



Insight Report - Malaysia: ASEAN Animal Health Regulatory Benchmarking Survey Prepared for: Asia Animal Health Association

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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:

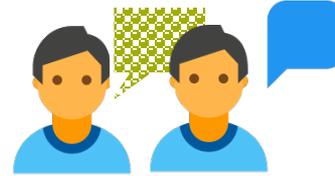
- Assess the impact of regulatory framework that impacted AH industry
- Evaluate the adoption of technology/innovation within the AH regulatory framework
- Gauge the extent of technical harmonization within each country, and across the region
- Evaluate the readiness of the AH regulatory framework for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

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



Total interviews: N=12

Respondent profile	Sample, n=12
MNC Business Managers	6
Local Business Managers	3
MNC Regulatory Managers	2
Local Regulatory Managers	1



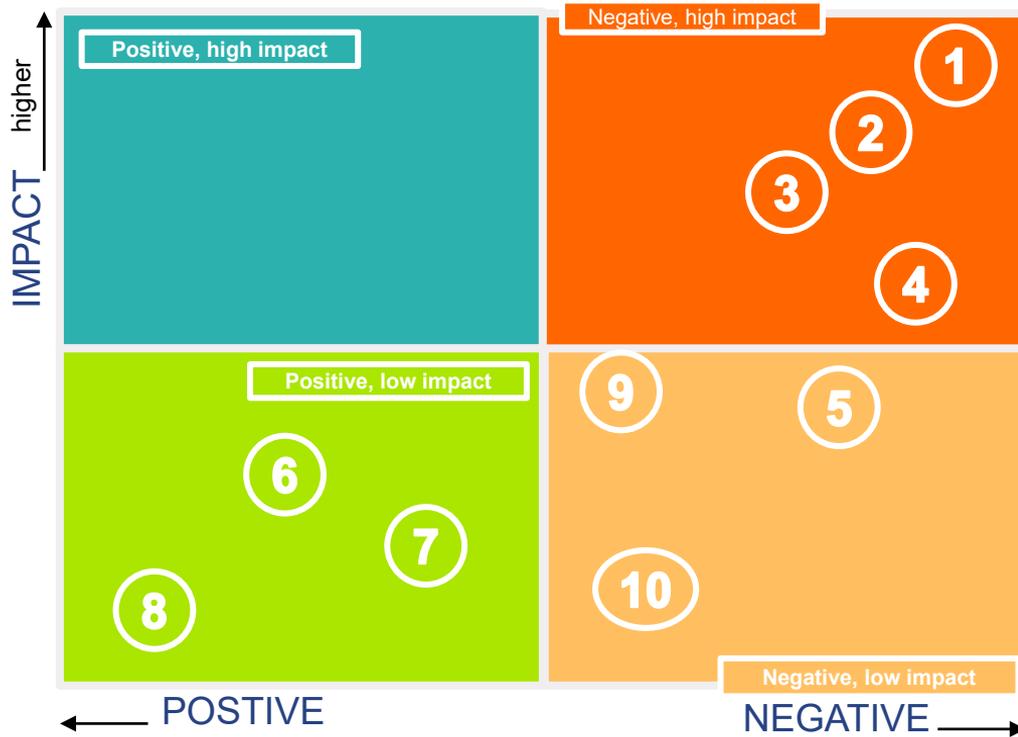
1- 1.5 hours face-to-face /
phone interviews with targeted
managers

*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

The unpredictable time in product registration and difficult standard set for AH products registration are the main challenges faced.

Having said that, we learned that Malaysian regulatory are more engaging nowadays and open to be more collaborative with AH companies to bring new products to the country



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 Delay in registration
- ② Unattainable standard = as pharma products
- ③ Stringent requirements for vaccines
- ④ Inefficient AH regulators / staff
- ⑤ Halal requirements
- ⑥ E-system registration
- ⑦ Waiver of fees for products registered with DVS
- ⑧ The fast track registration process for companion animals' product
- ⑨ Stability data requirements
- ⑩ Limit the no. of vaccines registered

Additional comments on the change in behavior and attitudes of regulatory agencies in Malaysia....

Change of behavior and attitudes of regulatory bodies



- DVS tends to be more lenient and understanding the needs of AH industry as the regulators who work in DVS are mainly veterinarians.
 - They regularly initiative meetings or discussions with manufacturers. They are willing to listen to feedbacks raised during these meeting and will be recorded (minutes) for further action. Such interaction is welcome by manufacturers.
- The regulatory authorities, especially NPRA often show interest in participating seminar organized by the manufacturers. Seminars provide additional knowledge and education to them especially on new technology, product. Eventually this could help to speed up application process (less doubts or query for regulators).

