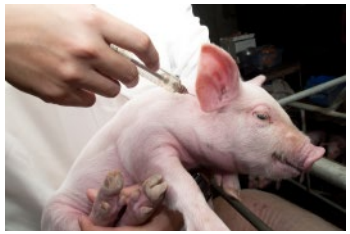









Insight Report – Philippines:
ASEAN Animal Health Regulatory Benchmarking Survey

Prepared for: Asia Animal Health Association

Report date: 24. September. 2018

Report content

Background & Study Objectives

The 1st ASEAN Animal Health Regulatory Benchmarking Survey…

Background

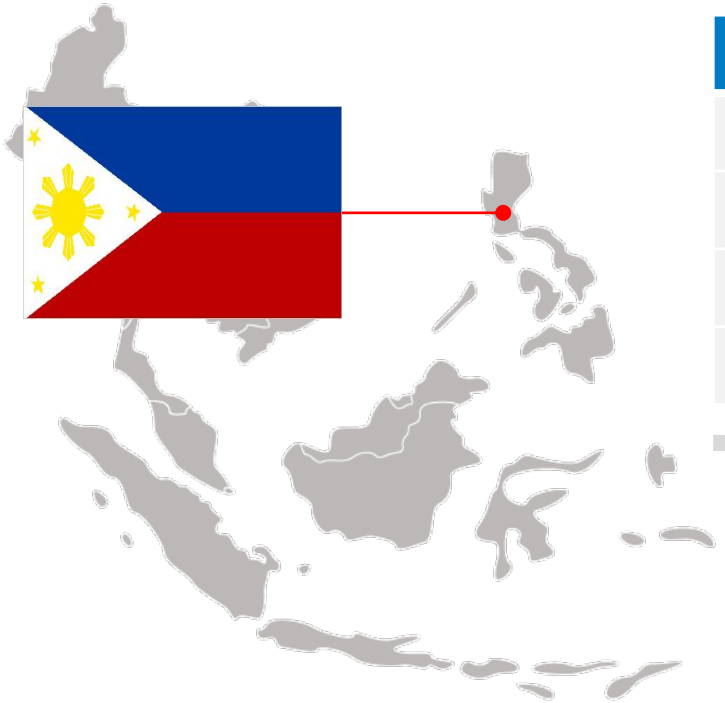
AAHA (Asia Animal Health Association) is conducting a study to review, track and benchmark the veterinary products' regulation framework and practices across 7 ASEAN countries, namely Thailand, Myanmar, Malaysia, Indonesia, Philippines, Cambodia and Vietnam.

Scope of work

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

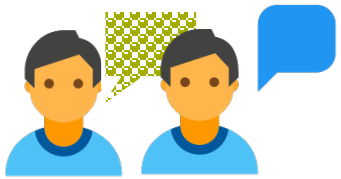
- Assess the impact of regulatory framework that impacted AH industry
- Evaluate the adoption of technology/innovation within the AH regulatory framework
- Gauge the extent of technical harmonization within each country, and across the region
- Evaluate the readiness of the AH regulatory framework for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

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



Total interviews: N=10

Respondent profile	Sample, n=10
MNC Business Managers	5
Local Business Managers	2
MNC Regulatory Managers	3
Local Regulatory Managers	--



