

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

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Background & Study Objectives

The 1st ASEAN Animal Health Regulatory Benchmarking Survey...



Background

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



Scope of work

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

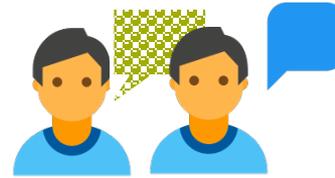
- Assess the impact of regulatory framework that impacted AH industry
- Evaluate the adoption of technology/innovation within the AH regulatory framework
- Gauge the extent of technical harmonization within each country, and across the region
- Evaluate the readiness of the AH regulatory framework for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

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



Total interviews: N=12

Respondent profile	Sample, n=
MNC Business Managers	5
Local Business Managers	2
MNC Regulatory Managers	3
Local Regulatory Managers	1

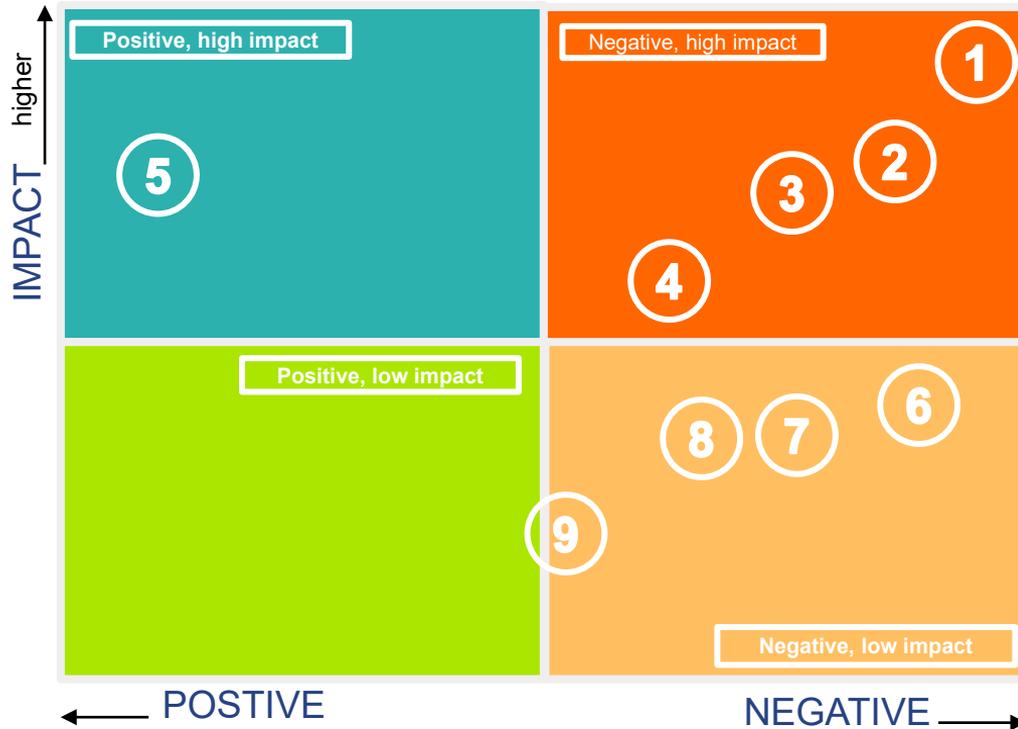


1- 1.5 hours face-to-face /
phone interviews with targeted
managers

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

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

By and large, the AH regulatory challenges faced in Indonesia are catalysts of poor administration (and knowledge) of regulatory bodies



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 Inconsistent review process and lack of the capability of the authority | ⑤ E-system registration |
| ② Complicated registration process for recombinant vaccines | ⑥ Strong protectionism |
| ③ (Still in draft) Technology transfer for imported products | ⑦ Difficulty in field trial for new products |
| ④ Classification of ionophores as AGP | ⑧ Difficult registration requirements for CA health products |
| | ⑨ Restriction of AI vaccine import |

Ultimately, there are multiple challenges with product registrations in Indonesia. The lack of knowledge and inefficient registration system are the main catalyst for these challenges

Negative, high impact

Inconsistent review process and lack of the capability of the authority

1. Lack of knowledge to assess the registration dossier

- >> Both MNCs and locals professed that the regulatory officers lack knowledge about AH products. Thus, they tend to request unnecessary additional documents from AH companies and also take longer time in assessment.