With 3 different agencies involved in registration of AH products, the 'rules' vary. Registration for pharma products with NPRA generally is more difficult compared to other regulatory bodies such as DVS or Pesticide Board

Negative, high impact

Delay in product registration

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

For pharma product (under NPRA), generic/me-too-products will take 1.5 – 3.0 years (time on the guideline is set for 210 working days (roughly 8 months). For innovative products, it can be up to 3-5 years.

For vaccines (under DVS), products will need 2-3 years (at least) for registration, whilst for derma product (under Pesticide Board) it can take 2-4 years for approval (2x longer than the guideline)

Inefficient AH regulators / staff

>> NPRA lacks veterinarians. Many they are (human pharma) pharmacists. There is also lack of training / knowledge transfer to existing staff to allow them to review / approve/review products in a timely manner

There is also shortage of manpower / dossier reader to review all the dossiers/ documents/trials results/etc. required.

Due to govt. practice of swapping regulatory officers to different departments, this also contribute to poor knowledge of AH products.

With 3 different agencies involved in registration of AH products, the 'rules' vary. Registration for pharma products with NPRA generally is more difficult compared to other regulatory bodies such as DVS or Pesticide Board

Negative, high impact

Unattainable standard
– based on pharma
product registration

- >> The registration of animal health pharma product followed the requirements from human pharma products.
To get pharma product registered, companies will need to provide lots of documentation, safety studies and trial results which is more relevant and applicable for human drugs (not animal health).
- >> This situation deter companies to bring innovative products to Malaysia.

Stringent
requirements for
vaccines (and some
extent pharma)

- >> Manufacturers are expected deliver **all** the documents/dossiers, data, trials and certifications (GMP /FSC/COA) listed on the checklist.
Additionally, regulatory body at times asked for additional documents/paperwork that are not in the standard list and expect companies to deliver them

- Following The Feed Act, 2014 (under DVS) all new imported AH products need to register before the pre-shipment from the origin country. Without that, products will be return to suppliers
- For custom clearance, the manufactures must able to provide the approved permit, import license and all the approved documents to the custom officer.

With 3 different agencies involved in registration of AH products, the 'rules' vary. Registration for pharma products with NPRA generally is more difficult compared to other regulatory bodies such as DVS or Pesticide Board

Negative, high impact

Limit the no. of
vaccines registered

>> DVS restricts number of vaccines that have the same function/purpose available in the market. They have the view that the market does not need (more) products!
This restrict the product options for farmers/pet owners as many 'new' generic products are not available in the country.

Although the halal certification had not been a major obstacle for product registration, it does create some hurdles as some companies need to find substitute for some porcine ingredients in their product.

Negative, low impact

HALAL requirements

- >> HALAL certification is not required, BUT authorities will check the content of product to ensure none contains non-halal substance such like porcine. Manufacturers will state whether their product meets the halal requirement in the product dossiers. In recent years, manufacturers are asked to change the content/ingredient of their products to comply with this requirement. This could increase cost, delay registration and re-formulate the product.

Stability data requirements

- >> Minority said NPRA requires all products (both new and old) to have stability data test – Zone 4B for up to 2 years as there is concern on humidity in Malaysia will impact the quality of the product. The requirement also stated that the test needs to be done in Malaysia (not just reports/data from US or EU)



“In the past 4 years, they were requesting stability data zone, 4B and then suddenly now we can’t submit different stability data zone. After a product is manufactured, they need to test it, so they need to put in a condition for 2 years... every 6 months they will test... test... test so to see their specification meet the requirement or not...” (MNC)

The move to E-registration is welcoming. Improvements are still needed as the e-system is yet to be reliable and problem-free

Positive, low impact

E-system /online registration

- >> NPRA is now paperless, hence no manual submission. Reduced workload and time as registration can be done through e-submission. Payment is also online. It is also easier to keep track the registration status. However, current e-system/registration is not very effective (yet) as the program/system is relative slow (e.g. long time to upload documents)

Waiver of fees for products registered with DVS

- >> Reduce the cost of product registration!

The fast track registration process for companion animals' product

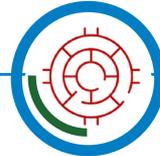
- >> The new initiative from the regulatory bodies to fast track registration process. This will allow manufacturers to import and introduce more products to the market in a more timely manner (no need to go through stringent registration requirements).

By and large, most companies agreed that product registration cost is relatively reasonable for Malaysia. None are concern with the cost. Most are more interested to get their products registered in a timely manner....



