ASEAN Animal Health Regulatory Benchmarking Survey 2020

Key Takeaways from the Survey

- Regulatory agencies are staffed by scientifically sound, ethical and engaged professionals
- Opportunities exist for best practice sharing, training and talent development
- Opportunities to review fee structure to improve resources and outcomes
- Harmonization possible in defined areas, e.g., site inspections reports, documentation, testing SOPs, etc
- Increased dialogue between all stakeholders is encouraged
- Requirement for Free Sales Certificate (FSC/CPP) at the time of the dossier submission delays the regulatory approval and access to new products
- Adoption of digital tools/e-dossiers is a positive development

The Asian Animal Health Association

- The Asian Animal Health Association (AAHA) is an allied industry member association incorporated in Singapore. The association's objective is to identify, develop, and execute strategies that support the future development of the animal health industry in the Asia Pacific.
- AAHA was founded 20 years ago to cover Asian countries, mainly Southeast Asian countries. AAHA consists of 6 member companies: Boehringer-Ingelheim, Ceva, Elanco, MSD, Virbac and Zoetis.
- AAHA is a member of HealthforAnimals, the global animal health association.
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Introduction

An efficient, transparent, consistent, and scientific regulatory environment is essential to ensure the free availability of safe, effective medicines; to promote and protect the health, welfare and well-being of food and companion animal populations; to deliver efficiencies and competitiveness for producers and to encourage innovation.

Previously there was limited information available to assess regulatory performance in ASEAN markets - a quick search of public sources revealed the number of regulatory approvals, however, this data was incomplete and often did not differentiate new products, product renewals, generic registrations, or API approvals, etc. Tables 1a & 1b (below) list the new biological and pharmaceutical approvals from 2013-2018 for markets where data was available. As mentioned above, it was often difficult to distil accurate new product approval data from this source, but there appeared to be more positive trends in biological approvals in PH and TH than MY and ID. Whilst the pharmaceutical trend was flat to slightly decreasing in all markets with the 2014 MY outlier figure possibly a combination of new product approvals and product renewals.

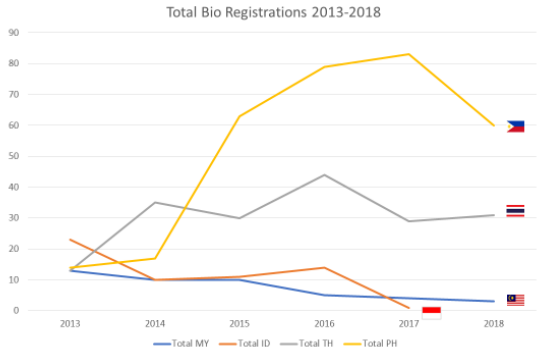


Table 1a. Total Bio Registrations by market from 2013-2018

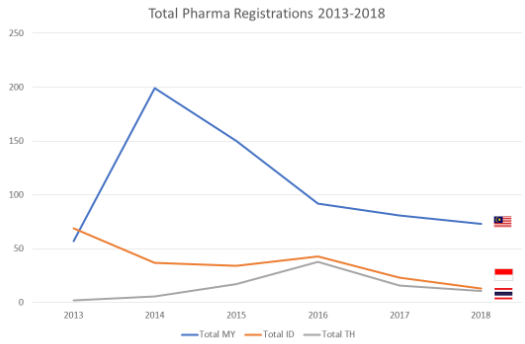


Table 1b Total Pharma Registrations by market from 2013-2018

In-depth surveys of the regulatory environment in several other global markets have provided insights that resulted in greater cooperation among all stakeholders, improved efficiencies and delivered better regulatory outcomes – which was the objective for the ASEAN Animal Health Regulatory Benchmarking Survey.

This is the first assessment, conducted on behalf of the Asian Animal Health Association (AAHA) by an independent market research company, of the regulatory environment in ASEAN markets. It was an inclusive survey with regulatory managers from local & multi-national companies, regulatory consultants and national regulators participating across 62 surveys and 95 interviews in 7 ASEAN markets (ID, KH, MM, MY, PH, TH, VN).

AAHA intends to work together with all stakeholders by sharing the insights provided in the survey data and the suggestions for enhancement drawn from the analysis, to create an on-going process of mutually beneficial improvements.

Executive Summary

General Findings and Recommendations

- The Survey identified clear opportunities for best practice sharing, training, talent development and process harmonization with the potential to improve efficiencies and provide faster access to new medicines.

- There have only been sporadic improvements in regulatory approval timelines across the region in recent times. Notable improvements have occurred where additional resources have been applied at the departmental level; conversely, approval timelines have increased in several markets, especially where additional local trials or testing have been required.

- Compounding the delay in regulatory approvals is the requirement that a regulatory submission will not be accepted until there is documentary evidence of regulatory approval in the country of manufacture (FSC/CPP). A mutually acceptable system whereby the FSC/CPP could be supplemented during the review process and prior to approval, could accelerate new product access for vets, producers and consumers across ASEAN markets.

- Government fees for regulatory submissions were low compared to other global markets - if increased fees could be channelled directly to the regulatory agency, the additional resources could result in improved agency performance. There is precedence in the region for this (Thailand).

- Resources at the department level were often restricted, which impacted regulatory assessment timelines, reduced training programs, and limited the opportunities for knowledge/skill development of personnel. The effects of restricted training were most acutely felt in the ability to technically assess innovative products. Therefore, an opportunity exists to create an AAHA supported extension training program of knowledge and best-practice sharing for regulators within ASEAN markets. Subject matter experts from within and beyond ASEAN markets could provide training on agreed topics to enhance regulatory skills and knowledge.

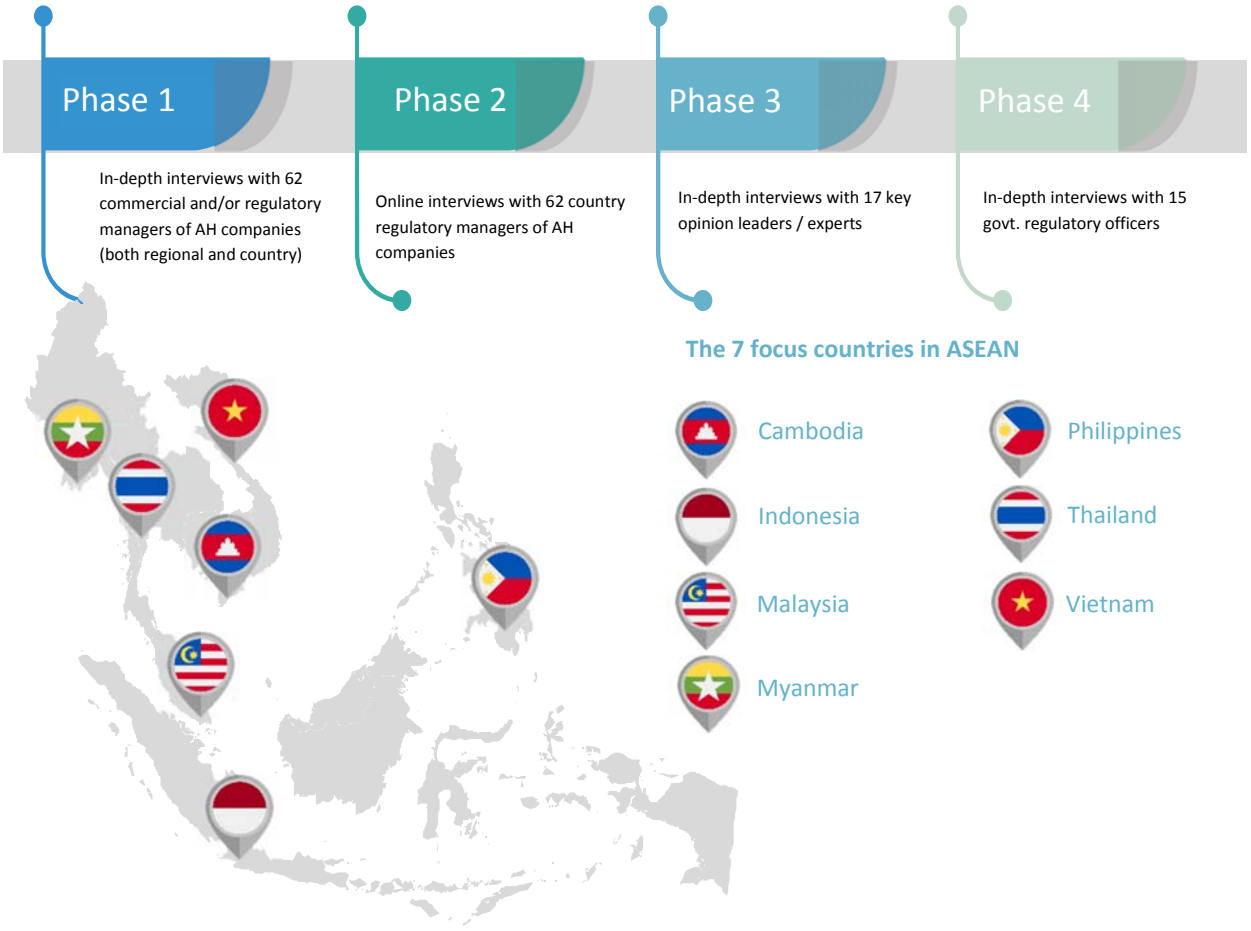
- Harmonization opportunities exist - sharing or mutual recognition of international documents and reports, such as site inspections reports (GMP), quality certification & test SOPs. An exploration of areas for harmonization could yield efficiencies in time and cost savings for the regulatory authorities across ASEAN markets.