Lack of knowledge from VDAC where sometimes they ask irrelevant document so that make registration process becomes longer, such as for Cocci why they ask titer/titre, meanwhile Cocci doesn't need titer/titre. Sometimes, they want to know in detail the technicalities for product that will registered while it's confidential information for the company. - MNC

2. Inconsistency in evaluating the registration dossier (lack of checklist / standard protocol)

- >> All agreed experts in VDC standard check list or protocol in their assessment of products. Currently, the decision is left with the regulator that assess the products. Some regulators are more rigid/strict...others are more lenient!



They don't have a standard to assess one product. This is sometime not fair. For example, if this product A, someone in the meeting said we cannot passed this. Next meeting, this guy didn't come in, another guy come in and it is different, they pass this. - MNC



For example we don't estimate for field test while now we have to do field test. The loss is the timing from 6 months becomes 1 years. It's a cost. So the launching will takes more time. - Local

Ultimately, there are multiple challenges with product registrations in Indonesia. The lack of knowledge and inefficient registration system are the main catalyst for these challenges

Negative, high impact

Inconsistent review process and lack of the capability of the authority

3. Irregular expert meetings for innovative products' approval

- >> For innovative products, expert meetings in VDC is needed to assess and verify the documents. These meetings are not held regularly, and no specific schedule. The meetings are held only when experts are available to attend. The interval of meetings can be as long as 3-4 months.

This will ultimately caused delay and challenges to get a new product into Indonesia market

4. Insufficient AH committee meeting to assess re-registration and new (existing active ingredients) products

- >> VDAC is involves in assessing re-registration or new product registration with active/indication already exist in Indonesia.

The VDAC meeting are held regularly, twice per month and max 20 products to be discussed. With a huge backlog of products to be reviewed, it is common that AH manufacturers will have to wait between 2-7 months before their products are approve for registration.

The 'long' period is can also be due to the fact that the committee might requires additional documents during their review.

Ultimately, there are multiple challenges with product registrations in Indonesia. The lack of knowledge and inefficient registration system are the main catalyst for these challenges

Negative, high impact

Difficulty with recombinant vaccines

- >> Registration of recombinant products is very challenging in Indonesia. The registration process is very complicated as it involves different ministries e.g. Ministry of Environment, thus time consuming. Moreover, the registration procedure for these products are still unclear / not finalized!
- 🔊 *Not clear the process or registration of innovative products, when there's never been such a product, so which ministry have to also give green light, what that have to be done, and who's the one who gives the next thing, so it's really the work flow, which is not clear that block and take time. - MNC*
- 🔊 *Registration can take up to 10 years. Many of the ASEAN countries like Malaysia, Thailand, Philippines, Vietnam, recombinant products already registered but Indonesia not register yet. - MNC*

Additional comments on registration of recombinant vaccines....

Authority is slowly improving the registration framework for recombinant products



- With the support and lobbying of MNCs, the BioSafety Commission had developed the questionnaire to take into consideration recombinant vaccine in the environmental risk analysis document. This questionnaire is now approved by the Ministry of Environment, and the expectation is that - - registering GMO products will / are now easier. .

Ultimately, there are multiple challenges with product registrations in Indonesia. The lack of knowledge and inefficient registration system are the main catalyst for these challenges

Negative, high impact

(Still in draft)
Technology transfer
for imported products

- >> For imported products, the registration number is only valid for 10 years and re-registration cannot be done. AH companies will have to transfer their technology and produce locally. MNCs believe that this is government strategy to attract foreign investor to build manufacturing site in Indonesia or work together with local companies that has a factory to produce the drug.
- MNCs think it is not feasible to invest a factory and produce drug for Indonesia market only due to the tremendous investment cost.

The Indonesia AH regulatory bodies are putting more regulatory pressure to have more AH products produced locally (especially vaccines). They are also making registration of some products – e.g. CA AH products rather difficult due to unrealistic registration requirements.

Negative, low impact

Strong protectionism

>> Few MNCs claimed that they are having a tougher registration process compared to local companies. Authority prioritised local companies as they have better connection to the authority and no language barrier.

🔊 *The registration goes much faster for local company often less work to be done, less documents to be provided such as FSC not required by local company and I have the feeling that they are prolonging the process like they questioning us several times but not all in a time which I think it's not happen for the local company. – MNC*

Difficulty in local (field) trial for new product

>> Some found difficulty in looking for commercial farm/institution to conduct local trials. Moreover, AH companies have to submit trial proposal and get approval from VDAC before they start any field trial. Sometimes, they have to revise their proposal 2 to 3 times until VDAC finally approved.