Most expensive

- ISO/IEC 17025 cost - - The general requirements for the competence of testing and calibration laboratories
According to local manufacturers, laboratory test required by NPRA to meet the accredited ISO 17025 can only be done in Singapore (need GLP (Good Laboratory Practice)).
- Stability data – Zone 4B
Due to the test requirements (and multiple tests needed), this have significant impact on registration cost
- High registration fees with Pesticide Board
RM10,000 for 1 product, which is about 2x higher than vaccines / pharma products



Most challenging

- Apart from the challenges stated in Slide 7, there are no other difficulty faced **currently** with product registration.
- BUT...there are some concern about PIC/S requirements in the **future**.
 - Without additional (more) reference countries in the future, it might be challenging to get some product registered in a timely manner if the country of origin of these products is not in the list of reference countries.....

Once the AH products are registered, AH companies generally do not encounter significant issue in selling or marketing their products in Malaysia

There are however, a few 'rules' they need to follow and these are said to be manageable.

Negative development

Strict requirement for product labels.

- Labels need to have Malay language (other languages are allowed). Most manufacturers preferred to print the product label in the country of origin, leading to higher cost in marketing and selling AH products in Malaysia

Strict control of sales channel

- Many pharma products can only be purchased upon having vet's prescription.

Need for e-permit (MAQIS – Malaysian Quarantine & Inspection Services) requirements

- In addition to import permit, all vaccines require MAQIS permit

Positive development

High quality of locally produced AH products

- Malaysia is one of the members of PIC/S and regulators ensure locally produced products comply with PIC/S GMP standard. The country's standard is at par with EU countries, hence well accepted by EU or US countries.

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

No issue highlighted with respect to safety and manufacturer / quality for AH products produced locally or imported. Hence, no major improvement needed in the near future.



Safety

- Majority of the AH products are imported from more developed countries with high safety standard. For local manufacturers, all the local production and plant's facility has fully follow the PIC/S GMP guideline that required by authorities.



"We have a product safety sheet on our products...Product safety sheet it will give the information of the expiry date and how to use it, to which animal you need to administer the drugs. We don't face any problem for the safety because to me the farmers also know safety is very important. So, they really do it very well with the safety precautions, the warning in the label." (Local)

Manufacture/Quality

- Both MNC and local manufacturers are satisfied with the quality of AH products produced/manufactured. According to them, it is the interest of the manufacture (at country of origin) to follow the best practice guideline/specification and minimize any possible issue as it is hurt their reputation and business if production line is not running smoothly or their products cannot be exported!



"When we manufacture, we have our own set of specification which is higher than approved specification. If the product is lower than our expectation, we will just scrap it and rerun the whole process. Hence, the quality is also the main strength in our company. For the manufacturing site, because they have been manufacturing for so long and the requirement is so high so...and only get higher (standard) not lower...." (MNC)



Efficacy and R&D are not concerning. All efficacy data will be provided for registration and all R&D/trials done in the country of origin.....



Efficacy

- Expectedly, no specific issues experienced with regards to efficacy. Local trials are not needed for product registration and in the recent years, not unexpected complains received. For local manufacturers, they will do their own lab test for efficacy and the result met all the requirements set out by the authorities.



“Local efficacy study maybe takes around 6 months or year, can further delay the process. Currently, our authorities do not need local trials and can accept efficacy studies from other country, so issue on this front. It will be getting more difficult because I can see that sooner or later they will have done the efficacy study locally. Hopefully in the next 5 years but I don’t hope that happen, it will be more work to do.” (MNC)

R&D activities

- Most AH products are imported, and R&D have done at the origin countries before production and export. This is not a major concern/task/activities for most MNC companies whilst for local manufacturers, R&D is not needed as they focus on generics / feed additives



None deem the above certifications or requirements challenging...



- Only NPRA (or pharma products) requires PIC/S because NPRA Malaysia is PIC/S member.
- None of the companies we talk to faced issue with this requirement at the moment.

- Only NPRA requires GMP for registration and it is not mandatory for DVS (but good to have)
- For imported products, manufacturer will provide local GMP to importers.
- For local manufacturers, NPRA will audit their manufacturing plant once in every 2 years, before renewing the certification.



“To renew GMP, we have to submit the documents, for example, your company profile, all these details everything such as the product spec, COA, your vendor, raw material, your customer, you have done all in proper order”(Local)



FSC



- All products irrespective of local or imported products needs FSC
- To comply FSC requirements, local manufacturers must produce the product locally and sell the product in Malaysia. Besides that, they need to show proof of sales invoice/order in Malaysia.