- Regular and more active communication between industry players, regulatory bodies and experts could help promote both better implementation and enforcement of existing regulations and policies, as well as provide a valuable opportunity for inputs to draft and propose new regulations and initiatives.

- While most regulatory departments have implemented some form of the electronic platform, the successful utilisation of digital tools/e-dossiers is variable. Again, an opportunity exists for shared learnings so that agencies can optimise their investments in these electronic platforms.

Survey Methodology

- The first ASEAN Regulatory Benchmarking survey was conducted to assess ASEAN Animal Health Regulatory outcomes.
- The survey was undertaken on behalf of AAHA, by Kynetec, an independent research company based in Kuala Lumpur.
- Multi-national and local animal health companies, local government regulators and key independent regulatory scientists across 7 ASEAN markets participated in the survey which was conducted over a 4-phase project that started mid-year 2018 and was completed in mid-year 2020.
- The survey collected qualitative and quantitative benchmark data that included the number, timings, and costs of registrations as well as the challenges faced in the product registration process & commercialization of products, as well as the extent & opportunity for technical harmonization across the region and the readiness of the ASEAN Animal Health regulatory framework for the future.



Timelines for new product registrations

General findings

- In the past 5 years, there have not been any significant improvements in regulatory timelines in ASEAN markets except for Thailand (across all sectors - both Companion and Production Animal pharma & biologicals) and Indonesia (Companion Animal pharma & biologicals).
- In Companion Animals in Indonesia and notwithstanding some improvements noted above (and to a lesser extent Malaysia), the timeline for product registrations is still longer compared to other ASEAN countries.
- In Production Animals in Indonesia (and to a lesser extent Malaysia), timeline for product registration is again longer compared to other ASEAN countries. Vietnam mainly, but also Philippines timelines have increased, especially for biologicals - a reflection of local trial requirements.

Table 2 below includes superimposed EU regulatory timelines of 16-17 months for Companion Animal and Production Animals pharma & biologicals (data from HfA 2020 benchmark survey). However, the Free Sale Certificate (FSC)/Certificate of Pharmaceutical Product (CPP) issue should be noted here. The requirement to wait until an FSC/CPP is available prior to dossier submission significantly adds to these approval timelines and delays access to new medicines for ASEAN vets, producers, and consumers by up to 2 years (in the EU example: 16-17m for EU approval plus 1-2Q document preparation, legalisation, and submission). The possibility to submit the FSC/CPP during the review process could allow access to new medicines up to 1.5 years earlier.

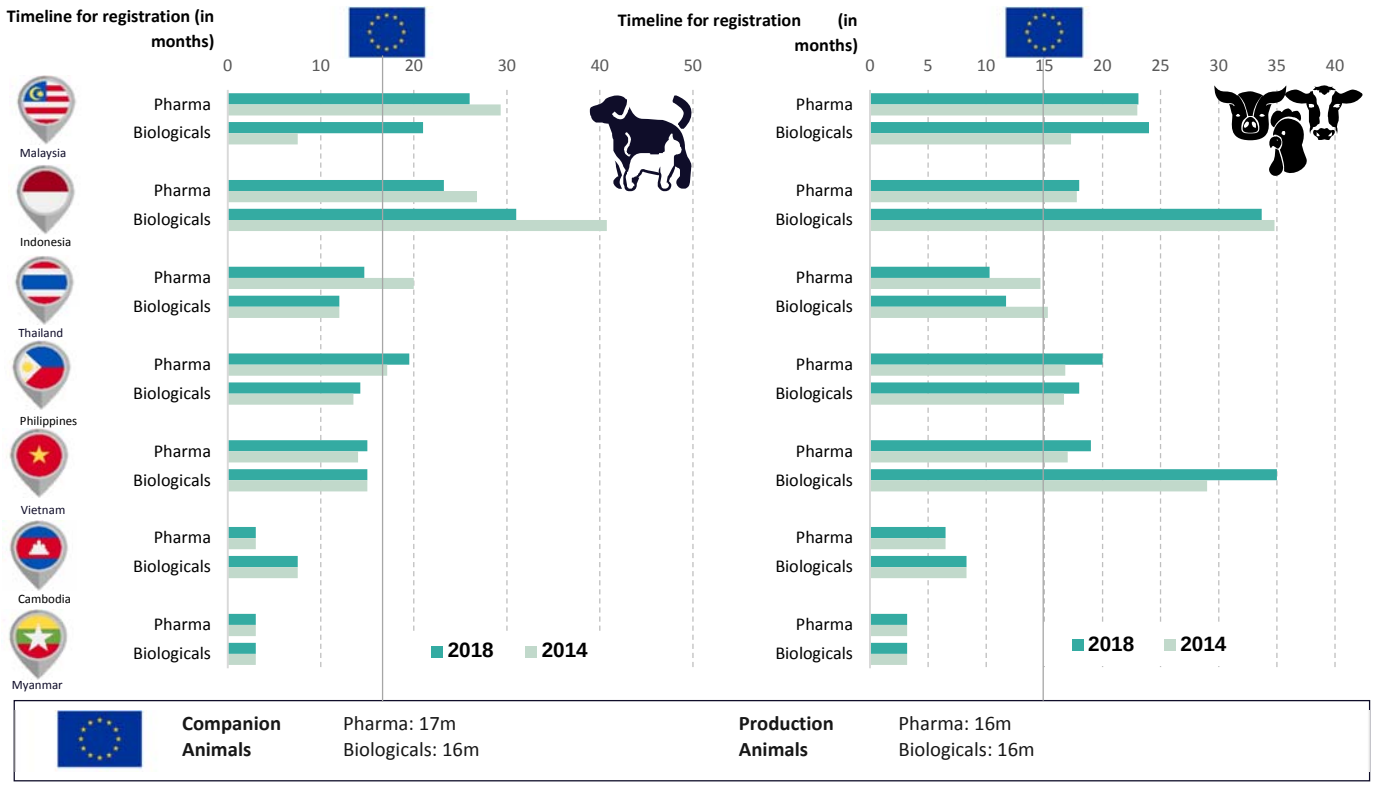


Table 2. Regulatory timeline for companion and production animal products by country 2014 vs. 2018

Cost of Product Registration

(i) General trends in ASEAN Region

- Over the past 5 years, the cost of product registration in Indonesia, Vietnam, Thailand, and to a lesser extent in the Philippines and Myanmar have increased. Apart from Thailand, the increased cost was linked to a change to the registration process, e.g., more stringent requirements for local trials, laboratory testing fees, etc.
- In Thailand, the regulatory body (FDA) increased product registration fees to improve efficiencies and especially reduce the timeline for approval.
- In the Philippines, government fees for animal health product registration are generally low. However, there are some (significant) costs associated with local (farm) efficacy trials and the extension of validity permits.
- In Vietnam, there have been increased costs for all key therapeutic areas in the past 5 years. These increases were due to local trials, new regulations and an increase in quality testing fees.
- In comparison to other ASEAN countries, the cost of product registration in Indonesia is high. The government fee proportion of the costs is just 10% as the increases were due to new regulations (including the need for local trials).
- AH product registration cost in Malaysia is one of the lowest in the ASEAN region. There had not been any changes in product registration fees in the past 5 years, and in 2018, the government had waived the registration fees for biologicals.