🔊 *For us the longest one to get proposal approved is we went back and forth until 4 times maybe for 6 months only to start the trial. – MNC*

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Negative, low impact

Restriction of Avian Influenza vaccine importation

- >> AI vaccine used in Indonesia must be produced locally by using local strain. MNCs are at disadvantage whilst local companies like this arrangement. The AI vaccine market is now monopolized by few local vaccine manufacturers.
- MNC companies felt that this is not the right move as it discourages innovation as local companies are not likely to be innovative and come up with new idea or vaccination technology.

Difficult registration process for companion animal health products

- >> Minority has complained that they have difficulty in bringing companion AH products into the market due to difficult to meet the same registration requirement as livestock AH products. Limited availability of companion AH product leads to unregistered products circulating in the market as there's demand in the market.



The authority take the registration of companion animal products same as livestock products. Because for livestock product, we've many files have to be attached, from A to Z, but, they do the same for companion animal product. Sometimes, we cannot fulfil completely as what we can provide for the livestock products.
– Local

Implementation of online registration system is seen as a positive move, but improvement on the system is still needed (as it is not working effectively at the moment).

Implementation of
online product
registration and import
permit

Positive, high impact

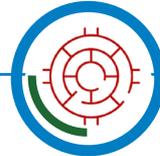
- >> Online registration for all products and import permit just started on March, 2018. Few mentioned that it reduces bureaucracy, human errors like lost of documents, and more transparency in the registration progress. But currently, they still faced some technical issue – unable to upload files. Manual filling is still allowed if there is problem in online registration.

Currently, the most expensive aspect is local trial and the most challenging aspect is the verification of dossier in product registration



Most expensive

- Local (field) trial requested by MOA.
MOA request trials requires AH companies to purchase the subject (may it be poultry or companion animals) for testing. AH companies will need to borne the full costs of testing and also reports produced. The cost is like a hundred millions Rupiah or as high as 50 thousand Euros. - MNC
- A few said that registration of biological products...
Registration of such product requires more steps / analysis/ protocols.



Most challenging

- The most challenging aspect in **product registration** is - - **inconsistency in assessment and verification of registration dossier**
No standard check list, lack of knowledge of regulators and unexpected additional requests.
- There will be improvement in next 5 years because regulator has implemented online registration system and ASOHI is working closely with the government in evaluating and improving the regulatory process.

In general, no major concerns or issues faced with selling and marketing their products in Indonesia.

Some general 'rules' do apply....but all companies, both local and MNCs can comply (easily) to them

Negative development

Classification of ionophores as AGP

Ionophores cannot be used as prevention, but only for treatment purpose for maximal of 7 days and has to get prescription from the veterinarian. Some believe that grouping ionophores as AGP is not a right decision as it is not used therapeutically in chickens to treat bacterial infections.

This impacts the coccidiosis cases in the farm and AH companies have to re-register the ionophore products to change its classification from prevention to treatment.

On the bright side, farmers started to focus on vaccination to prevent the disease and bring in a new trend, natural product like herbal products (turmeric) to control coccidiosis.

Illegal (unregistered) product in the market

There are companion animal health products being sold without proper registration but there is less enforcement from the authority. This is due to the fact that it is very difficult to get CA products registered. Refer to page 11

Positive development

Product specification has improved

For example, side effect reactions need to be mentioned in the leaflet for customer to refer.

Almost all managers claimed that they have no issue in selling the product as long as they registered the products.

It is expect that certain criteria needs to be meet on labelling – e.g. who's importing it, expiry date, batch number, certain control and functions.

Regulators will do inspection at warehouses and check/validate that all requirements were met. None of the companies experiences issue (before) on this aspect!

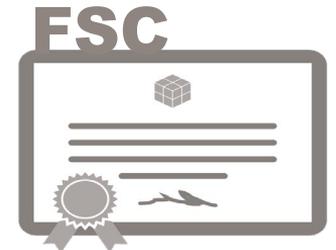
Overall, there's no major issue in term of GMP and FSC.

Indonesia does not require PIC/S and Halal certifications.