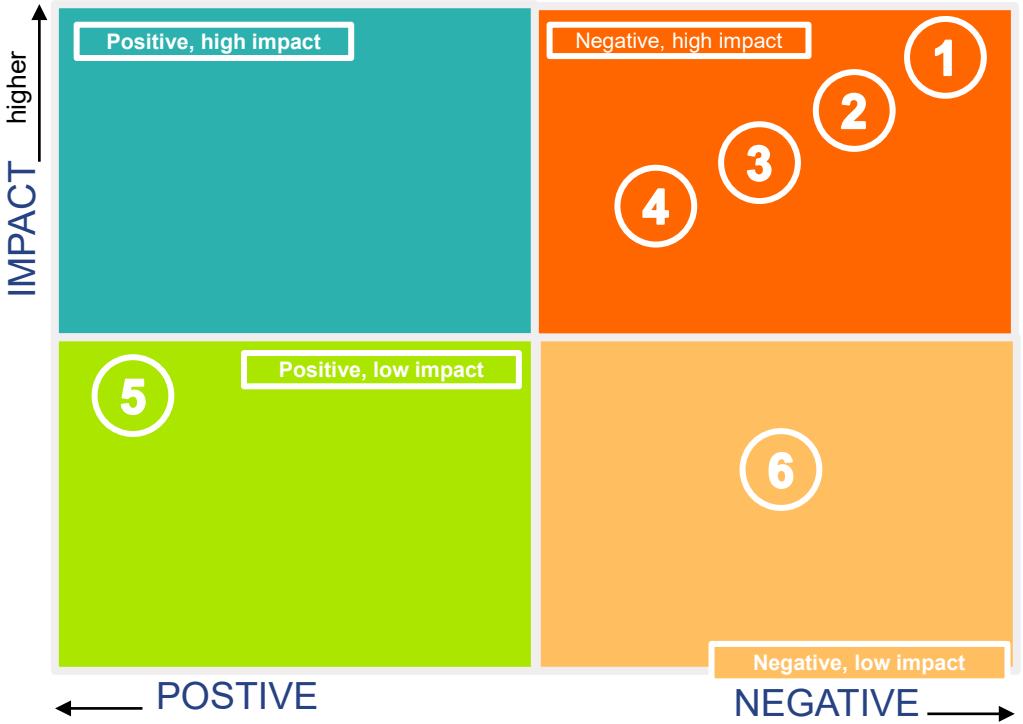
1- 1.5 hours face-to-face / phone interviews with targeted managers

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

Farmers are not keen to participate in farm efficacy trials. This results in limited farms for efficacy trials, hence delay in registration process.

However, Philippines is still considered as one of the fastest regulatory review times in ASEAN and it has shown some attempts in modernization by online registration for pharma products



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. Lack of qualified personnel/regulators
2. Farm efficacy trials challenging (limited farms willing to participate)
3. Inefficient online registration processes for pharma products
4. Inconsistent evaluation
5. Fast review time (compared to other ASEAN countries)
6. Lack of commitment to regulatory review times

Additional comments on the behavior and attitudes of regulatory agencies in Philippines….

Acceptance of registration paper/dossiers approval from other countries	AH regulatory accept registration paper/dossiers approval of other countries (especially the US). This helps the industry tremendously as it speeds up approval of AH products in the Philippines.
Fast track of product registration when in need	▪ Whenever there's disease outlook (or market needs), regulatory are very responsive to approval effective (new) products quickly
Supportive of antibiotics alternatives	▪ Although there's no specific enforcement on making sure antibiotics are not used as growth promoter, regulators encourages antibiotics alternatives ▪ Hence, in the Philippines there are lots of products in nutritional segment like enzymes and toxin binders – that get registered promptly, without lots of questions from the regulatory bodies.

Companies have to deal with regulators that are not familiar with AH products or those who are inexperienced and follow the procedure to the ‘dot’.

Negative, high impact

Limited qualified & experienced personnel under Joint Administrative Order (JAO)

>> FDA is lacking manpower, and new joiners are fresh graduates. Since they are inexperienced they will follow all the requirements in the checklist. However, the checklist is adapted from human pharma products, hence it is impossible to follow all the rules ‘wholesale’ to AH products. Since these officers are inexperienced they ‘stick’ to the rules with little opportunity to compromise.

Most of the FDA officers are pharmacists not veterinarians so there is a mismatch of knowledge and what they are suppose to do. This leads to slower approval process because they need more time to study and understand the documents. They will also raise lots of questions.

BAI officers who are well-trained and have deep knowledge are retiring – there’s lack of handover and knowledge transfer

“These people are not well-experienced evaluators. They are really young like 22 years old, like fresh graduates. So when you encounter these guys, they will be ask for everything in the checklist which is fine but sometimes they are too strict that there’s no room for compromise. It is difficult to establish a relationship. These millennial kids, they have a certain behavior or attitude that “I am the evaluator, so I will be followed.”