Importance & feasibility of ASEAN technical harmonization

ASEAN technical harmonization is desired, but unlikely to be achieved in the near future.

Progress

- It is not new discussion about technical harmonization for AH products across ASEAN. Currently, with AH industry followed human pharma standard and it is relatively challenging for some companies.

Challenges & benefits to the industry

- It is challenging to implement harmonization for AH products in ASEAN as different country has different agencies i.e. Vietnam and Indonesia AH products are regulated by 1 agencies, whilst Malaysia and Thailand is regulate by 3 different agencies.
- Furthermore, different country position on the important of animal health and meat production industry is very different. Some ore gear towards exporting countries, others for focus on delivering food sustainability locally.
- If technical harmonization can be successfully implemented...
 - It will benefit the AH industry as the manufacturers use ONE same set of dossiers where it can be use across all ASEAN countries
 - It will also benefit the regulatory bodies - - with standard checklist and accepting the regulation/standard set by other (ASEAN) countries, it will ease regulator affairs staffs' workload and time saving.

ASEAN Technical Harmonization



Although AAHA is known (at least with MNCs), all felt that local organization – MAHNIA is more supportive to their local needs.



- Majority of the MNC manufacturers heard about AAHA but not the local ones. It is considered low profile! It is considered a platform to share AH information within the MNC manufacturers. BUT many managers we talked to do not fully appreciate the role/function of AAHA.....

 *“Actually, we don’t get much from them although we just know that our bosses attend meetings. AAHA is more regional but they don’t really have a local chapter. We do sometime get some articles about from them....” (MNC)*



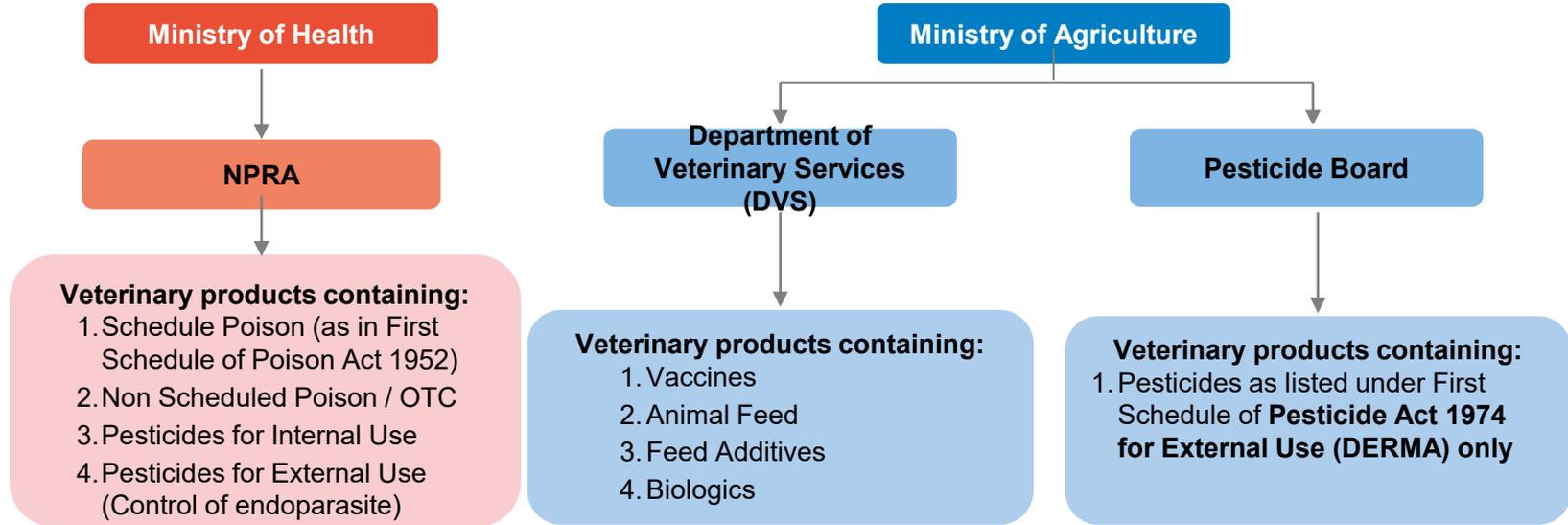
PERSATUAN KESIHATAN DAN INDUSTRI PERMAKAPAN HAIWAN MALAYSIA
MALAYSIAN ANIMAL HEALTH AND NUTRITION INDUSTRIES ASSOCIATION

- Feedbacks from the managers is – local association such as MAHNIA is more ‘approachable’ and visible to them in proactive assisting them in solving regulatory issues.
- Throughout the years, MAHNIA has build a strong connection with the authorities in Malaysia. The organization is not only the voice of the industry, but also farmers. They will organize meetings and have discussion with various authorities on all AH industry matters including updating the authorities on AH trends, voice out the manufacturers’ opinion and etc.
- MAHNIA also helps to educate or clarify queries from authorities when facing doubts / problems on AH products.

