In 2017, The Ministry of Agriculture and Rural Development launched the Việt Nam National Action Plan for management of antibiotic use and control of antibiotic resistance in livestock production and aquaculture in the 2017-20 period. With financial support from the United States Agency for International Development, this plan was developed in collaboration with the Food and Agriculture Organisation of the United Nations (FAO) to guide the actions of the agriculture sector and complement the Ministry of Health's national action plan on combating drug resistance in the 2013-20 period. The implementation of the plan is expected to help mitigate the public health risk arising from antibiotic usage in livestock production and aquaculture in Việt Nam.

In 2017, Vietnam will impose a ban on all kinds of antibiotics in livestock farming after 2020, and those currently used in animal feed are only allowed until the end of this year, said representative from the Livestock Production Department under the Ministry of Agriculture and Rural Development. The rampant use of antibiotics in farming has caused immunity among bacteria and damaged the health of consumers due to higher-than-permitted residues. Authorities are now facing many difficulties in controlling the use of antibiotics because farmers can easily buy those drugs without veterinarian's prescription.

Future trend - The animal health agency called on vulnerable localities to ensure vaccination of livestock to prevent dangerous disease outbreak…

News reported by Vietnamnet.vn…

In 2018, The Department of Animal Health (DAH) under the Ministry of Agriculture and Rural Development has warned about the threat of bird flu outbreak following one A/H5N6 bird flu outbreak recorded in the past 21 days. According to a report of the Hai Phong Animal Health Division, the disease first broke out in a farm belonging to Mai Van Tinh. Tình raised 3,200 poultries, of which nearly 3,000 chickens tested positive for A/H5N6 virus. The 200 ducks were not affected as they had been vaccinated. Tinh bought the chickens from the northern province of Thai Nguyen without any quarantine papers and did not give them any vaccine. When they started dying, Tinh did not report it to the local authorities and culled the birds by himself. Meanwhile, foot-and-mouth and blue-ear diseases are also likely to break out among livestock that are unvaccinated or transported to former hotbeds. The animal health agency called on vulnerable localities to augment monitoring, vaccination and control of livestock transportation and slaughtering.

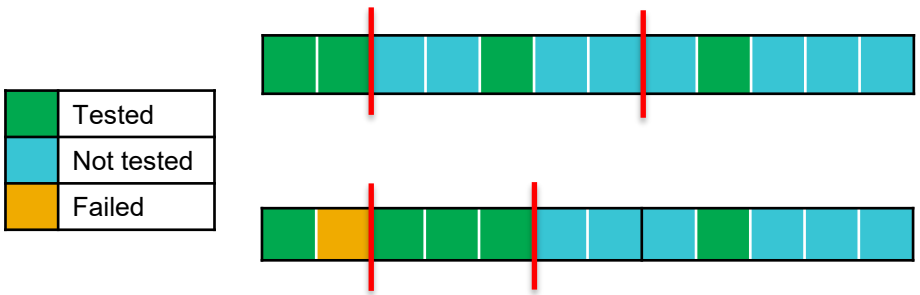
Circular 13 (Article 34): Testing of quality of imported veterinary drugs – General requirements

1. Importers have to submit the dossier to the Department of Animal Health before the shipment arrived, including:
   - ✓ Application (2 hard copies)
   - ✓ Shipping documents: Purchasing contract, Packing list, Invoice, Bill of Lading.
   - ✓ Marketing Authorization license / quota import license
   - ✓ Certificate of Analysis
   - ✓ Artwork & Label (pattern of original artwork and sub-label)
2. If not required to take sample, DAH sign on the Application and the importer can conduct customs clearance normally.
3. If sampling for QC test is required, the importer is allowed to ship the goods to the location stated on the Application of quality control for imported vet medicines, must keep them in 100% intact condition, not allowed to be processed, sold or used and waiting for the test result to decide if they can be released or not.

Source: Zoetis Vietnam

Circular 13 (Article 34): Testing of quality of imported veterinary drugs – Batch release test and frequency of sampling

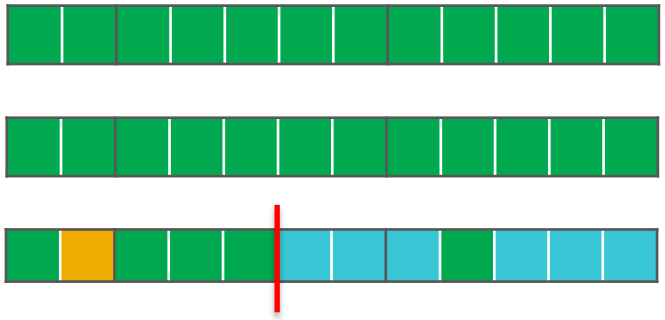
For pharmaceutical, raw material, chemical: analysis test



2 first shipments will be tested. If all passed, 1 shipment among next 5 will be tested randomly and if passed, 1 shipment among EVERY 5 will be tested randomly.

2 first shipments will be tested. If 1 shipment failed, the next all 3 shipments will be tested and if passed, 1 shipment among EVERY 5 will be tested randomly.

For vaccines & antibodies



Sterile, purity and safety test : All shipments to be tested.

Potency test : All shipments to be tested for **PRRS, FMD, Rabies, Flu vaccines**.

Potency test for other vaccines : One shipment among 5 will be tested. If passed, same process. If failed, next two shipments will be tested.

Source: Zoetis Vietnam

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