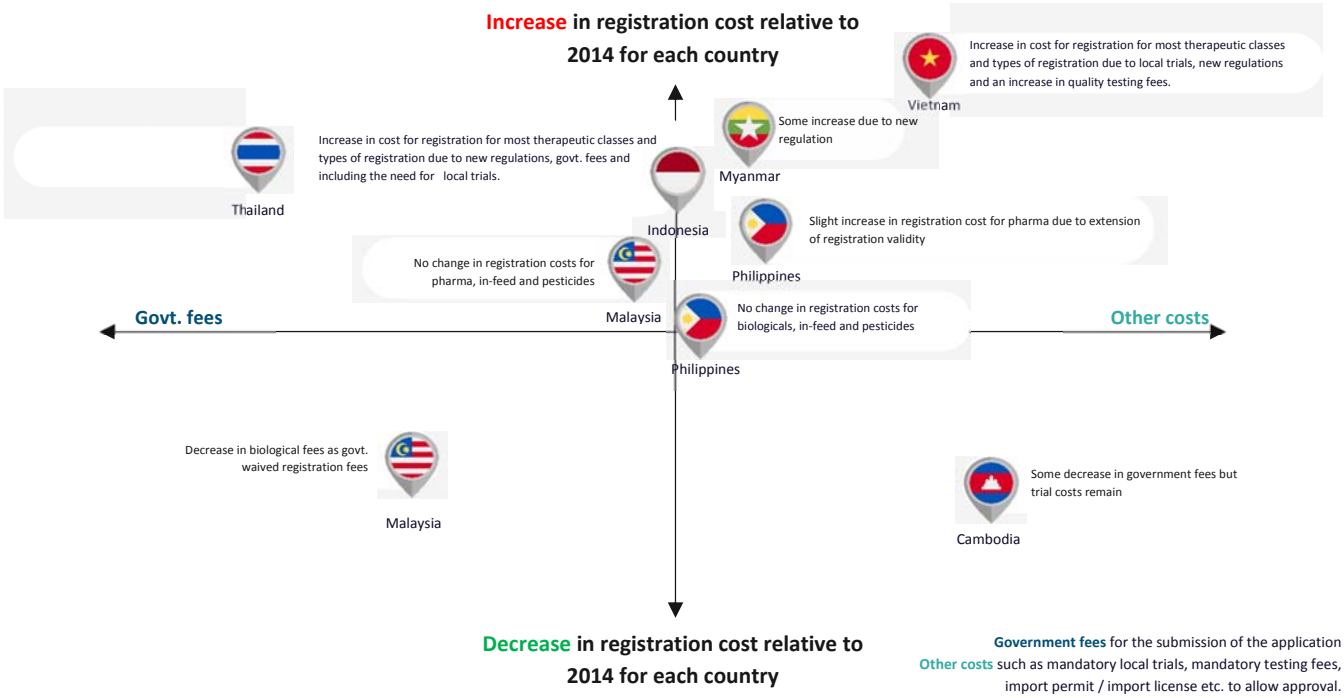
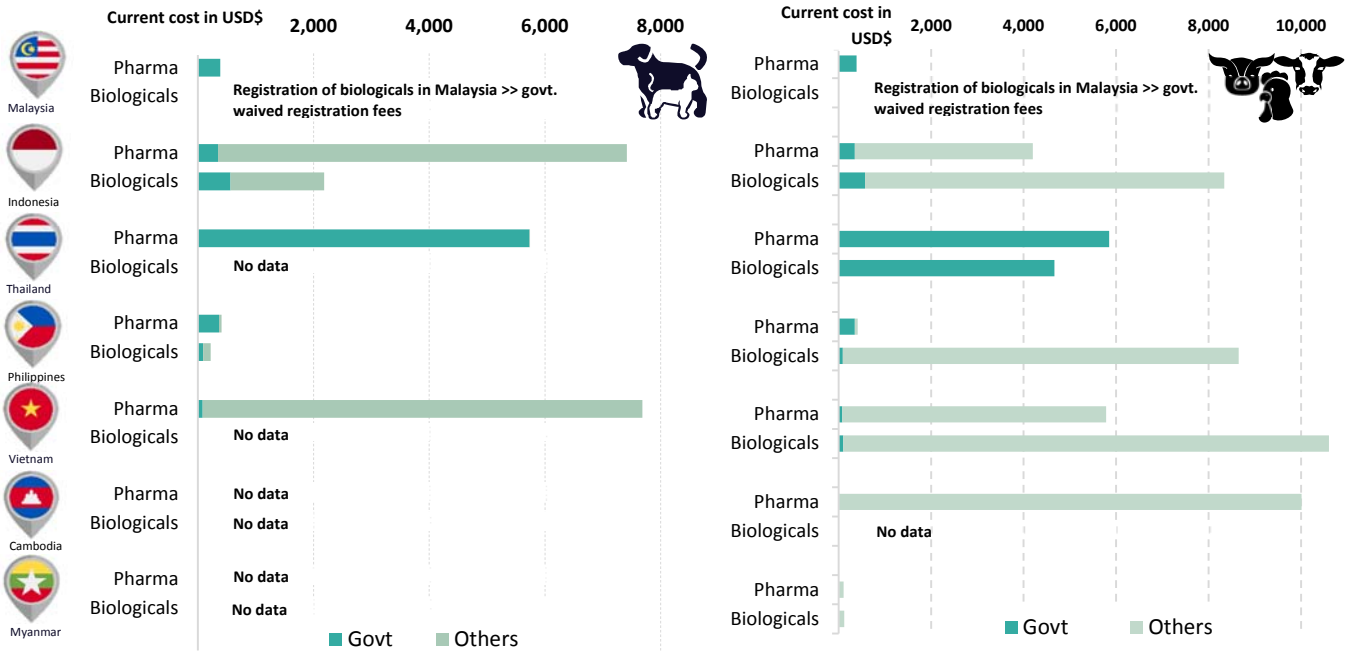


Table 3. Relative changes in registration costs by country since 2014

(ii) Comparison within ASEAN Region

The graphics below provide detail on the comparative cost in ASEAN markets for pharmaceutical and biological registrations in companion and production animals. Significant cost increases in companion animal pharmaceuticals in Indonesia & Vietnam, and production animal pharmaceuticals and/or biologicals in Indonesia, Vietnam, Philippines & Cambodia were usually associated with additional testing or clinical trial requirements. Only Thailand had a significant increase in government fees, however, this resulted in markedly improved outcomes (see timeline section later).



Government fees for the submission of the application.

Other costs such as mandatory local trials, mandatory testing fees, import permit / import license etc. to allow approval.

Note: We only show data if we have feedback from at least 2 different companies.

Table 4. Changes of costs of registration of companion animal and production animal products 2014-2018 by country

The overall cost of registration for animal health products in ASEAN is still low compared to other regions. Note, in Australia the higher fees are used to contract highly qualified external assessors.

Cambodia	Indonesia	Malaysia	Myanmar	Philippines	Thailand	Vietnam
10,000	2,000 - 8,250	<500	<100	<100 - 8,500	4,500 - 6,000	5,800 - 10,500

Table 5. Total cost (in USD) of product registrations in ASEAN markets in 2018

Australia	Japan	New Zealand
13,000	5,000	4,000

Table 6. Total cost (in USD) of product registrations in other Asia-Pacific, ex-ASEAN markets

Bringing new Animal Health products to market: Challenges and Improvements

General findings

- There is complexity in product registration in the ASEAN region due to many country-specific requirements such as farm trials and product testing (Vietnam, Philippines and Indonesia).
- GMP site inspections are a requirement in many markets, but the duplication of inspections by ASEAN markets causes logistical problems and adds expense locally.
- The FSC/CPP requirement at the point of dossier submission delays approval timelines as submissions remain on hold until certificates can be generated.
- In Malaysia & the Philippines, the involvement of multiple regulatory bodies adds to the complexity.
- Indonesia, Malaysia, Vietnam, Thailand and Philippines have moved towards, or have already implemented, online product registration systems which have brought/will bring transparency, speed and streamline the process.

Across the 7 countries, there were **5** common challenges identified in bringing new products to market.

- Indonesia is perceived as the most challenging country to get a product registered. Pressure on the regulatory departments, frequent change to regulations, the need for many expert committee meetings (with often challenging scheduling) and the pending knowledge transfer proposals in the new Omnibus bill were some of the factors cited during the survey.
- In Thailand, although the timeline is relatively predictable, due to the strict requirements (and recent PIC/S implementation), the product registration process was currently rated by some regional managers to be quite difficult. However, once PIC/S is fully implemented (and the US biomanufacturing issue resolved), the belief is that the overall process will improve.
- Malaysia still a little unpredictable. There is a PIC/S requirement for pharmaceuticals but not for biologicals - a reflection of the multiple regulatory agencies in Malaysia.
- In the Philippines regulatory timelines have been quite predictable, but recent changes in the reporting structure of the regulatory body are challenging.
- Vietnam is predictable, but the complexity/requirements are increasing.

- Myanmar and Cambodia are currently perceived as the most straightforward, as often an import permit approval is sufficient to bring products into the country. As full drug regulatory frameworks are established, the process may become more complex.

Table 7 (below) plots the predictability of the timeline against the overall difficulty of the process based on the previously listed points as assessed by the local and multi-national regulatory managers.