- In Indonesia, the local GMP is called CPOHB (Cara Pembuatan Obat Hewan Yang Baik)
- All local manufacturers must have CPOHB certificates for all their products.
- For MNC and importers, they will request GMP certificates from their manufacturing site(s) (oversea) and then submit it to the authority bodies. None had any issue with GMP certification before.
- Some local manufacturers professed they do faced issue with CPOHB.
 - Some production plants are old (post 1990s) and they are forced to upgrade the plant or move to a new facility. Furthermore, there's a crash between regulation and business needs - - some products that have lower demand (lower sales), hence, it is not cost effective to upgrade the plants/facilities.



- Minority do faced issue with FSC requirements!
- If the products is not sold in the country of origin, then companies need to submit two FSC (from 2 countries) that the products are marketed in.
- For innovative product, one FSC will have to be from developed countries such as EU/ US. The 2nd FSC can be from any other country.....



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

In terms of safety, the only potential issue faced is users (farmers) are following the usage guidance recommended.

None experienced unmanageable issue with manufacturing / quality



Safety

- None faced any issue on safety with their AH products. As the standard of registration and testing are strict and comprehensive, AH products sold in Indonesia have high safety standard.
- Local companies mentioned that the only difficulty is - - to control farm/farmers' usage habits/patterns. Some farmers do not follow the antibiotic withdrawal period recommendation before selling. This could potentially impact safety of food / to consumers.



"For safety, the first thing is documentation, we already have safety details. They will assess our document is right or wrong. Then our product will be tested on field, whether it's safety or not in Indonesia, there is no problem."
(MNC)

Manufacture/Quality

- So far there is no major issue faced by both MNCs and local companies.
- Minor issue is - - sometimes there are complaints from distributors about product quality but the companies are managed to solve it.



"Occasionally we do get product complaints from the distributors and we just submit the report to internal quality department for investigation to find out the root cause and we do the analysis and find the corrective measure. Need to make sure it would not happen again, but so far, no big issues.." (MNC)



Local efficacy standards need to be followed. This requires some customization for Indonesia. R&D activities are also / need localization.



Efficacy

- Indonesia has different efficacy standard for ND vaccine.
- The requirement is - - higher titer requirement (6.5) compared to other countries because authority believes that ND virus in Indonesia is more vicious compare to other ASEAN countries like Malaysia and Philippines.



“We ask supplier to customize for Indonesia requirement, so we ask batch specially for Indonesia. By having to meet the requirements of Indonesia prices will be different from the other countries, so the production is also different. Another thing is if it turns out we have excessive demand but we cannot request stock from other countries because the standard is different, so we have to wait until the next production.” (MNC)

R&D activities

- MNCs have no comment in term of R&D as they are not involved in it.
- Feedback from (one) local manufacturer - - As AI vaccine should be produced by using local strain and AI virus is easy to mutate, thus local companies are now working closely with the regulatory bodies in monitoring the AI virus on the field.



Importance & feasibility of ASEAN technical harmonization

Technical harmonization seems not likely to be implemented in the near future. This initiative will benefit MNCs, but there are some concerns raised by local AH companies

Progress

- The topic of harmonization has been discussed, but no implementation. Some (MNC managers) are not even aware of this topic / discussion.

Challenges & benefits to the industry

- The current view is regional wide harmonization is difficult. Not every component of regulation / requirement can be harmonized because every country has their own culture or needs.
- 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 lagging behind in introducing new products due to long or unclear procedures. MNC companies supported harmonization as there will be saving in effort (less paperwork / dossiers) and resources to get products quickly to the markets in ASEAN.
- Local companies have concern with harmonization. It will encourage more imported products to Indonesian market due to lower barrier of entry.
- If harmonization is to take place, local regulators will need to be properly trained to ensure there is more coordinated effort from all parties involved.

ASEAN Harmonization



AAHA is seen to play passive role in Indonesia.

Managers want AAHA to support the industry by highlighting best practice on regulatory matters (from other ASEAN countries) to the govt.



- Few managers professed that AAHA is less active in Indonesia compared to local AH association, ASOHI.
- Both MNCs and local companies suggested that AAHA can help regulatory bodies at regional level by organizing workshops on benchmarking the AH regulatory environment with other countries.

 *“Maybe workshop to give some benchmark on regulation with other countries. Just like ASEAN, we have example maybe from Singapore and Thailand that also included as the good one. The application of consistent rule, how they apply the rule.” (Local)*

- All managers agreed that ASOHI is the voice of AH companies in Indonesia. All AH companies (both MNC and locals) in Indonesia should be the member of ASOHI.
- ASOHI acts as a harmonious partner for the government and AH companies by continuously giving input to the authority from their point of view.
- They will organize meetings to discuss all AH industry matters (issues in regulation and registration) and propose to the authority for implementation and improvement.