Future outlook of ASEAN regulatory framework

Appendix

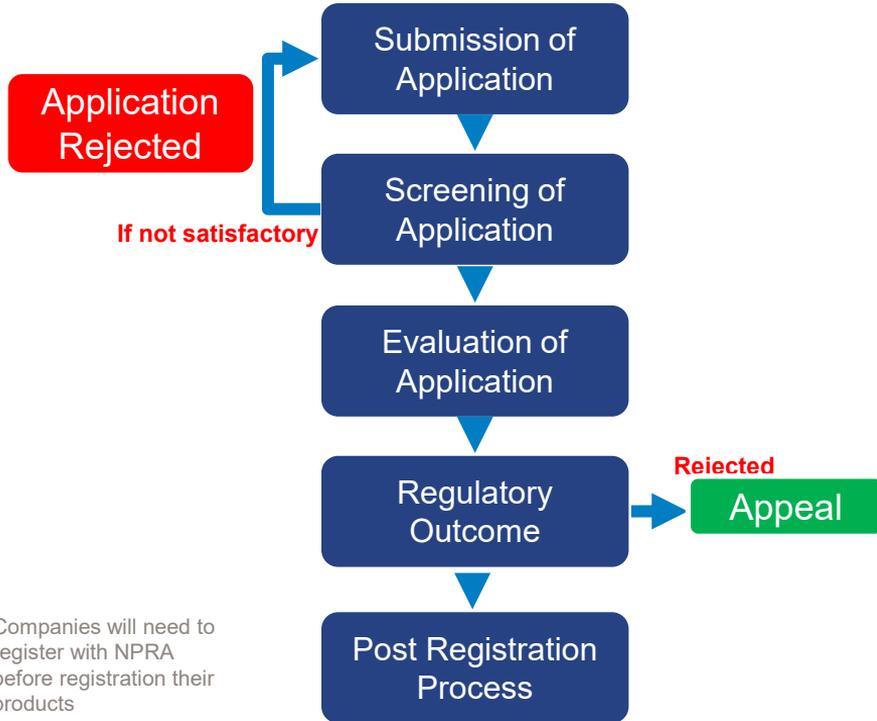
There are 3 regulatory bodies involved in the registration and approval of animal health products



- * Products containing feed additives in combination with schedule poisons will be regulated by the NPRA
- * Products containing pesticide ingredients and combination with scheduled poisons will be regulated by the NPRA

NPRA: Process of registration AH Pharma products

Flow of Registration

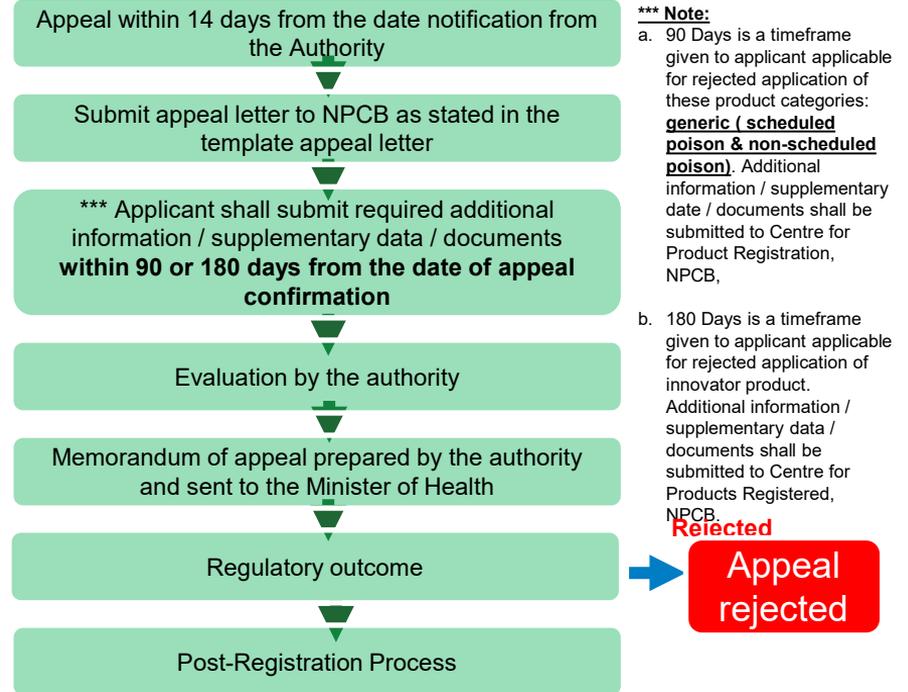


Companies will need to register with NPRA before registration their products

Note:

The same process of appeal is applicable to registration of a product which has been **suspended / cancelled** by the Authority.