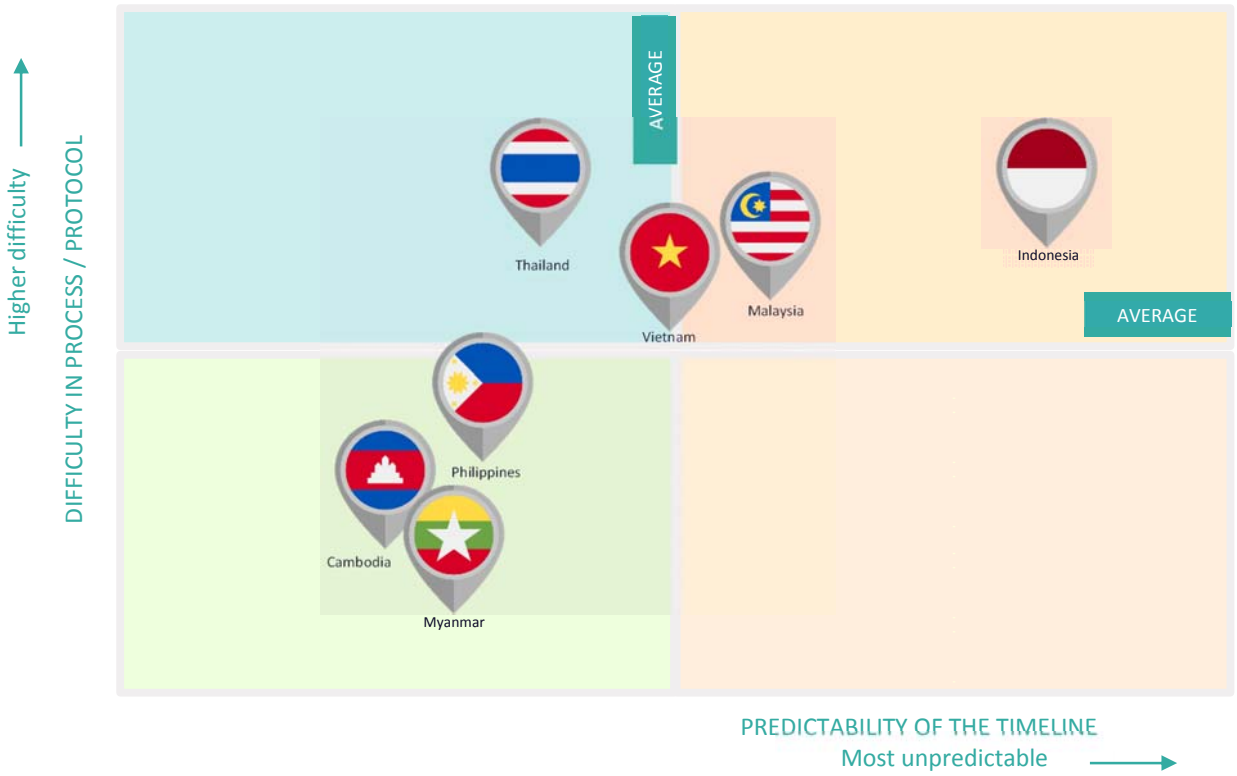


Table 7. Comparison of difficulty of process and predictability of the timeline by country

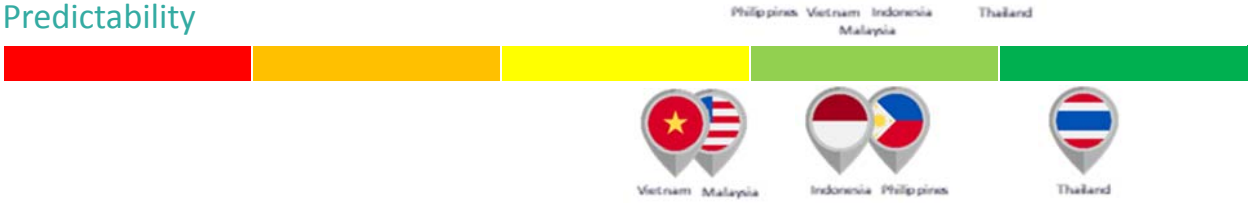
Other attributes of the regulatory process that can influence prioritization of markets

When a strategic decision has been made by a company to introduce a product to a market, there are a number of other factors that can contribute to a timely and predictable regulatory outcome. In the graphic below, regulatory managers from local and multi-national companies together with government officers, were asked to score their markets for (i) the scientific basis of the assessment; (ii) how free from outside influence the process was and again; (iii) predictability of the process.

Science based assessment

Free from outside influence

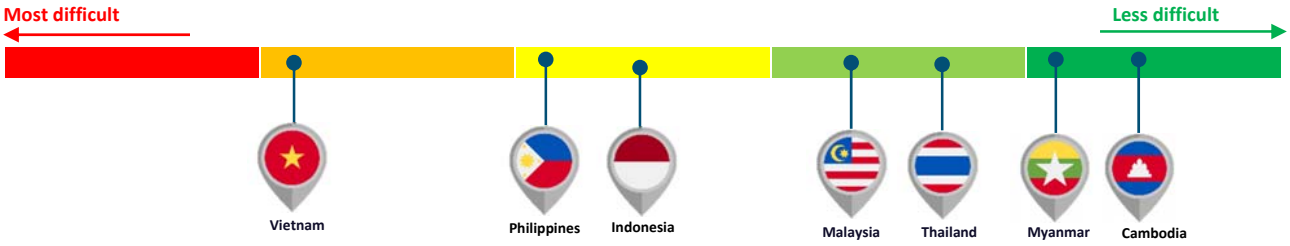
Predictability



Commercialization of Registered Animal Health Products: Challenges and Improvements

General findings

- Maintaining commercialization of Animal Health products in ASEAN markets is not considered challenging.
- However, in Vietnam, there are some challenges due to recent compulsory testing/checks for each shipment of imported products - In 2016, regulatory bodies started to have stricter control on the quality of imported products. Vaccines and antibiotic were tested in all shipments for sterility, purity & safety. Potency tests for PRRS, FMD and flu (avian) vaccines was also compulsory for all shipments. By Q4 2019, we learned from experts / KOLs that although this requirement is not as rigid as 2016, there are still some random checks done.
- For the Philippines, manual checking to curtail falsification issues slowed down the issuing of import permits.



ASEAN Technical Harmonization

General findings

- Multinational Animal Health companies support this initiative, as it should ensure easier (and faster) product registration.
- However, local AH veterinary companies in some countries, have concerns that if they cannot meet the harmonized standards, it will become more difficult to get their products registered.
- All stakeholders agreed that full ASEAN technical harmonization would be difficult because of differences in agenda, focus, regulations/laws, administrative structure, and resourcing. However, Government regulators

suggested some aspects that may be easier to harmonise: for example, testing methods, basic rules/checklist and scientific practices/processes including SOPs for testing.

Readiness of current regulatory framework for the future

General findings

- There is a variation in the perception of the readiness of the current regulatory framework for the 21st century between the groups surveyed.
- AAHA members said that the current regulatory framework in all ASEAN countries needs some development to be ready for the 21st century, especially in assessing new technical innovations where more knowledge, training and consistency is needed.
- Government regulators and KOLs agreed that the broad regulatory framework is good enough for the future but certain areas require significant improvement.

Summary and Suggestions

ASEAN - Common findings

- Scientifically sound, ethical, and engaged professionals
- Resources at department level often restricted
    - Impacts regulatory assessment timelines
    - Low training opportunities - limits the ability for knowledge/skill development of personnel
    - Affects ability to assess innovative products technically
    - Low fees relative to other global markets
- Adoption and successful use of digital tools/e-dossiers variable
- Harmonization opportunities - site inspections reports, other documentation, testing SOPs, etc
- FSC/CPP rules delay submission timelines

ASEAN - Suggested areas for enhancement

The Survey identified opportunities for best practice sharing, training, talent development and process harmonization with the potential to improve efficiencies and provide faster access to new medicines.

ALL participants agreed that improvements are needed in:

- Training for regulators - improved skills & knowledge
- Clearer explanation and interpretation of the regulations
- Harmonization of the regulatory framework across ASEAN
- Better implementation and enforcement of existing regulations & policies
- More active communication and dialogues between industry players, regulatory bodies, and experts
- Focus on e-technology – increase efficiency and reduce workload

ASEAN - Proposed action plans

Short term

- AAHA to facilitate an extension strategy for best practice and knowledge sharing through workshops, trainings, seminars and talks with govt. regulatory officers to enhance their knowledge and skillsets.
- To examine FSC/CPP submission requirements - if it can be supplemented during the regulatory assessment, it will significantly accelerate new product access for ASEAN markets.
- To increase government registration fees IF it can increase efficiency (shorten the timeline, improve predictability and reduce complexity) in product registration. Note: a more efficient system would encourage more submissions irrespective of any fee increase.
- For AAHA to actively participate in providing a feedback loop on new regulation (before implementation) and encourage regulatory bodies to set a more consistent standards in the registration process (through technical harmonization).

Long term

- **Harmonization efforts** - where resources are limited, focus on areas that lend themselves to standardization (e.g., testing methods, can reduce the additional tasks and/or reduce duplicated efforts by countries) to reduce costs and drive efficiencies.
- Adoption / use of digital tools (e.g., online product registration) has been good (5/7 markets) but some teething problems - the industry to continue to support the implementation of digital platforms.

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Country Specific Findings

Some common abbreviations used in the next sections:

- AAHA – AH Veterinary companies (regulatory managers)
- KOL- Key opinion leaders/ experts
- GO- Govt. regulatory officers

Key Points by Country

Cambodia

- Currently a permit based system but now establishing a more systemic regulatory framework.
- Opportunities for knowledge/best practice sharing and to incorporate learnings from other ASEAN members.
- Opportunity to incorporate electronic platforms and an appropriate 'fee for service' structure.

Indonesia

- Some improvements in regulatory timelines in recent years, but still among the longest across ASEAN markets, especially biologicals.
- Scored above average on science-based decision making, predictability and compliance.
- Frequent changes to regulations, expert committee structure and frequency of meetings are challenging.
- Awaiting 'Omnibus Bill' and potential technical transfer implications.

Malaysia

- Adoption of E-system welcomed as was Special Exemption list to help clear a backlog.
- Multiple regulatory bodies reviewing AH products presents challenges (DVS, NPRA, Pesticides) and brings complexity.

Myanmar

- Current a permit-based system provides market access, although recent increased lab charges are an additional hurdle.
- Now establishing a more systemic regulatory framework.
- Opportunities for knowledge/best practice sharing and to incorporate learnings from other ASEAN members.
- Opportunity to incorporate electronic platforms and an appropriate 'fee for service' structure.

Philippines

- Regulatory timelines have been quite predictable but recent changes in the reporting structure of the regulatory body are challenging.
- Use of permits and manual inspections at importation has caused delays.
- Improvement in e-Dossier and possible PIC/S membership offers opportunities.

