

# Insight Report – Myanmar: ASEAN Animal Health Regulatory Benchmarking Survey Prepared for: Asia Animal Health Association

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# Background & Study Objectives

# The 1<sup>st</sup> 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 **1<sup>st</sup> and 2<sup>nd</sup> 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:

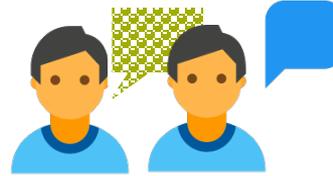
- Assess the impact of regulatory framework that impacted AH industry
- Evaluate the adoption of technology/innovation within the AH regulatory framework
- Gauge the extent of technical harmonization within each country, and across the region
- Evaluate the readiness of the AH regulatory framework for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

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



## Total interviews: N=4

Respondent profile	Sample, n=4
MNC Business Managers	2
Local Business Managers	-
MNC Regulatory Managers	1
Local Regulatory Managers	1

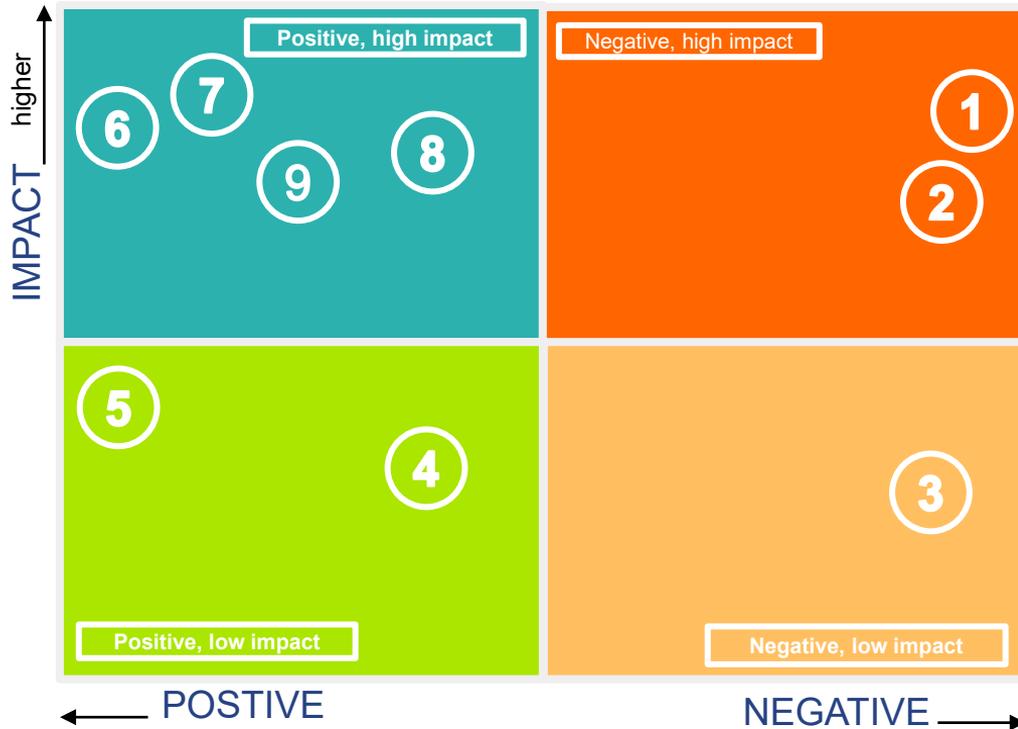


**1- 1.5** hours face-to-face /  
phone interviews with targeted  
managers

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

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

Currently, getting AH products to market is a simple exercise. The key to is get a good local partner as there is no need of product registration, but local partner needs to support in import permit!



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 Weak regulatory enforcement
- ② Prohibit the importation of avian influenza (AI) vaccine
- ③ Local protectionism
- ④ Adopt the regulation & practices of developed countries
- ⑤ Trust MNC AH companies
- ⑥ Simple (basic) procedure (No product registration)
- ⑦ Short and fast procedures
- ⑧ Initiative in upgrading current process – introducing new AH law
- ⑨ Powerful and effective local federation to support registration

# Expectedly, enforcement in Myanmar on AH regulation is weak and corruption is rampage.

Negative, high impact

## Weak regulatory enforcement

- >> One MNC mentioned that the law is not strictly carried out. Some companies do not comply to the law (like sending in fake documents) but are not punished by the authorities. Besides that, illegal products can easily be smuggled into the market too.