Securing local farms to conduct farm efficacy trials cause companies increased expenses and loss of business opportunities. Despite FDA's attempt to modernize their application process, there are still hiccups with their online system.

Negative, high impact

Farm efficacy trials challenges	>>	BAI requires farm efficacy trials for vaccines with new strains. The challenge is getting local farms that are willing to allow companies to use their farm to do the testing. The process can delay up to 6 months to a year The farmers are skeptical of the presence of regulatory officers – they are afraid the authorities will find some non-compliance activities in the farm and fine them
Inefficient online registration processes for AH pharma products	>>	Implementation of online registration system for pharma products (FDA) is a positive move. But as AH product is not perceived as important as human pharma…it is common that veterinary products tend to be sidelined! Documents are to be submitted through USB and will be given a tracking number. The officer will copy the content into their system but sometimes the documents in the system will get 'lost'. It will usually take about 3 months before being review by an evaluator. Checking tracking number to find out application status do not work very well as it is common to get message such as 'received by FDA CDRR' for up to six months. Companies will still need to visit FDA to check!

Companies complained about inconsistency of evaluation by BAI (vaccines). There is no fixed set of requirements that is followed by all evaluators.

Negative, high impact

Inconsistent evaluation with no fixed set of requirements

>> When different head of department takes over, there seems to be different rules. These instances are mostly observed in BAI

For vaccines, the officers do not have a fixed checklist of requirements, it seems to change according to who the evaluator is….

So there's a (constant) need for visit the local authorities to find out what's their latest requirements

"Requirements. It is like this, sometimes they have checklist of requirements that only serve for 1 or 2 months, sometimes on the 3rd month, it will change again. So the mere fact that you have to be with the local authorities for visits regularly, yet you can't master the requirements because it is like you are always a new client because the requirements keep on changing each time. There are always changes on the checklist of requirements for variations, amendments, notifications."

Philippines regulatory review time is not a set fixed time but merely serve as a guideline.
Companies have to be prepared to do regular follow-up if they want to ensure their products get approved in a timely manner.

Negative, low impact

Lack of commitment to regulatory review times >> It can be unpredictable, sometimes it is faster, other times, registration will be delayed. Regulators are not committed to deliver on the timeline specify in the check list/guideline. Frequent follow up is needed

"There's no commitment. It seems that it's just a guideline. OK, in 60 days you have to get this status more or less. But in reality, doesn't happen."

Philippines has one of the fastest regulatory review times in ASEAN.

Positive, low impact

One of the fastest regulatory review times in ASEAN >> Timeframe is acceptable, if you discount the farm efficacy trials. It is faster than most countries in ASEAN.
For pharma products (under FDA), registration will take average two years
For vaccine (BAI) is faster because there is more resources available. Usually turnaround time for BAI is 18 months excluding farm efficacy trials. Farm efficacy trials typically take 6 months
For companion animals, it would be even faster, maybe even 1 year, because it's easier to get minimum 5 pets to try the drugs than 100 hundred animals per farm. Efficacy trials for companion animals will take 2 months

Although most companies do not have problem with increased fees, they are not confident if the increased fees will bring about higher service from the regulatory bodies. Companies' main issue tend to be 'poor quality' of regulators.

Most expensive

- FDA increases registration fees to 300%

  Announced in May 2018 but was put on hold as representatives of AH companies are writing position paper to question this increase. Companies generally do not mind to pay more but they expect improved /more efficient services!
- Import permit

  Previously, an import permit is valid for 6 months and the fee is PHP500. Now with online application, the fee remains for same, but the permit is for every shipment.