Process of Appeal For Veterinary Product



*** Note:

- a. 90 Days is a timeframe given to applicant applicable for rejected application of these product categories: **generic (scheduled poison & non-scheduled poison)**. Additional information / supplementary data / documents shall be submitted to Centre for Product Registration, NPCB,
- b. 180 Days is a timeframe given to applicant applicable for rejected application of innovator product. Additional information / supplementary data / documents shall be submitted to Centre for Products Registered, NPCB.

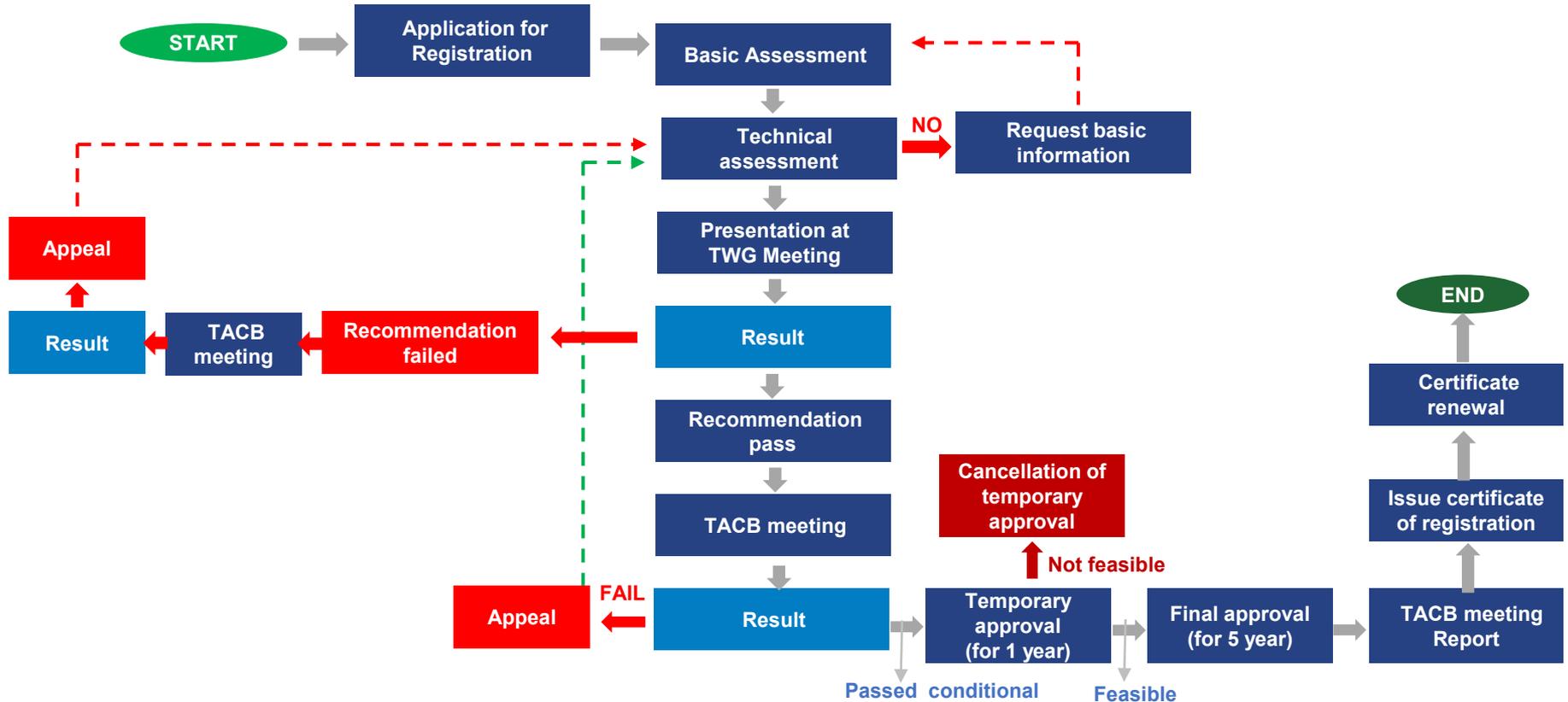
General requirements for documentation for NPRA

What are the relevant document / certificated is require?