Future outlook of ASEAN regulatory framework

In general, the current regulatory framework in Indonesia is not ready for the 21st century. There's tremendous room for improvements.

21st century



Current view

- Most shared the view that current regulatory framework does not 'Fit the 21st Century'. The current regulation is confusing. For example, the regulatory bodies failed to provide a clear guideline on how they are going to implement and monitor the ban of AGP.
- Complete overhaul is deemed not necessary, but everyone asked for improvements!

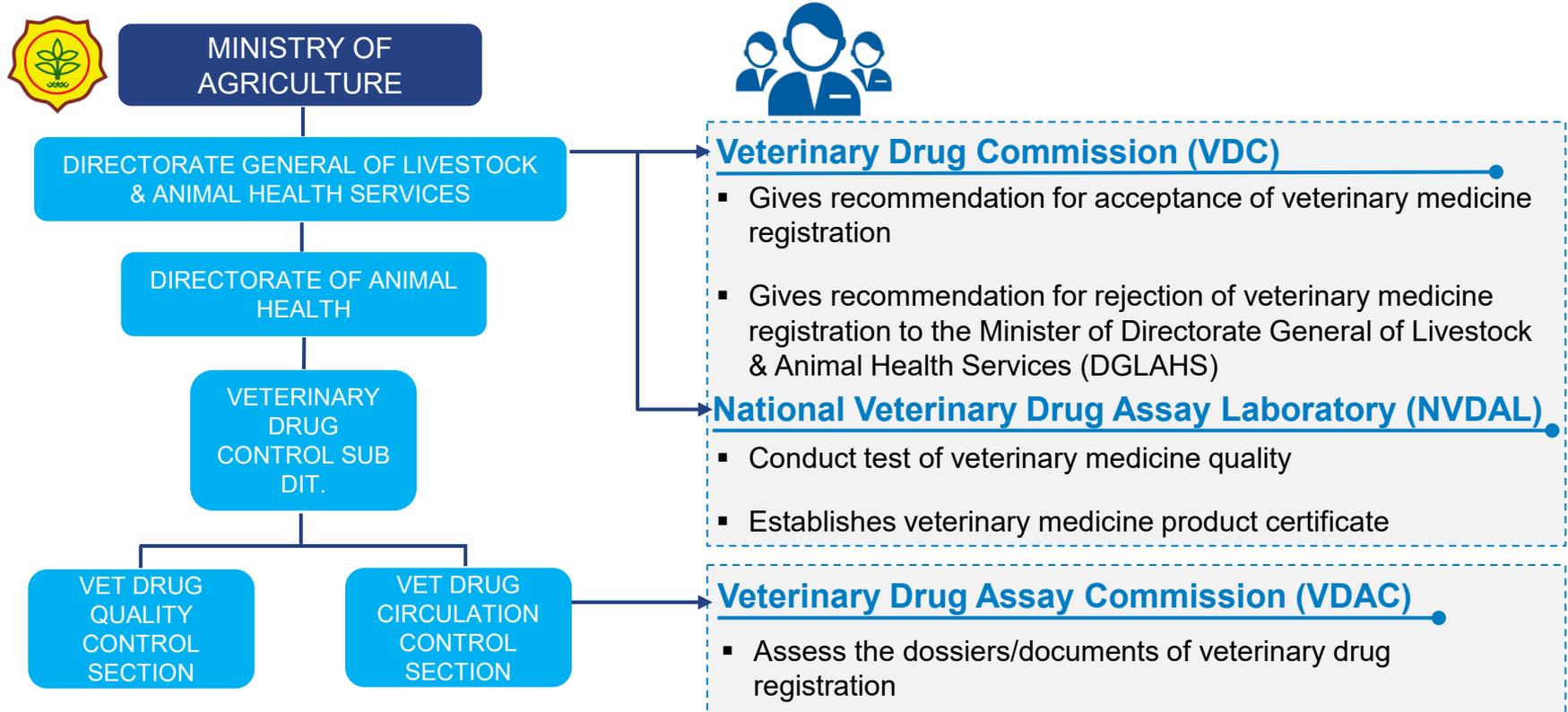
Action needed

- Simpler and clearer registration process – speed up the registration process
- Open discussion with stakeholders – improve current regulation and registration
- Improve skill & knowledge of regulators – avoid inconsistency in dossier assessment
- Benchmark registration requirements in other countries – understand different registration requirements in other countries
- Lower registration requirements for companion AH products
- Stricter control for the unregistered products (primarily companion AH) in the market
- More experts to provide best advice in drafting regulations