Most challenging

- On a macro level, the Ministry of Agriculture does not pay much attention to the animal health industry. Hence there's lack of funds being channeled to departments that deal with animal health. This is the root issue to all other challenges
- **This results in lack of manpower in both FDA and BAI**
- As long as there's separation between FDA and BAI for pharma and vaccine the process will not be smooth. Both organizations have different protocols - FDA uses human health standards to evaluate AH products – which leads to inappropriate documents checklist for different types of animal health products

Import permits are getting more tedious to obtain due to slower process and increased fees.

However, by and large, Philippines is still a relatively smooth market to sell due to the officers being willing to listen from companies and try to understand the product itself.

Negative development — Positive development

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. Good intention - to curb falsification issue and recycle of old permits. BUT, it created new issues – slower importation of goods, more paperwork and fees. Before this, companies can apply for online import permit with validity for 1 year. NOW, they need to get permit for every shipment (with online system). BAI will print out the import permit, stamp it, physically send it to Department of Agriculture for it to be signed manually. The change is the process can delay product shipment up to 3 weeks. For shipments that are still stuck at the port, companies have to pay extra fees for storage

Philippines is an easy market to sell and market AH products

- Even though regulators are not expert, they do not pretend they know better than the manufacturers
- They are open to ask and discussed with manufacturer is they cannot understand the product / technology.
- For products that are already registered in the EU / US, regulatory bodies are very much open minded about it because they 'trust' the assessment of these developed countries

"There's not really much restriction to, in registering new products. If they are really don't understand the product or technology, can pull them aside and talk to them, they will really try to understand the technology that the company is trying to bring in."

There seems to be less stringent post marketing monitoring due to unclear which agency is supposed to be accountable for it.

This contributes to proliferation of smuggled products due to lack of surveillance in the market.

Proliferation of smuggled products

- There are pharma products being sold in the market that are not fully registered, most probably being smuggled without clearance from FDA
- Products appear to be physically similar with different price tags. Swine farmers go for cheaper products without questioning the authenticity of product

Lack of authority by BAI in pharmacovigilance for companion animal products

- Registration for companion animal pharma products is under FDA. But if it comes to inspecting products at veterinary clinic, BAI is mandated to monitor. However they cannot monitor because the products are not listed in their agency

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

No major issues noted with safety and manufacture/quality requirements. However, some inconsistency issues noted in product labelling.

Safety

- Overall, there's no major issues faced with safety requirements. For pharma products, there are some occasional questions regarding dossiers which need clarifications. For vaccine products, they are more lenient whereby they only point out simple things like grammatical errors. This is possibly due to the lack of manpower to really read through the dossiers thoroughly
- However there is some inconsistency noted when it comes to product labelling. Different evaluators will have different interpretation of requirements. For example, for disinfectants, some evaluators think it's alright for the label to have no RX symbol because it's not a prescription product while others insist of having it….

Manufacture/Quality

- No issues faced with manufacture/quality requirements as the manufacturer at country of origin would have fulfilled all requirements there before exporting it. Even if there's some questioning of some slight deficiencies, the regulators are open to listening to justification by companies

"We seldom get questioning, of course if it's about the document will be released or below if it's not within the range of what we release, some questions like that. For example, it's an antibiotic and there's no anti-toxin included and in the parameters, they will just ask it and then we can provide justification where it is not included."

No major issues noted with efficacy requirements except with local trials challenges with farmers. R&D activities are done at country of origin.

Efficacy

- Expectedly, no specific issues experienced with regards to efficacy requirements. There's rarely any questioning on the Certificate of Analysis (COA)
- However there's some problems with local trials wherein it's somewhat difficult to get farmers to allow their farms to be used for testing.

"This is the part where it sits too long with the regulators. For BAI, they will ask for written consent from the farm, the design of the protocol will be the industry with the consent of the farm, so once it gets to the regulators, even with FDA, there are items that they will insist to change in the protocol. I think they have a set of consultants. So that's the part where we encounter difficulty."

R&D activities

- Most AH products are imported, and R&D has been done at the origin countries before production and export. This is not a major concern/task/activities for most MNC companies whilst for local companies, R&D is not needed as they are mainly focused in only importing products

PIC/S and FSC requirements pose slight challenges to companies. No issues with GMP requirement.