Thailand

- Regarded as being amongst the most predictable regulatory body in ASEAN markets.
- Increased 'fee for service' model has improved outcomes in Thailand.
- Adoption PIC/S has been challenging but benefits lie ahead - especially if US bio quality standards are recognised.
- Opportunity to revisit restricted advertising channels in Thailand.

Vietnam

- Low government regulatory fees but high costs associated with local trial requirements.
- Timelines good apart from where clinical trials delay approval date.
- Additional testing and checks on imported goods have caused delays - part of a trend of increasing complexity in regulations.
- Scientific basis of processes and regulations continues to increase.

Cambodia

Key points

- Currently a permit based system but now establishing a more systemic regulatory framework.
- Opportunities for knowledge/best practice sharing and to incorporate learnings from other ASEAN members.
- Opportunity to incorporate electronic platforms and appropriate 'fee for service' structure.

Cost of Product Registration in 2018

Cost (in USD) of product registration in 2018	
Govt. fees	--
Other fees	Pharma: 10,000

- Govt. fees for product registration are insignificant.
- There is some cost associated with mandatory local trials or testing fees for innovation.

Timeline for Product Registration in 2018

Timeline (in months) for product registration in 2018	
Pharma	Companion animal: 3 | Production animal: 7
Biologicals	Companion animal: 7 | Production animal: 8

- Easy to bring products to market: low complexity in product registration/import permit and a short timeline.

Overall Impact of Current Regulatory Environment in Bringing New AH Products to Market (feedback from animal health companies)

General findings

- In Cambodia there is a relatively easy registration process. There is one regulatory unit for all registrations and response time is fairly quick.
- There is, however, poor coordination with law enforcement resulting in smuggling activities for unregistered products.
- There is a general lack of resources around the regulatory agency and an opportunity to upskill the regulatory officers.
- Aiming to implement PIC/S may be an unattainable regulation standard until a basic regulatory framework is established.

Bringing Products to Market: Challenges and Improvements

Key Challenges experienced in bringing new AH products to market in the past 4-5 years.

	Feedback from:		
	AAHA	KOLs	GO*
Inadequate resources (money, facilities, labor)			✓
Limited ability to do registration of product (Encourage smuggled goods)	✓		✓
Regulators have limited AH knowledge	✓		✓

*Government Officers

Local managers from animal health companies said that the current product registration achievement on the three metrics listed below is to be good.

a) Science-based (3 out of 5-point),
b) Consistent & predictable in the review process (2.2 out of 5-point)
c) Independent and free from influence (2.2 out of 5-point)

Compared to 2014, there had not been any change (either better/worse) on these three metrics in 2018.

Commercialization of Registered Products: Challenges and Improvements

Level of difficulty of current regulatory environment on marketing & selling AH products to market

By and large, there are generally very few challenges faced in maintaining existing products in Cambodia.

ASEAN Technical Harmonization

Technical harmonization is not (yet) discussed in Cambodia. The country has just started to put together a more systemic regulatory framework, hence, slightly lagging behind other ASEAN countries.

When asked, the view is that ASEAN technical harmonization is quite difficult. Each country has a very different culture, making it hard for these various countries to compromise with each other.

The enforcement of regulations in Cambodia will enhance steps towards harmonization. If a harmonization standard can be established, authorities may pay more attention to the AH industry. Then the end goal of better regulations allowing safe and good quality AH products to access the market and at the same time limiting illegal products from entering the market, may be possible.

Proposed action plans

Short term

- Work closely with the regulatory body to improve the capability / knowledge and human resources of regulators – through training, and lobbying for more monetary allocation.
- More active communication with the regulatory body helps their collaborative development, as there will be many areas to work on. Discussions on the near-term and long-term goals are starting points for the collaboration.

Long term

- Adoption / use of digital tools (e.g., online product registration) has been good (5/7 markets) but some teething problems – the industry to continue to support the implementation of digital platforms.
- Encourage the regulatory body to set a registration fee that is a 'match' to other ASEAN countries that will ensure this is one (possible) monetary resource for them to improve registration efficiency.

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Indonesia

Key Points

- Some improvements in regulatory timelines in recent years but still among the longest across ASEAN markets, especially biologicals
- Scored above average on science-based decision making, predictability and compliance.
- Frequent changes to regulations, expert committee structure and frequency of meetings is challenging
- Awaiting 'Omnibus Bill' and potential technical transfer implications

Cost of Product registration in 2018

Cost (in USD) of product registration in 2018

Govt. fees	Pharma: 350 | Biologicals: 570 (no different between companion vs. production animals)
Other fees (companion animals)	Pharma: 7,065 | Biologicals: 1,618
Other fees (production animals)	Pharma: 3,848 | Biologicals: 7,768

- Compared to 2014, there is a significant increase in cost for registration for most therapeutic classes and types of registration due to local trials, new regulations and an increase in quality testing fees.

Timeline for Product Registration in 2018

Timeline (in months) for product registration in 2018

Pharma	Companion animal: 23 | Production animal: 18
Biologicals	Companion animal: 31 | Production animal: 34

- There is no change in Registration time for Production animals – both Pharma and Biologicals since 2014 (until 2018)

Overall Impact of Current Regulatory Environment in Bringing New AH Products to Market (feedback from animal health companies)

Bringing Products to Market: Challenges and Improvements

Key Challenges experienced in bringing new AH products to market in the past 4-5 years.

	Feedback from:		
	AAHA	KOLs	GO*
Inconsistency in evaluating the registration dossier (lack of checklist / standard protocol)	✓	✓	
Additional resources (money, facilities, and labor)	✓	✓	✓
Unpredictable registration timeline / significant delay in registration	✓	✓	
Strong local protectionism	✓	✓	

Key Positive improvements in bringing new AH products to market in the past 4-5 years

	Feedback from:		
	AAHA	KOLs	GO*
E-system /online registration	✓		✓
Acceptance of recombinant products	✓		✓

*Government Officers

Local managers from animal health companies together with Government Officers said that the current product registration achievement on the three metrics below were to be slightly above average.

a) Science-based (4.0 out of 5-point),
b) Consistent & predictable in the review process (3.3 out of 5-point)
c) Independent and free from influence (3.6 out of 5-point)

Animal health companies said that in 2018 (vs. 2014), there had been some improvements in the achievement of all 3 metrics, especially on science-based and honest, independent & free from political / commercial influence.

Specifically, for INDONESIA on local protectionism a few multi-national animal health companies and KOLs/experts claimed that they have a tougher registration process compared to local companies and that authorities prioritized local companies as they have a better connection to the authorities and no language barrier.

Additionally, there is a discussion on a new regulation to transfer knowledge / technology to local manufacturing sites. (Note: pharmaceutical and crop protection industries have this regulation already.)

To note, since 2018 there have been many changes in regulations which has gone someway to improve procedures and timelines - against this the perception remains that local companies, especially those that export product, are being favoured.

Commercialization of Registered Products: Challenges and Improvements

Level of difficulty of current regulatory environment on marketing & selling AH products to market

Key challenges experienced in the commercialization of AH products to market in the past 4-5 years

	Feedback from AAHA
Classification of ionophores as AGP	✓
Illegal (unregistered) product in the market >> some products sold without proper registration	✓

By and large, there are generally very few challenges faced in maintaining existing products in Indonesia. The industry and govt. regulators shared the same view on areas of improvements.

- Conduct pharmacovigilance/ post market surveillance to ensure proper usage of AH products.
- Include the product registration number on product advertisement >> to check the authenticity of the products.
- Monitoring of the exported vaccines (feedback by govt. regulators).

ASEAN Technical Harmonization

The topic of harmonization has been discussed, but has not been implemented yet.

The current view is that if the registration procedure can be harmonized, it will bring tremendous benefit to AH companies. It will ensure no country is lagging in introducing new products due to prolonged or unclear procedures.

However, the current view is that a regional-wide harmonization would be difficult. Not every component of regulation / requirement can be harmonized because every country has its own culture, needs or capabilities.

Some KOLs said that the application of ASEAN harmonization is a threat to domestic AH companies. Local players will face huge difficulties when ASEAN Harmonization happens as all the animal health manufacturing companies in the ASEAN region will be able to compete without barrier (or protection from govt.). Therefore, they will need to be prepared and trained to be more competitive.

Readiness of Current Regulatory Framework for the Future

The animal health companies do not consider that the current regulatory framework is ready for the future. KOLs / experts and govt. regulatory officers have a different view.

Listed below are some suggested actions that may get the industry ready for the future:

- Provide relevant and effective training for the regulatory officers. They need to be better equipped with the best working procedures in order to implement the regulations for the country.
- Upgrade the Sub Directorate of Animal Drug Control to a Directorate of Animal Drug. This can ensure enough power and budget is given to the authority in order to carry out their work more effectively.
- Increase the speed of registration and frequency of trials done. In VDC, they are reviewing 15 products every three months which is too slow according to the experts.
- Have more budget from the government to carry out the PPOH meetings.
- Always fine-tune the regulations according to the latest issue in the industry.

Proposed action plans

Short term

- Work closely with the regulatory body to improve the capability / knowledge and manpower of regulators – through trainings, and lobbying for more monetary allocation.
- More active communication with the regulatory body to help their collaborative development, as there will be many areas to work on. Discussions on the near-term and long-term goals are starting points for the collaboration.
- Set/agree on a target timeline for the registration review process with the respective regulatory bodies, and track the achievement rate.
- To examine FSC/CPP submission requirements - if it can be supplemented during the regulatory assessment, it will significantly accelerate new product access for ASEAN markets.