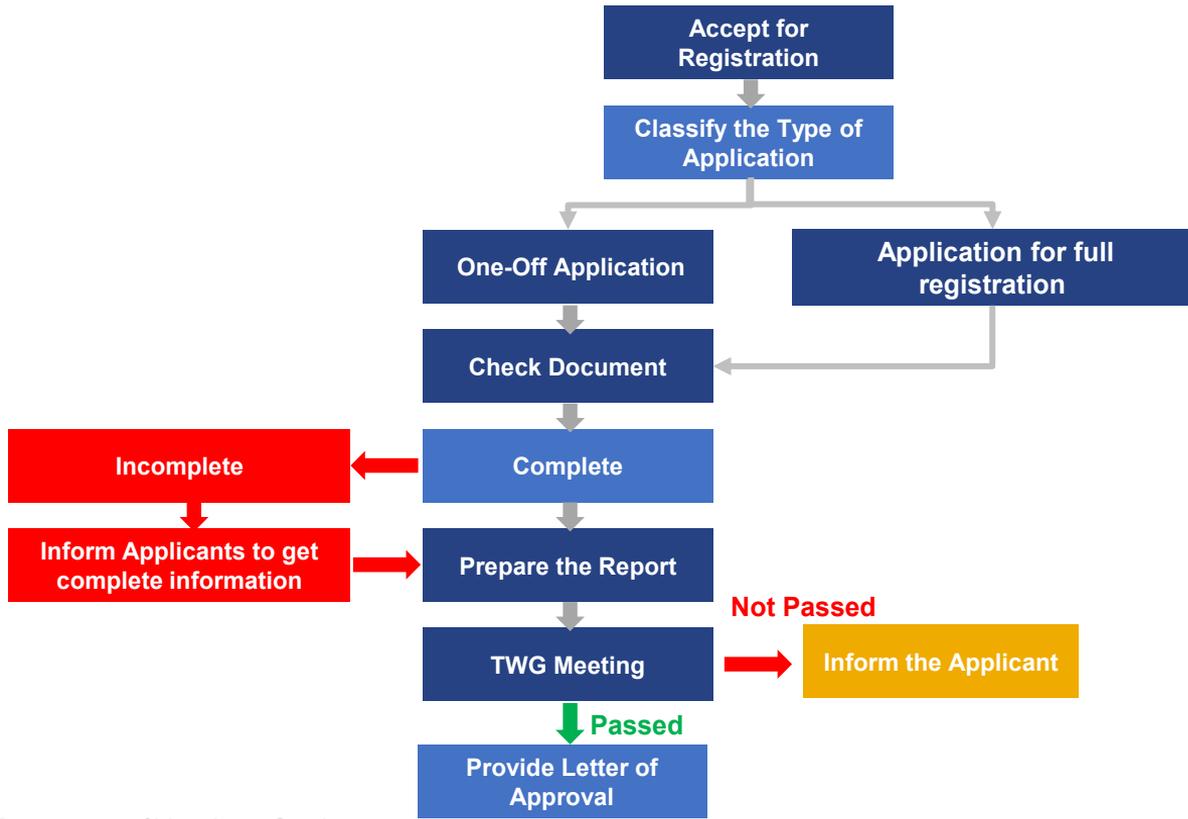


FOREIGN COMPANY / MANUFATURER	LOCAL COMPANY / MANUFATURER
<ol style="list-style-type: none">1. GMP - Guideline on Good Manufacturing Practice2. PIC/S - Pharmaceutical Inspection Co-operation Scheme3. CPP - Certificate of Pharmaceutical Product4. CFS - Certificate of Free Sale <p>(Note: All the above documents / certificate are from the competent authority in the country of origin as deemed acceptable by the NPRA)</p>	<ol style="list-style-type: none">1. GMP - Guideline on Good Manufacturing Practice2. PIC/S - Pharmaceutical Inspection Co-operation Scheme <p>(Note: All the above documents / certificate are from the competent authority in the country of origin)</p>