- **Philippines is not PIC/S country, but they want to be.** Hence, regulatory encourages companies to import products from PIC/S countries to get enough points to be part of PIC/S country.
- For products that are not from PIC/S countries, they need to sponsor foreign audit (Regulatory officer from other PICS country) for site inspection which can take up to 6 months to suit the officer's schedule due to lack of manpower

- As long as the manufacturing site has GMP certification, there is not likely to have problems encountered with manufacture/quality requirements
- Country of origin also need to be able to provide Certificate of Analysis. This ensure products meet the requirements

- Sometimes companies are unable to produce FSC from country of origin because the product is not sold in that country. Regulatory authorities sometimes don't understand this situation and flag it as incomplete submission. This will delay registration process → time loss
- It is said the authentication process for FSC is tedious. The FSC that is procured from country of origin needs to be notarized by the local lawyer and then authenticated by the Philippines Embassy at the country. Additionally, some provinces in China cannot issue FSC → need to provide explanation to the regulatory authorities in Philippines

Importance & feasibility of ASEAN technical harmonization

Some progress in ASEAN Technical Harmonization is observed, but full integration remains to be a wishful thinking….

Progress

- According to the managers, there are some harmonized guideline for product variation in the region. However, they generally find it not useful as this guideline tends to more stricter compared to the guideline by regulatory bodies in Philippines.
- Harmonization on others aspects is yet to be implemented.

Challenges & benefits to the industry

- Deciding on which country regulation to used as THE benchmark is the biggest hurdle. Countries that have more lenient regulations, it is seen as positive move – improve the standard of regulation, 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 → Labelling guidelines followed Philippines Generic Act which limits the companies to have common labelling across ASEAN
- It will make it easier for companies to register their products in ASEAN because they can use the same set dossiers for all countries.

Some progress in ASEAN Technical Harmonization is observed, but full integration remains to be a wishful thinking….(cont'd)

Challenges & benefits to the industry

- It will also benefit the regulatory agencies because they can accept documents approved in other ASEAN countries without having to send an officer for site inspection or do additional testing. This will ease regulatory affairs staff workload

"Harmonization is usually a few brains, Indonesia, Malaysia, the South East Asia, you bring them together, and then you discuss, how would we like to approach registration in the future. And if there is one country that say no, absolutely, I need to do in a certain way, if not, I cannot agree on the requirements you are asking me, so I am out. And of course you start to compromise. And very often, you find something in between of all, so it's a compromise. If you are on a better side, it's probably not improving, it's not making things easier. Let's say if there's a joint approach of Indonesia and the Philippines, they will be a big change for us and it will not be for the good."

Future outlook of ASEAN regulatory framework

FDA needs to invest in human capital while BAI have to modernize their registration process like FDA.

Current view

- Compared to EU or USA standards, Philippines AH regulatory framework does not fit for 21st century, although it is considered to be one of the better ones amongst ASEAN
- Post marketing surveillance is still poor, there's no inspection on product efficacy after product is being registered
- FDA seems to be more sophisticated with its online system, however there are still many flaws to it, mainly due to inefficient processes..

Action needed

FDA

- ➢ Improvement of e-registration system.
- ➢ 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

BAI

- ➢ To have online registration. To have everything online including the submission. No more face-to-face interaction.
- ➢ To have a more standardized checklist of requirements for product evaluation

Appendix

There are 2 regulatory bodies involved in the registration and approval of animal health products under Joint Administrative Order (JAO)

Ministry of Health

↓

Food and Drug Administration (FDA)

↓

Veterinary products containing:

1. Oral Dosage forms such as capsules, tablets, bolus paste, powder for suspension, granules for suspension etc.
2. Injectables such as solutions, suspensions, powder for suspensions, parenteral, etc.
3. External preparations such as topical suspensions, creams, ointments, lotions, spray, pastes, gels, powders, medicated soaps, etc.
4. Ophthalmic crams, ointments, solutions or suspensions