Long term

- Adoption / use of digital tools (e.g., online product registration) has been good but some teething problems - industry to continue to support implementation of digital platforms.
- Encourage the regulatory body to streamline the registration by electing 1 single body/unit responsible for the AH product registration. Although in Indonesia, the agency responsible for AH product registration is the Ministry of Agriculture, different departments of the MOA are involved. It will be more efficient if only 1 department is in-charge of the whole registration process.

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Malaysia

Key Points

- Adoption of E-system welcomed as was Special Exemption list to help clear a backlog.
- Multiple regulatory bodies reviewing AH products presents challenges (DVS, NPRA, Pesticides) and brings complexity.

Cost of Product Registration in 2018

Cost (in USD) of product registration in 2018

Govt. fees	USD389 (no difference between companion & production animals)
Other fees	--

- Compared to 2014, there is no change in cost for pharma, in-feed and pesticide regulated under NPRA.
- For Biologicals regulated under DVS, the registration fee has even been waived!
- All parties (including govt. regulators) agreed that the current registration fees are low.

Timeline for Product Registration in 2018

Timeline (in months) for product registration in 2018

Pharma	Companion animal: 26 | Production animal: 23
Biologicals	Companion animal: 21 | Production animal: 24

- Compared to 2014, there is a minor (<6 months) improvement in the timeline for pharmaceutical products for companion animals. None for production animals.
- Compared to 2014, there is a significant increase (> 6 months) in the registration timeline for biologicals.
- Both animal health veterinary companies and KOLs/experts said the predictability of the timeline for AH product registration is poor.
- Registration for Pharma under NPRA continues to enhance in timeline and process. NPRA has also been upgraded as a statutory body since 2019.
- Registration for biologicals under DVS had encountered many challenges such as the lack of skills / human resources.
- Rapid organizational change - waiver of registration fee since 2018 also did not help.

Overall Impact of Current Regulatory Environment in Bringing New AH Products to Market (feedback from animal health companies)

Bringing Products to Market: Challenges and Improvements

Key Challenges experienced in bringing new AH products to market in the past 4-5 years.

	Feedback from:		
	AAHA	KOLs	GO*
Inconsistency in implementation of regulation due to lack of skills / manpower in regulatory agencies*	✓	✓	✓
Unpredictable registration timeline / significant delay in registration*	✓	✓	
Lack of facilities (such as labs) reduces the ability to conduct testing for new product for registration*	✓	✓	
Unattainable standard as animal health product registration is based on standard set by (human pharma) ^	✓	✓	
Small size of market segment#	✓		

*These challenges are likely referring to biologicals regulated under DVS

^This challenge is referring to Pharma registration regulated under NPRA.

#This challenge is likely more specific to Companion Animal (including equine) products.

Key positive improvements in bringing new AH products to market in the past 4-5 years

	Feedback from:		
	AAHA	KOLs	GO*
E-system /online registration	✓		✓
Waiver of fees for products registered with DVS	✓		
The fast-track registration process for companion animal products	✓		✓

*Government Officers

When asked, local managers from animal health companies and Government Officers considered the current product registration achievement on the three metrics below to be somewhat average.

a) Science based (3.5 out of 5-point),
b) Consistent & predictable in review process (2.8 out of 5-point)
c) Independent and free from influence (3.4 out of 5-point)

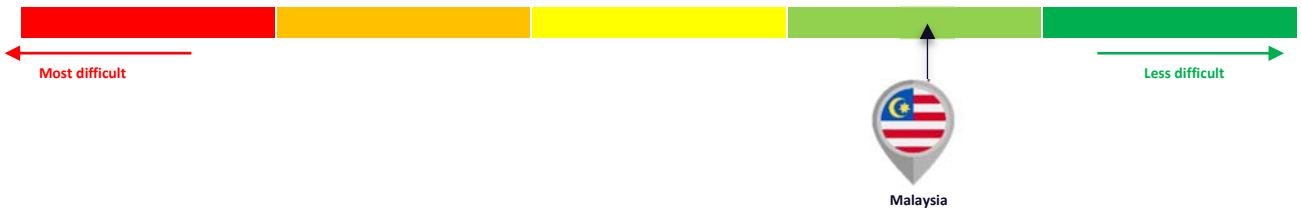
Animal health veterinary medicine companies said that in 2018 (vs. 2014), there is no significant changes (+ve. / -ve.) on these three metrics.

Specifically, for MALAYSIA on HALAL requirement: not a requirement (yet) in Malaysia, BUT there are strict requirements and checks on product ingredients – no porcine substance/derivatives, otherwise the product will be rejected. This is considered a barrier for faster innovation adoption in Malaysia especially for livestock products and for pharma products.

Note: the strict requirement of no porcine substance/derivatives allowed is only applicable to products regulated under DVS. There is no such requirement for products regulated under NPRA

Commercialization of Registered Products: Challenges and Improvements

Level of difficulty of current regulatory environment on marketing & selling AH products to market



Key challenges experienced in commercialization of AH products to market in the past 4-5 years

	Feedback from AAHA
Strict requirement for product labels >> needs to be in Malay language (in addition to other languages)	✓
Strict control of sales channel >> Many pharma products can only be purchased upon having a vet's prescription	✓

By and large, there are generally very few challenges faced in maintaining existing products in Malaysia**.** The industry and govt. regulators shared the same view on areas of improvement.

- Conduct pharmacovigilance/ post market surveillance to ensure proper usage of AH products
- Abolish License B - a temporary license released by NPRA for storage of poison (feedback from experts / KOLs)

ASEAN Technical Harmonization

The views from animal health companies, experts and govt. regulators are coherent.

- All agreed that it will benefit the industry if technical harmonization can be done.
- All viewed that it is challenging to implement harmonization for AH products in ASEAN as different countries have different agencies. It is also important to consider that the position of different countries is different on animal health and meat protein production - some are geared towards exporting countries, others for focus on delivering food sustainability locally.

Readiness of Current Regulatory Framework for the Future

The animal health companies and experts do not consider that the current regulatory framework is ready the future. Government regulatory officers have a different view.

Here is some suggested actions that may help get the industry ready for the future:

- Improve the regulator skills - veterinarians as dossier readers and do farm visitations.
- Increase manpower - speed up the registration process.
- Clear guidelines - leading to better efficiencies and a shorter timeline for approvals.

- AH products should be looked after by ONE agency, not by three regulatory bodies.
- More open dialogue with manufacturers - gain better appreciation with innovative products.
- Lower/simplify requirements for pharma products.
- Increase registration fees, especially for vaccine if monies can be channeled to improving approval process.

Proposed action plans

Short term

- Actively propose trainings / seminars / talks to govt. regulatory officers to help enhance their knowledge and capability. Lobby for additional manpower at regulatory bodies.
- Encourage regulatory bodies to base the registration process / standard solely on the animal health industry (not human pharma).
- Actively participate in providing a feedback loop on new regulations (before implementation) and encourage regulatory bodies to set a more consistent standards in the registration process (through technical harmonisation).
- To examine FSC/CPP submission requirements - if it can be supplemented during the regulatory assessment, it will significantly accelerate new product access for ASEAN markets.

Long term

- Promote the importance of post market surveillance as it improves stewardship on the usage of animal health products.
- Encourage / support the use of an electronic / digital platform for product registration – speedier, more transparent and better traceability.
- Recommend the regulatory body to increase govt. registration fees IF it can increase efficiency (shorten the timeline, improve predictability, and reduce complexity) in product registration.

Myanmar

Key Points

- Current permit-based system provides market access although the recently increased lab charges are an additional hurdle.
- Now establishing a more systemic regulatory framework.
- Opportunities for knowledge/best practice sharing and to incorporate learnings from other ASEAN members.
- Opportunity to incorporate electronic platforms and appropriate 'fee for service' structure.

Cost of Product Registration in 2018

Cost (in USD) of product registration in 2018	
Govt. fees	No fee, only import permit
Other fees	< 100

- Some increased in fees for import license due to new registration rules / regulations now vs. 5 years ago.
- Similarly to Cambodia, the cost of animal product registrations is 'meagre'.

Timeline for Product Registration in 2018

Timeline (in months) for product registration in 2018	
Pharma	3 months for both companion and production animals
Biologicals	months for both companion and production animals

- Easy to bring products to market.
- Low complexity in getting import permits and a short timeline for product registration.

Overall Impact of Current Regulatory Environment in Bringing New AH Products to Market **(feedback from animal health companies)**

Bringing Products to Market: Challenges and Improvements

Key challenges experienced in bringing new AH products to market in the past 4-5 years

	AAHA	KOLs	GO*
Inadequate resources ($$$, facilities, labor)	✓	✓	✓
Higher fees for lab test and documentations reduces the competitiveness of local companies		✓	

*Government Officers

Local managers from animal health companies said that the current product registration achievement on the three metrics below is to be above average.

a) Science based (3.2 out of 5-point),
b) Consistent & predictable in review process (3.7 out of 5-point)
c) Independent and free from influence (3.8 out of 5-point)

According to stakeholders in the AH veterinary companies there has been an improvement on these three metrics in 2018 compared to 2014.