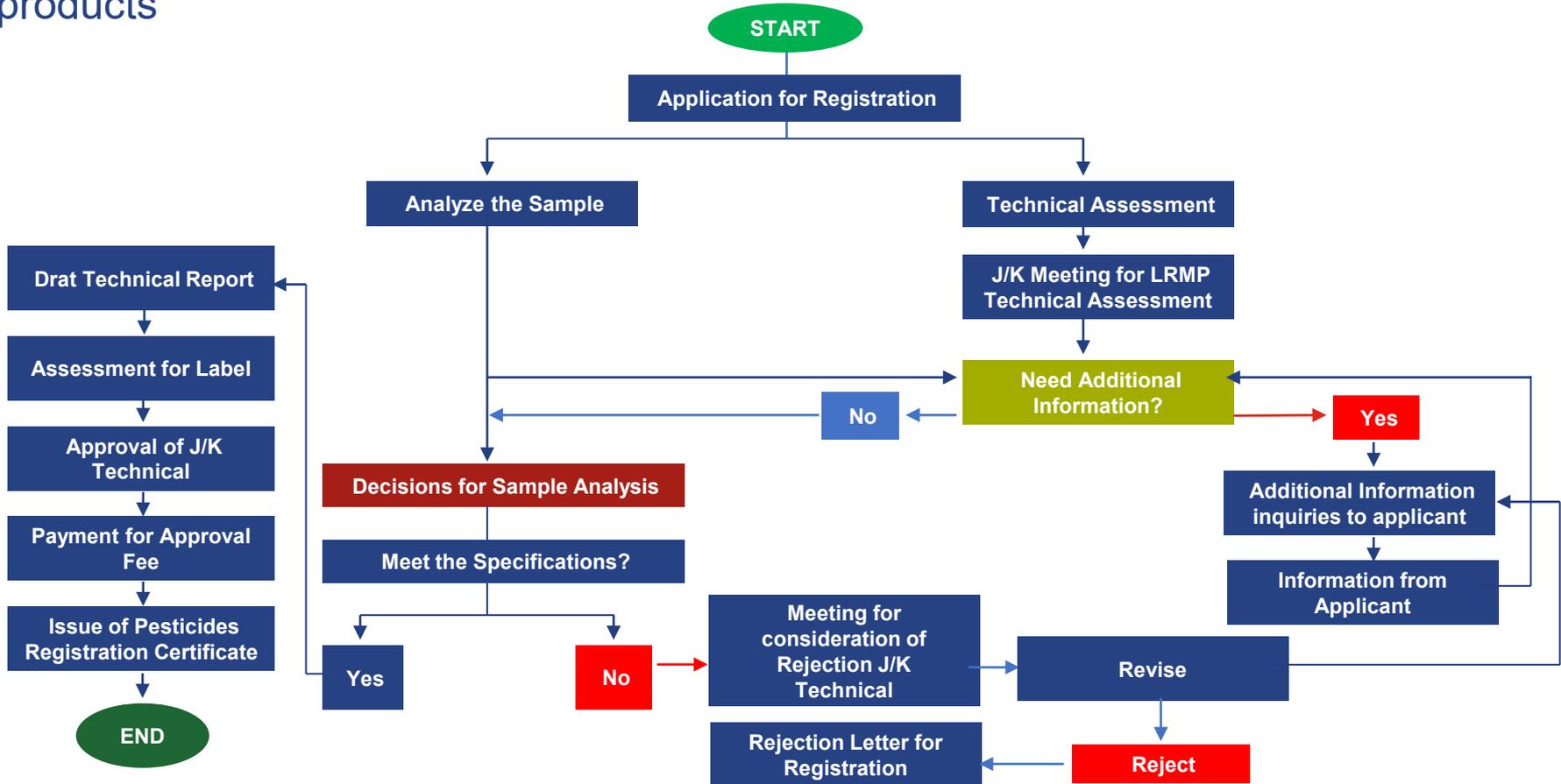
DVS: Process of registration (new) Vaccine products



DVS: Process of registration (new) Biologicals products



Pesticide Board: Process of registration (new) Pesticide products



ANIMAL FEED BOARD DECISION ON THE USE OF COLISTIN ANTIBIOTIC (POLYMYXIN E) IN FEEDS AND FEED ADDITIVES



The 11th meeting of the Animal Feed Board on 25 June 2018 have decided on the following:

- i. Termination on the use of the colistin antibiotic (polymyxin E) in feeds and feed additives for treatment, disease prevention and growth promoter (AGP) on food animals effective on 1 January 2019. Users, retailers and distributors are notified to terminate all use, sale and distribution of the antibiotic on or after the mentioned date.
- ii. It is known that Colistin is the last line of defense for the treatment of infections by Gram-negative bacteria or Multidrug Resistant Organisms (MDRO) in humans.

With respect to this, all importers, manufacturers, retailers and users of animal feeds and feed additives must comply with the decision of the Animal Feed Board.



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