Department of Agriculture

↓

Bureau of Animal Industry (BAI)

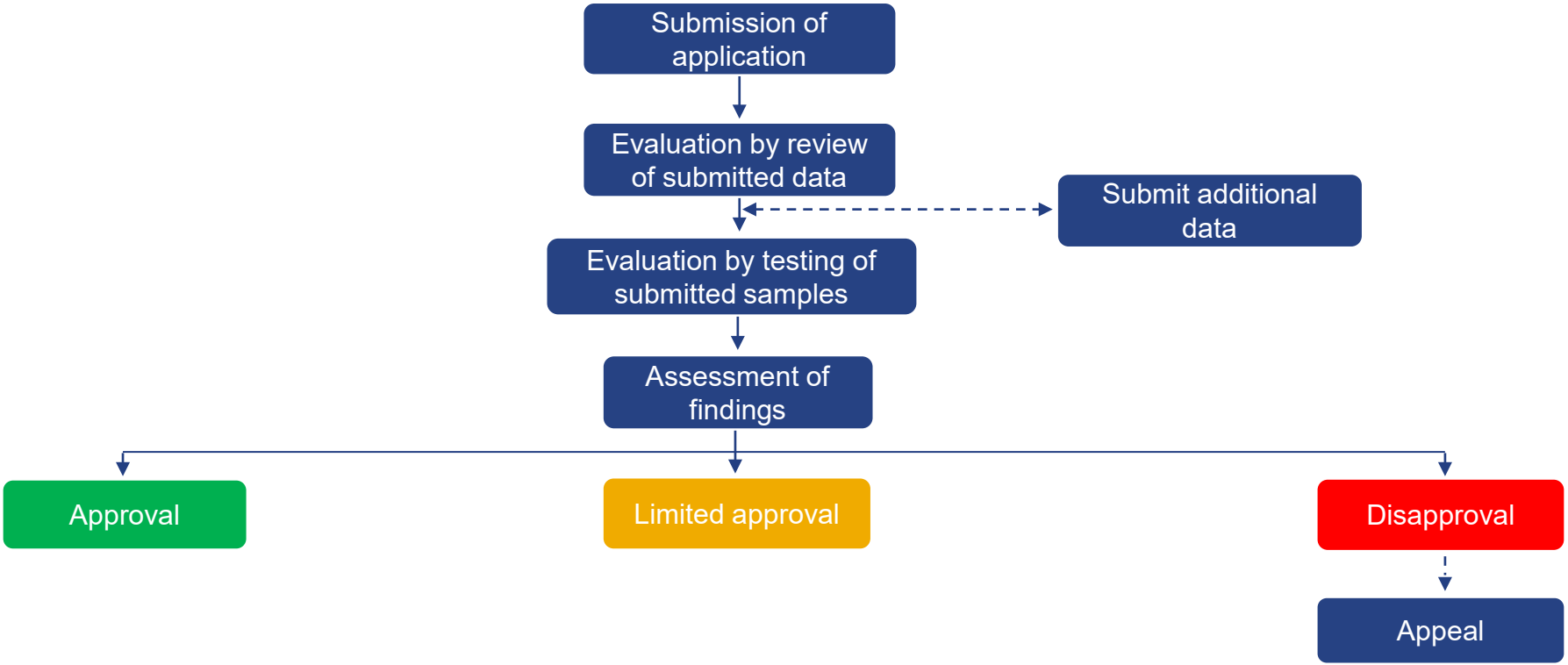
↓

Veterinary products containing:

1. Pre-mixes and water soluble powder added to feeds, supplements and additives
2. Veterinary vaccines, diagnostic kits and reagents and veterinary medical devices
3. Non-medicated soap and shampoo, toothpaste, colognes, conditioners, talc, coat shine oil, breath freshener, plaque remover, etc.
4. Dips for animals and eggs
5. Disinfectants that are intended for veterinary use
6. Probiotics that are intended for animal facilities