Commercialization of Registered Products: Challenges and Improvements

Level of difficulty of current regulatory environment on marketing & selling AH products to market

By and large, there are generally very few challenges faced in maintaining existing products in Myanmar.

ASEAN Technical Harmonization

Technical harmonization is not (yet) discussed in Myanmar. The country has just started to put together a more systemic regulatory framework, hence, lagging behind other ASEAN countries.

The view is that ASEAN technical harmonization is quite difficult. Each country has a very different culture, making it hard for these various countries to compromise with each other.

Stakeholders foresee that ASEAN technical harmonization will benefit MNC companies. If harmonization is implemented in Myanmar, there will be no issue for MNC as the product quality and standard of the MNC is already advanced and well aligned with the standard practice.

AH Regulators Goals: Short & Long Term

Short term (2-3 years)

- To develop a ONE STOP system. The aim is to set up one system / unit that process all the documents received from the AH companies. It is also intended to speed up the registration process and allow companies to market their product in Myanmar in a timely manner. Potentially, the regulatory agency also wants to move to an online application.
- To have a systematic, efficient and transparent system in place. This will require setting up a product, manufacturer and importer database. It also requires setting a standard protocol that companies can follow to get a product registered.

Long term (4-5 years)

- To prepare a proper / systematic regulatory framework for registration of animal health veterinary medicines. Regulators believe that the issue of the import permit is a short term / temporary measure and so to further enhance the industry, a proper regulatory framework that is at par with the standard of other countries is needed.

Proposed action plans

Short term

- Work closely with the regulatory body to improve the capability / knowledge and manpower of regulators – through trainings, and lobbying for more monetary allocation.
- More active communication with the regulatory body to help their collaborative development, as there will be many areas to work on. Discussions on the near-term and long-term goals are starting points for the collaboration.

Long term

- Adoption / use of digital tools (e.g., an online product registration) has been good (5/7 markets) but some teething problems - industry to continue to support the implementation of digital platforms.
- Encourage the regulatory body to set a registration fee that is 'a match' to other ASEAN countries that will ensure this is one (possible) monetary resource for them to improve the registration efficiency.

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Philippines

Key Points

- Regulatory timelines have been quite predictable but recent changes in the reporting structure of the regulatory body is challenging.
- Use of permits and manual inspections at importation has caused delays.
- Improvement in e-Dossier and possible PIC/S membership offers opportunities.

Cost of Product Registration in 2018

Cost (in USD) of product registration in 2018	
Govt. fees	Pharma: 365 | Biologicals: <100
Other fees	Pharma: <100 | Biologicals: 129 (for companion animal), 8,560 (for production animals)

- In the past 5 years, govt. fees have increased slightly (<10%) for pharmaceuticals and no change for biologicals.
- Govt. fees for animal health product registration is generally low. However, there are some (significant) costs associated with local (farm) efficacy trials and the extension of validity permits.

Timeline for Product Registration in 2018

Timeline (in months) for product registration in 2018	
Pharma	Companion animal: 17 | Production animal: 20
Biologicals	Companion animal: 14 | Production animal: 18

- The timeline for product registration is 'good', although there is a minor increase in time needed for registration now vs. 2014.
- Animal health companies do not consider the registration timeline in Philippines can be further improved if there are limited experienced and professional evaluators.

Overall Impact of Current Regulatory Environment in Bringing New AH Products to Market (feedback from animal health companies)

Bringing Products to Market: Challenges and Improvements

Key challenges experienced in bringing new AH products to market in the past 4-5 years

	Feedback from:		
	AAHA	KOLs	GO*
Inadequate resources ($$$, facilities, labor)	✓	✓	✓
Frequent changes of regulation / evaluation	✓	✓	✓
GMP PIC/S*	✓		✓
Unpredictable review time	✓		✓

Key positive improvements in bringing new AH products to market in the past 4-5 years

	Feedback from:		
	AAHA	KOLs	GO*
(More) timely registration	✓	✓	✓
Implication of online product registration	✓	✓	✓

*Government Officers

Local managers from animal health companies and Government Officers said that the current product registration achievement on the three metrics below is to be good.

a) Science based (3.8 out of 5-point),
b) Consistent & predictable in review process (3.5 out of 5-point)
c) Independent and free from influence (3.2 out of 5-point)

Compared to 2014, the feedback from the industry is that there is poorer consistency and predictability in the review process. Ratings on science based and transparency is average, no change in the past 5 years.

Commercialization of Registered Products: Challenges and Improvements

Level of difficulty of current regulatory environment on marketing & selling AH products to market

Key challenges experienced in commercialization of AH products to market in the past 4-5 years

	Feedback from AAHA
Tightening of import permits (manual checks and for each shipment) Approval of import permits now becomes slower due to manual checking in order to curtail document falsification issues, leading to increased paperwork and fees	✓

By and large, there are generally very few challenges faced in maintaining existing products in Philippines. The industry and govt. regulators shared the same view on areas of improvements.

- Conduct pharmacovigilance/ post market surveillance to ensure proper usage of AH products.
- Revamp / improve the online registration especially on automatic renewal function.
- More stringent regulations on variation as it pertains to pack sizes, change of manufacturing sites, and change in active ingredients.

ASEAN Technical Harmonization

- Animal health veterinary companies agreed that technical harmonization makes it easier for companies to register their products in ASEAN because they can use the same set dossiers for all countries.
- Deciding on which country regulation to use as THE benchmark is the biggest hurdle. For countries that have more lenient regulations, it is seen as positive move – improving the standard of regulation, but for countries that have stricter regulations, it's seen as a compromise. It is important to identify which areas are open to be discussed and which areas are non-negotiable.
- Difficult to align national law and policies of different countries as labelling guidelines followed the Philippines Generic Act which limits the companies to have common labelling across ASEAN.

Readiness of Current Regulatory Framework for the Future

- Compared to developed countries, Philippines AH regulatory framework does not fit for the 21st century, although it is one of the better ones amongst ASEAN.
- Here are some suggested actions that may help get the industry ready for the future:
    - Improvement of e-registration system. To have everything done online including the submission. No more face-to-face interaction.
    - Reduce multiple evaluation stages to only 2 reviews – the pre and final review.
    - Higher investment in human capital by recruiting more qualified staff and training.
    - To have a more standardized checklist of requirements for product evaluation.

Proposed action plans

Short term

- For AAHA to actively participate in providing a feedback loop on new regulation (before implementation) and encourage regulatory bodies to set a more consistent standards in registration process (through technical harmonization).
- To examine FSC/CPP submission requirements - if it can be supplemented during regulatory assessment it will significantly accelerate new product access for ASEAN markets.
- Promote the importance of post market surveillance as it improves stewardship on the usage of animal health products.

Long term

- Encourage regulatory bodies to base the registration process / standard solely on the animal health industry (not human pharma).
- Adoption / use of digital tools (e.g., online product registration) has been good (5/7 markets) but some teething problems - industry to continue to support implementation of digital platforms.

Thailand

Key Points

- Regarded as amongst the most predictable regulatory body in ASEAN markets.
- Increased 'fee for service' model has improved outcomes in Thailand.
- Adoption PIC/S has been challenging but benefits lie ahead - especially if US bio quality standards are recognised.
- Opportunity to revisit restricted advertising channels in Thailand.

Cost of Product Registration in 2018

Cost (in USD) of product registration in 2018	
Govt. fees	Pharma: 5,800 | Biologicals: 4,667 (no difference between companion vs. production animals)
Other fees	Insignificant (no difference between companion vs. production animals or pharma vs. biologicals)

- Compared to 2014, there is a significant increase in the cost for registration for most therapeutic classes and types of registration due new regulations.

Timeline for Product Registration in 2018

Timeline (in months) for product registration in 2018	
Pharma	Companion animal: 15 | Production animal: 10
Biologicals	Companion animal: 12 | Production animal: 12

- Compared to 2014, there is a significant improvement in the timeline to get product approval in the market.

Overall Impact of Current Regulatory Environment in Bringing New AH Products to Market (feedback from animal health companies)

Bringing Products to Market: Challenges and Improvements

Key challenges experienced in bringing new AH products to market in the past 4-5 years

	Feedback from:		
	AAHA	KOLs	GO*
Unattainable regulation standard: difficulty for AH companies to comply (including difficult requirement for stability data)	✓	✓	
Compliance with PIC/S and GMP*	✓	✓	
Lack of resources, especially manpower	✓		✓
Regulators lack the knowledge of new APIs/products / ingredients	✓		✓

Key positive improvements in bringing new AH products to market in the past 4-5 years

	Feedback from:		
	AAHA	KOLs	GO*
E-system /online registration			✓
Compliance with PIC/S and GMP*	✓		✓
Timely product registration	✓	✓	✓

*Government Officers

Local managers from animal health companies and Government Officers said that the current product registration achievement on the three metrics (below) is to be good.

a) Science based (4.6 out of 5-point),
b) Consistent & predictable in review process (4.3 out of 5-point)
c) Independent and free from influence (4.0 out of 5-point)

Compared to 2014, had observed significant improvements in science based and transparency (free from political / commercial influence) in product registration achievement. Still room to improve on consistency and predictability.