These negative phenomena affect those companies who followed the proper procedures in the country. The reasons for the weak regulation enforcement can be corruption and limited knowledge of officers on AH products.

- 🔊 *Another thing is no regulation. No regulation to who breaks their law. They allow the cheating company. All these things can affect the pharmaceutical... because they have to compete with the low quality products and also have the lower price, lower quality. - MNC*

## Prohibit the importation of avian influenza (AI) vaccine

- >> Few MNCs said that the AI vaccine is currently not allowed to be imported and sold publicly in Myanmar. The authority is concerned that mutation might occur from the AI strains and also to avoid the farmer from applying the vaccine incorrectly. But they will likely allow the importation soon.

- 🔊 *They are concerned about human death. Because they heard about human death from AI in China. So our government doesn't allow the operation of AI vaccine. I heard that the information, the government will allow for import very soon. They worried about the mutation and new coming out AI strain that can kill the people. The government they also don't have the laboratory to remind the product quality. - MNC*

To bring product to market, foreign AH companies are required to get a local partner (e.g. distributors) to help them deal with regulatory bodies.

Negative, low impact

Local protectionism

- >> One MNC mentioned the issue where the foreign companies cannot submit the documents by themselves to apply for license. They will need a local company or hire a third party to submit the application for importing their AH products.
- 🔊 *They do not really support foreign company, especially Myanmar. Foreign company cannot register the product by themselves, they need a local company to do the registration, for example, even though you sell the brand in the country, you have no right to submit to get the license. They are trying to prevent the foreigner and support or promote the local. We cannot, we have to hire the third party. - MNC*

# One advantage MNC AH companies have in Myanmar is - - the regulatory bodies have better impression of imported products from large reputable agencies in US & Europe

Positive, low impact

Adopt the regulation & practices of developed countries

- >> Few MNC mentioned Myanmar follows the decision made by the major countries (E.g.: EU and US). The authority will approve those AH products that were also allowed to be registered in those major countries. If some AH products were banned, they will likely to ban those products too.
- 🔊 *I think another thing is they depend on the major countries. If major countries banned, for example one product is banned in EU, they will concern too. It is not the correct way. As you know, EU and USA always have different opinion. But they do not do export, so they don't care much about EU. If US don't approve it, they will not approve it too. – MNC*

Trust MNC AH companies

- >> Few MNC mentioned that the authority in Myanmar trust the reputation of MNC companies and willing to approve AH products from them rather than some unknown companies from China, India and etc.!

# There is no product registration process in Myanmar. AH companies will only need to get import license for products they want to introduce to the marketplace

Positive, high impact

Simple (basic procedure)  
(No product registration)

- >> Bringing AH products into the Myanmar's market does not require product registration. The local (distributor) and MNC companies will only need to get the import license to sell their products in the country.

Hence, there is no major issue or difficulty in bringing new products to the market. The authority treats innovative and generic drugs the same – no differentiation.

- 🔊 *This country, we do not need to make product registration. Everything comes in along the region in our country. – MNC*
- 🔊 *Maybe easy to adopt for innovation. They didn't involve so much in innovation to their farmer, this is my opinion, but they did not stop the innovation too. Some countries like Indonesia do not allow the vaccine to get the registration. When we go to Myanmar, they allow to import. - MNC*

Short and fast procedures

- >> Both MNC and local agreed that only short duration is needed to bring AH products into the country since there is no product registration. The timeline is about - - 2 weeks to 2 months.

- 🔊 *Mostly not more than 6 weeks. Yeah same for all product. Because this is the import license. Not register import. Next year they can stop you to import. This is one year to register, easy for them. – MNC*
- 🔊 *The process will take about 45 working days, sometimes shorter and sometimes longer. It depends on the situation at the government body. – Local*

The market expectation is that Myanmar regulation on AH products will change (improved). This could make registration more difficult – more processes involved, but most companies viewed it as positive development as it will help regulate the industry.

Positive, high impact

Initiative in upgrading current process – introducing new AH law

>> Livestock Breeding and Veterinary Department (LBVD) is drafting a new veterinary drug law. The new law will likely to change the current procedure for introducing AH products into Myanmar.