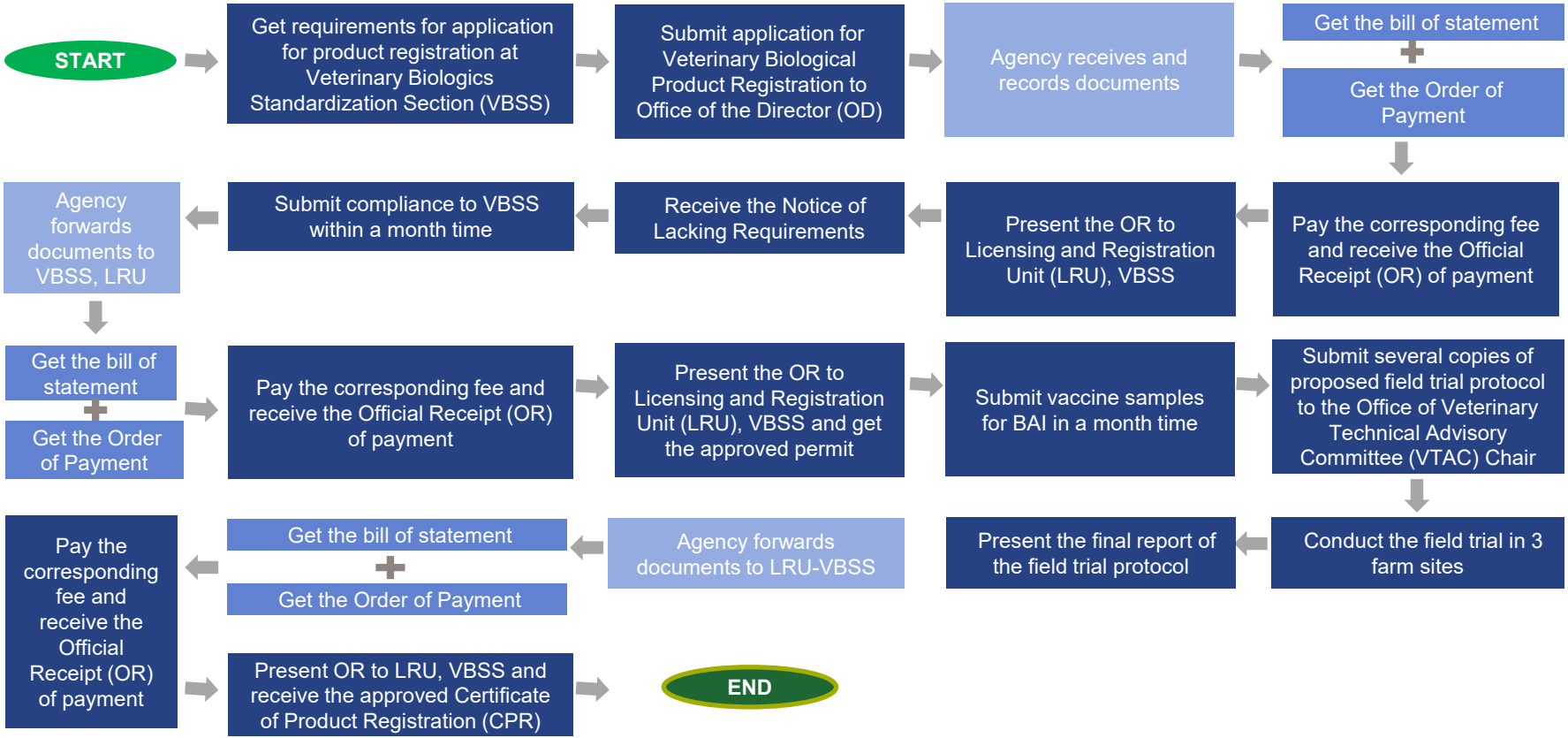
Source: Joint DOH and DA Administrative Order 24 September 2013