Specifically, for Thailand on PIC/S

- Due to the high standard of GMP PIC/S compliance, there are issues with non-PIC/S compliant manufacturing plants (from China and US – those registered with USDA after the implementation of PIC/S GMP in 2016). There were many additional procedures (including manufacturing site inspections) and required documentation to get products registered (or for existing products maintained). This can be a costly and time-consuming exercise.

Commercialization of Registered Products: Challenges and Improvements

Level of difficulty of current regulatory environment on marketing & selling AH products to market

Key challenges experienced in commercialization of AH products to market in the past 4-5 years

	Feedback from AAHA
Restricted advertising >> companies can only advertise vaccines and antibiotics on specific channels	✓
Requirement for bilingual labelling (English and Thai)	✓

The industry and govt. regulators shared the same views on areas of improvements.

- Conduct pharmacovigilance/ post market surveillance to ensure proper usage of AH products.
- Provide a platform for advertising - having a public media whereby companies can advertise their products.

ASEAN Technical Harmonization

- Currently, the AH industry follows the human pharma standard (Compliance with ASEAN Harmonization) for product registration, and it has some practical difficulties.
- Without doubt, many from the industry support the idea of harmonization. However, it will take time and effort for alignment across ASEAN countries as products might be classified differently, with different procedures and protocols.
- Govt regulators did voice that there are some aspects of the technical framework that can be more easily harmonized. One possible aspect could be classification of products (hazardous vs. others).

Readiness of Current Regulatory Framework for the Future

- Different stakeholders agreed that the current framework is fit for the future. As the authority had made huge improvements by implementing high standard regulations, new technology and improving timelines for making the AH industry better, the Thailand AH industry is moving towards 'modernization'.
- Here are some suggested actions that may further help get the industry ready for the future:
  - Provide training to officers – Make sure they are well prepared before the new regulations.
  - Hire more experts and veterinarians – Not pharmacists to review the work of AH.
  - More e-technology – speed up procedures using well developed e-submission.
  - Focus more on post marketing – field sampling using a caution system to monitor products sold (the whole process including import, storage etc.).
  - Public hearing and discussion before putting in place new rules or regulations.

- Separate human and AH regulations – Different departments to manage AH as AH needs & requirements are different from human health.

Proposed action plans

Short term

- Encourage the regulatory body to provide some exceptions / extensions (if request by AH veterinary companies) during the 1st review – at times, companies need extra time to get all the paperwork if the initial submission is rejected or not complete.
- Actively participate in providing a feedback loop on new regulations (before implementation) and encourage regulatory bodies to set more consistent standards in the registration process (through technical harmonization).
- To examine FSC/CPP submission requirements - if it can be supplemented during the regulatory assessment, it will significantly accelerate new product access for ASEAN markets.

Long term

- Encourage regulatory bodies to base the registration process / standard solely on the animal health industry (not human pharma).
- Promote the importance of post market surveillance as it improves stewardship on the usage of animal health products.
- Encourage/ support the use of an electronic / digital platform for product registration – speedier, more transparency and better traceability.

Vietnam

Key Points

- Low government regulatory fees but high costs associated with local trial requirements.
- Timelines good apart from where clinical trials delay the approval date.
- Additional testing and check on imported goods has caused delays - part of a trend of increasing complexity in regulations.
- Scientific basis of processes and regulations continues to increase.

Cost of Product Registration in 2018

Cost (in USD) of product registration in 2018	
Govt. fees	Pharma: 85 | Biologicals: 100 (no different between companion vs. production animals)
Other fees	Pharma: 5,700 - 7,600 | Biologicals: 10,500 (data for biologicals is only for production animals)

- There had been an increase in costs for all key therapeutic areas in the past 5 years. These increases were due to:
  - local trials
  - new regulations
  - an increase in quality testing fees.
- All stakeholders agreed that Govt. registration fees are one of the lowest in ASEAN

Timeline for Product Registration in 2018

Timeline (in months) for product registration in 2018	
Pharma	Companion animal: 15 | Production animal: 19
Biologicals	Companion animal: 15 | Production animal: 35

- There had been an increase in registration time for biologicals (for production animal) in the past 5 years due to testing requirements. For Animal health companies, the timeline for registration is sometimes unpredictable, largely due to a lack of resources, however, it's not (very) complex to get products registered.
- Both experts/KOLs and govt. regulatory officers said that the registration timeline is good (fast).

Overall Impact of Current Regulatory Environment in Bringing New AH Products to Market (feedback from animal health companies)

Complexity in product registration is caused by stringent regulation including farm trials and country-specific testing. The system is predictable but complexity/requirements is increasing.

Bringing Products to Market: Challenges and Improvements

Key challenges experienced in bringing new AH products to market in the past 4-5 years.

	Feedback from:		
	AAHA	KOLs	GO*
Unattainable / difficult requirements (e.g., stability data / trials / etc.)	✓	✓	✓
Unable to meet the predictable timeline	✓		
Tough requirement for local production >> manufacturing plant needs to comply to WHO's GMP and ISO 1750		✓	

Key positive improvements in bringing new AH products to market in the past 4-5 years.

	Feedback from:		
	AAHA	KOLs	GO*
Simplification of registration (1-door policy)	✓	✓	✓
Implementation of online product registration		✓	
Implementation of regulatory/ administration reforms in accordance to Circular 13 and 18	✓	✓	

*Government Officers

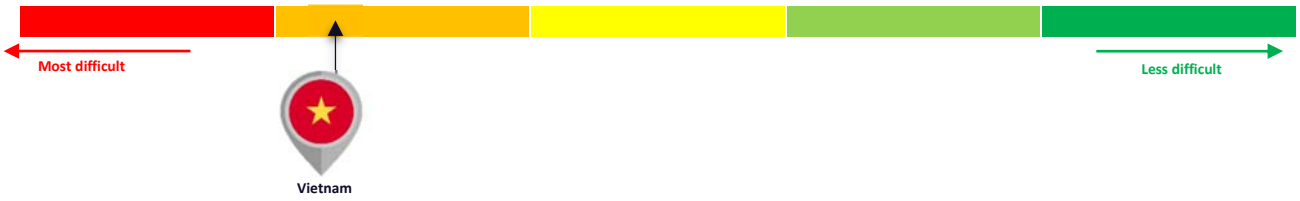
When asked, local managers from animal health companies and Government Officers considered the current product registration achievement on the three metrics below to be somewhat average.

a) Science Based (3.7 out of 5-point),
b) Consistent & predictable in review process (2.7 out of 5-point)
c) Independent and free from influence (3.3 out of 5-point)

Compared to 2014, had observed significant improvement in science based. There has not been (significant) change on the other two metrics: consistent & predictable in review process and honest, independent & free from political / commercial influence.

Commercialization of Products: Challenges and Improvements

Level of difficulty of current regulatory environment on marketing & selling AH products to market



Key challenges experienced in commercialization of AH products to market in the past 4-5 years

	Feedback from AAHA
Lack of capability & capacity for the import checks of AH products	✓

Vietnam is considered the most challenging due to recent compulsory testing/checks for each shipment of imported products

- In 2016, regulatory bodies started to have stricter control on the quality of imported products.
- Vaccines and antibiotics were tested in all shipments for sterility, purity and safety.
- Potency tests for PRRS, FMD and flu (avian) vaccines was also compulsory for all shipments.

ASEAN Technical Harmonization

The majority are not aware of ASEAN harmonization.

Currently, Vietnamese regulatory bodies are improving their regulatory framework by setting up regulations based on a global standard, e.g., OIE, FDA or USDA.

There is a perception that 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 do not set up regulations to protect them.

The current view is that Vietnam is not ready to implement ASEAN harmonization. It lacks facilities (for example: labs), technology and manpower to fulfill ASEAN technical harmonization.

Readiness of Current Regulatory Framework for the Future

- Different stakeholders shared similar views - the current regulatory framework is not ready for the future, especially in the area of assessing new technical innovations: more knowledge, training and consistency is needed.
- Regulatory bodies had set up high requirement, but they do not have the capabilities to implement it.
- A major overhaul is not needed but tweaking the current framework should be done.
- Listed below are some suggested actions that may help get the industry ready for the future:

- Have commitment in timelines for product approval, shipment release and feedback to any queries. Ensure a proportionate level of quality control, shipment testing and market surveillance. Align product registration requirements with more developed countries.
- Exemption of lab test/field trial if the regulators are not able to conduct the test in a timely or effective manner, and instead consider accepting international data/documentation.
- 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 a standard farm for trial.

Proposed action plans

Short term

- Actively participate in providing a feedback loop on new regulations before implementation and encourage regulatory bodies to set more consistent standards in the registration process to reduce the likelihood of different interpretations by different parties.
- To examine FSC/CPP submission requirements - if it can be supplemented during the regulatory assessment, it will significantly accelerate new product access for ASEAN markets.
- Set/agree a target timeline for the registration review process with the respective regulatory bodies and track the achievement rate.

Long term

- Recommend the govt. regulatory body to increase govt. registration fees IF it can increase efficiency (shorten the timeline, improve predictability and reduce complexity) in product registration.
- Encourage / support the use of an electronic / digital platform for product registration & an online product database, to reduce the timeline, provide better tracking of registration & be more independent from external influences.
- Work closely with the regulatory body to improve the capability / knowledge and manpower of regulators – through training, and lobbying for more monetary allocation.


AAHA
Asian Animal Health Association
A Member of HealthforAnimals