But the new law was postponed for two years and failed to release due to many amendments are needed (advice by OIE). **Currently, the MNCs are concerned because they are not been loop into the discussions. They are concern the new laws might be at their advantage.**

- 🔊 *I was informed two years ago that Myanmar tries to implement registration regulation, but it was postponed. MLF tries to stop the registration. If Myanmar implement registration regulation, that means it is complicated for all animal health companies as a member of MLF to import the product or to produce product. Many arguments and proposals are created and it is postpone. Besides, OIE provide many suggestions to the new law. That's why this drafted law has changed many times. – MNC*
- 🔊 *I think they have to develop the process like other countries in Asia which have the registration process. It is not a problem for us to get the registration. So we can cut off the process of import license which shipment to Myanmar will be smoother than in the past, even though we have to wait for the registration which could take one year. - MNC*

In the industry, MLF is considered strong partner to have as the association will issue approval letter to allow companies to get an import license.

Positive, high impact

Powerful and effective  
local federation to  
support registration

- >> Both MNC and local mentioned that Myanmar has a strong local federation called Myanmar Livestock Federation (MLF).  
MLF has the authorized power to issue an approval letter to the companies before they can apply for import license. They are also the voice of the companies when the AH companies faced any problems in the industry.
- 🔊 *Myanmar has strong association and federation. Association and federation is NGO, is a member of animal health, just like AAHA and AHPA in Thailand. This is very strong. When we have issue, currently we don't have any issue, if we have any issue, we will go to the association and federation (Myanmar Livestock Federation). They can help us voice out our problem faced in Myanmar. - MNC*

By and large there is no major costs or challenges faced in bring AH products to the marketplace. It is however important to have a good, active and trustable local partner/distributors

### Most expensive

#### ▪ **Import license**

Most MNC companies' importation are fully managed by the local distributors. Few MNC mentioned the most expensive part in bringing the product into Myanmar (although no product registration needed) is - - import license.

Local distributors mentioned the most expensive part is the **certificate of quality check**.

The charges are shown below:

Quality checking fee: 90,000 Kyat, valid for a year

Import permit: 52,500 Kyat, valid for 3 months

- 🔊 *We send document and product sample to our distributor. They do the process. No product registration only import license. Not expensive. Only when import because you have to pay for tax 10-20%. Possibly import license will need to pay a little to the government but I am not sure the amount. - MNC*

### Most challenging

- Most MNC mentioned that there is no major challenge faced in bringing the AH products into Myanmar.
- Minority raised 1 issue - - **the recommendation letter** as this letter can only approved by the Director General of LVBD. Thus it's very difficult to book his time!
- In future, both MNC and local believe that the regulation will likely to change - - better framework equipped with product registration and higher requirements. The catalysts are the increasing awareness of consumers and knowledge transfer from international inter-government (E.g.: FAO, OIE and WHO) especially on AMR issue.
- However, the changes need to be well enforced.
- *I like the stricter SOP and the laboratory and the government working...I need everything. I mean the government they check nothing for the product quality. Even they have the SOP, they do not follow. We have to stop this problem. - MNC*

# Challenges faced with regulatory bodies/regulation : Selling & marketing products

The lack of focus by the govt. on AH sector also translate to low investment in facilities, including laboratory for testing in monitoring program.

**Negative development****No proper laboratory**

The laboratory of LVBD is not equipped with the standard R&D facilities and also knowledgeable officers. Thus they cannot carry out R&D (for quality test or disease detection) neither carry out the monitoring program.

**Positive development****No requirement on product labeling**

The regulatory in Myanmar did not make Burmese label mandatory for companies. The companies can only add in Burmese label upon request from customers.