FDA: Process of registration AH Pharma products



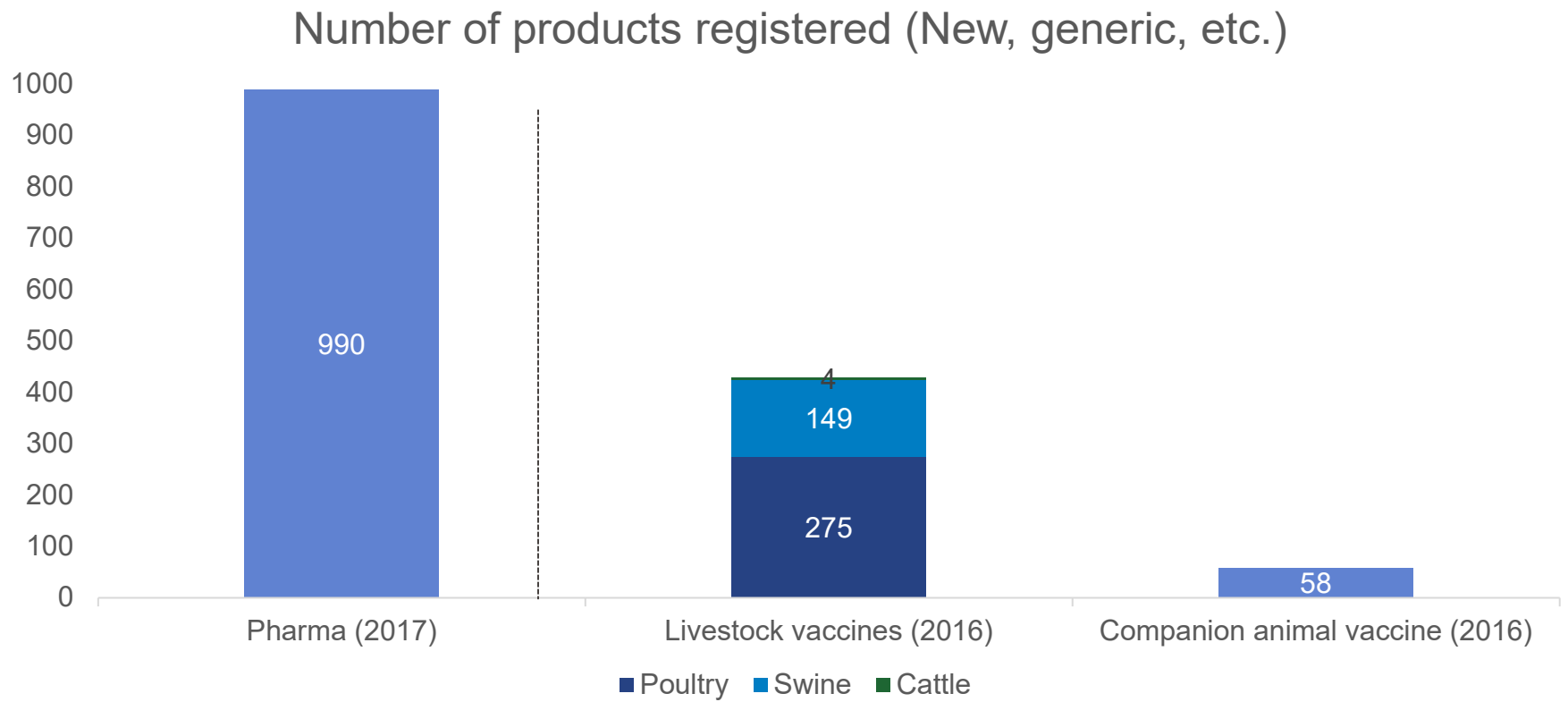
Source: Source: http://www.wipo.int/edocs/lexdocs/laws/en/ph/ph152en.pdf

BAI: Process of registration (new) Vaccine products



http://www.bai.da.gov.ph/index.php/regulatory/item/343

Number of products registered for both pharma and vaccines



http://www.bai.da.gov.ph/index.php/download

Kueh Ai Chen
Executive Director, Custom Research, APAC
aichen.kueh@kynetec.com
T +603 7496 7788
M +60 (12) 399 1359
www.kynetec.com