# No major issue with GMP and FSC faced by MNC in Myanmar

- All MNC mentioned that GMP is required for the AH product's importation.
- The government authority focus more on the GMP's expiry but not much on it's validity. Once expired, the companies will need 2 weeks time to get new GMP from manufacturing plant.
- *The government just taking only the valid date. Only the date, don't verify who release the certificate, never follow, just see the date. Usually small players are the one using fake one. Big player they always follow rules and regulations. - MNC*



- All MNC agreed that FSC is required for the AH product's importation.
- There is no major issue in providing the FSC to LVBD. Same as GMP, they will need to replace a new one if expired. The new one might take > 1 month to obtain from manufacturing plant.
- *Yes, needed for every product. I think use the time. I think it's more than one month. Because have approve from the government, the manufacturer plant. We have in Hungary and USA. And some of the France. Separate, vaccine, different. Yes, but I can use the previous document if the document not expired. I can send again to the Myanmar government. It's okay. - MNC*

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

# No issue highlighted with respect to safety and manufacturer / quality for AH products sold in Myanmar



## Safety

- Both MNC and local do not have any problem with safety as the regulation in Myanmar is very simple (without product registration). They follow decisions from other countries' when banning (or approval) of certain products.
  - MNC mentioned Myanmar should have safety trial and MRL. These can make sure the products are safe to animal and residue does not pass down to human after they consumed the treated meat.
- 🔊 *Currently no, I mean for safety. There are some countries have banned products. However the banned product is same for other country, because Myanmar cannot have the laboratory to prove it. They just follow other country, if it is proved, then it is fine. For example, chloramphenicol is a cause resistance and need to ban, so Myanmar just follows. – MNC*

## Manufacture/Quality

- Both MNC and local do not have any major issue with the manufacture or quality for the product registered and selling in Myanmar. Only one MNC mentioned that the LBVD ask for updated GMP if expired.
  - They agreed Myanmar actually follows the major country on the product approval, they usually do not test on the product for quality check.
- 🔊 *I think the safety of low potency. Once there is one consumer report that the product is not safe or there is an adverse effect after consume it, I think this is the issue. – MNC*



None claimed they experienced issue with efficacy of their products. R&D activities is not a concern, as all AH products are imported.



## Efficacy

- Both MNC and local do not have problem with the efficacy as well as the requirement for product registration in Myanmar is very low.
- 🔊 Yes, it should be effective result. Because once customers use it, I mean the regulation needs us to prove the result, its efficiency on the same as what you claim on the label. Once you claimed that this can treat this disease, customer must be able to treat this disease when they use it. – MNC

## R&D activities

- There is no R&D activities conducted in Myanmar on AH product. Both MNC and local only import the AH products from various developed countries.



# Importance & feasibility of ASEAN technical harmonization

ASEAN technical harmonization desired by MNCs. Local companies agreed it can improve the regulatory standard, but the drawback is - - it could make it more difficult for them to do business.

### Progress

- MNC agreed that the harmonization in AH registration currently does not happen in Myanmar. The requirement for Myanmar is different from the standard in most ASEAN countries.

### Challenges & benefits to the industry

- Each country has very different culture and norm which makes it hard for these different countries with different background to compromise each other for harmonization.
- If harmonization implemented in Myanmar, there will be no issue for MNC as the product quality and standard of the MNC is already advance and well aligned with the standard practice.
- It is a very beneficial act as bringing AH products into ASEAN countries will save time, money and effort. The product approved in any ASEAN countries will automatically be approved in another too.

🔊) *Yes, we have to respect the respective country and their local regulation. Just like UK thinks EU Union will try to get the better for them, they try to work together with EU, once UK thinks that Union is not mutual benefited because every country is so specific. They will choose to separate. - MNC*

## ASEAN Harmonization



Expectedly AAHA is not known to most in Myanmar. MLF however is very well known and ‘respected’.



- Local have not hear about AAHA or HFA.
  - MNC heard about the activities done by AAHA in Thailand, Vietnam, Malaysia and Indonesia but they have not heard of any AAHA’s activity done in Myanmar.
- 🔊 *I don't know because I don't hear about it, I only heard about AAHA which has many activities in Thailand, Vietnam, Malaysia and Indonesia. If we faced any problem, we will need to help on our own. - MNC*

- Myanmar Livestock Federation (MLF) is an influential local federation.
- Importation of the AH products need an approval letter in Myanmar. This federation has the power to issue the approval letter for companies to submit to the government agency.
- *This federation has the authority to approve letter, very powerful. MLF is the past of the approval process. This federation helping both local and MNC. Every company needs to import the product to Myanmar, they need the approval letter from MLF to submit to the agency. - MNC*

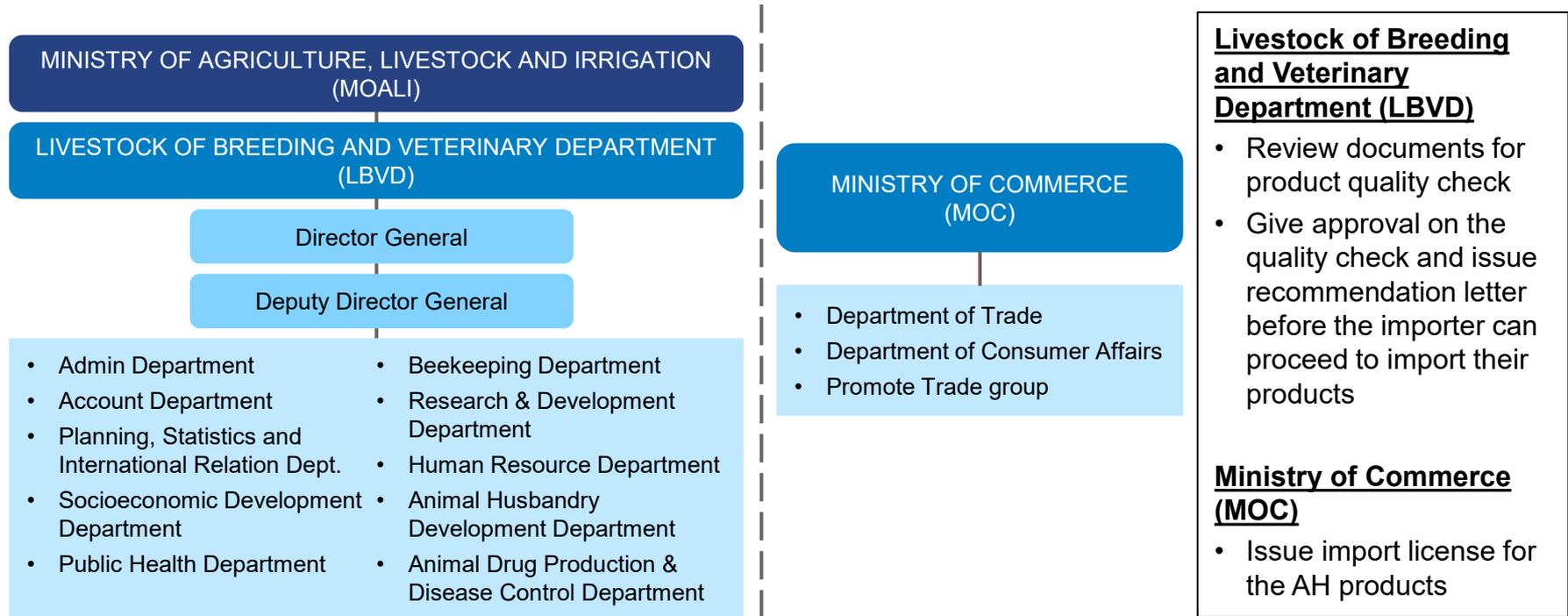


# Future outlook of ASEAN regulatory framework



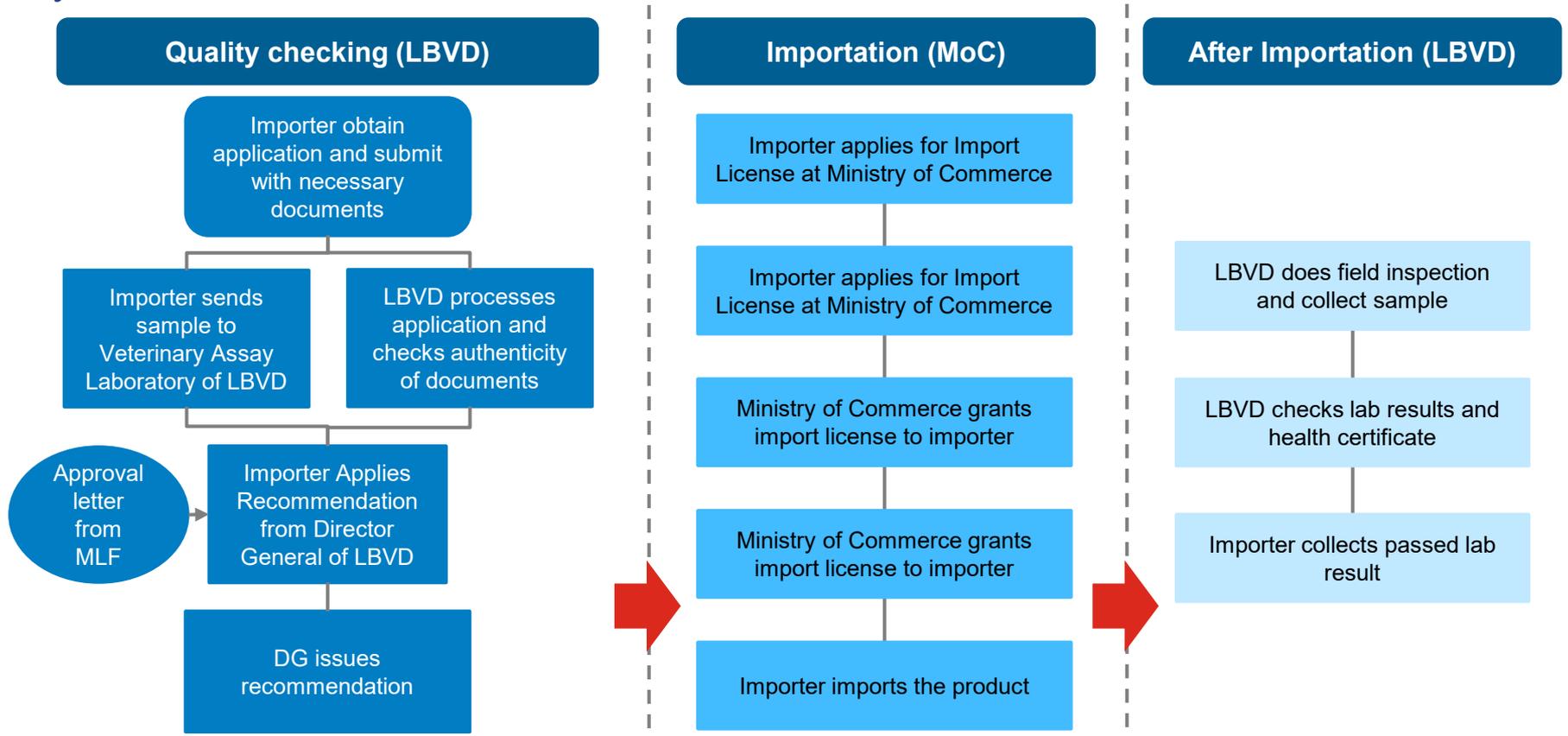
# APPENDIX: Desk Research

# There is only 1 regulatory body involved in the registration and approval of animal health products which is the LBVD



Products	Timeline for import application
Innovative and Generic drug	3 – 4 weeks

# The Regulation Framework for Veterinary Drug Registration in Myanmar



# General requirements for documentation for LBVD

## Requirements for LBVD

1. Import Application Form
2. Approval Letter from Myanmar Livestock Federation (MLF)
3. Laboratory Result
4. Application Letter with Company Letter head signed by company's director (Must be designated to Director General)
5. Original Invoice
6. Sale Contract
7. Company Registration issue by DICA (Directorate of Investment and Company Administration), Form 6 (Shareholders List), Form 26 (Directors' Detail)
8. Import License issued by Department of Trade
9. COA (Certificate of Analysis)
10. GMP Certificate (Good Manufacturing Practice)
11. Free Sale or Product License
12. Product Catalogue

## Requirement for Veterinary Assay Lab

1. Sample (200g)
2. Sample (2 Bot)/ Vaccine (3 Bot)
3. Inspection Request letter with company letter head
4. Certificate of Analysis
5. Composition
6. GMP
7. Product License
8. Free Sale Certificate
9. Dossier
10. Quality Control Procedure
11. Label of products (Producing Company, Registration Number, Ingredients, Pharmaceutical Form, Dosage, Side Effects, Indication and Contraindication, Production Date & Expire Date, Storage Conditon, Bath Number
12. Company Registration Certificate, Import License

# Future Trend

A new “Veterinary Drug Law” will be released in future although the exact released time is not disclosed by officials of Myanmar Government. However, the director of LBVD Yangon vaguely explained that the law will revise current importation process, routine inspection of veterinary products circulating in market, rights to control and sale of veterinary products, and rules that manufacturers need to follow.





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