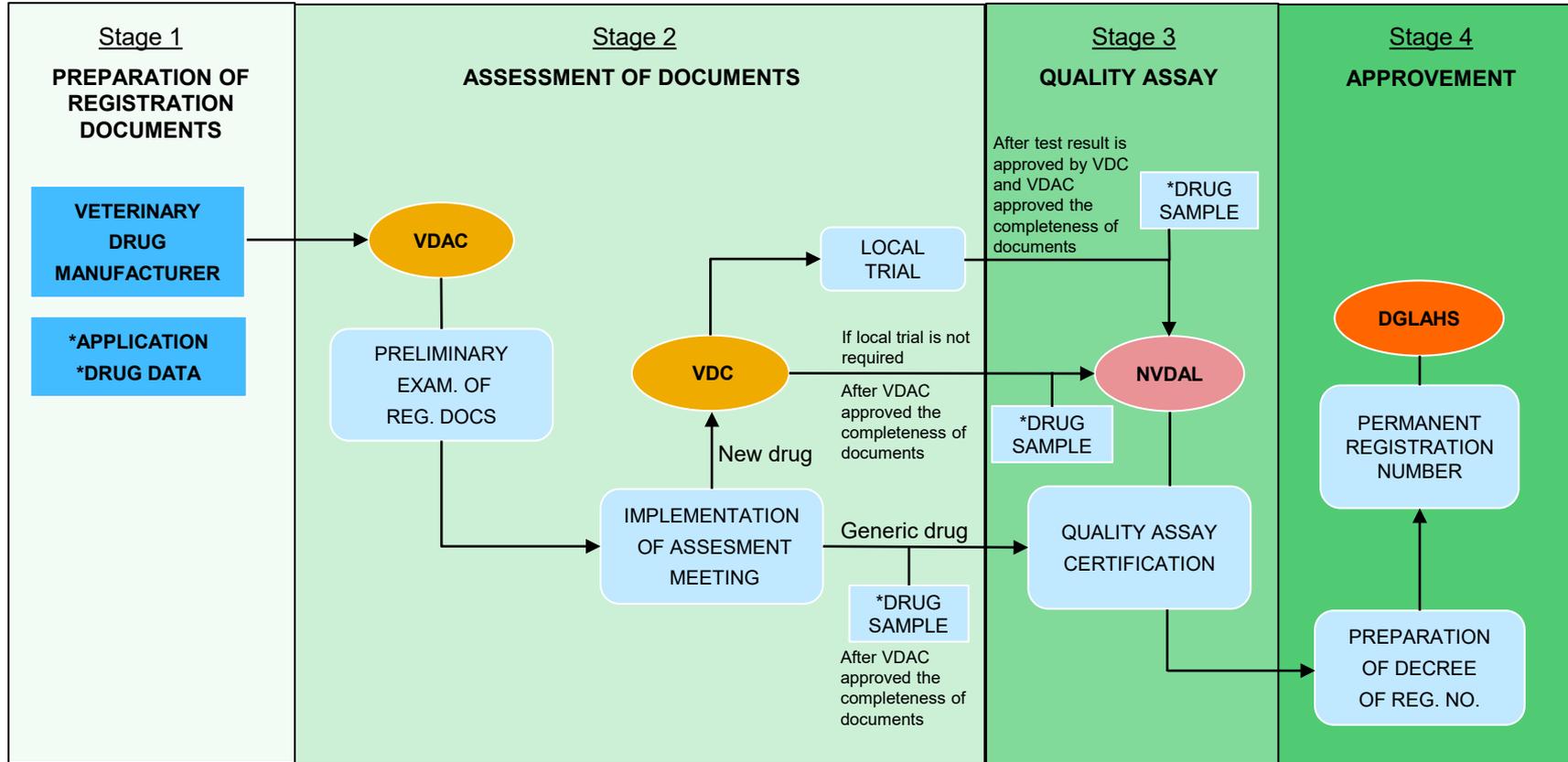
Appendix – desk research

Organization structure of the authority and their roles :

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



Flow chart of new registration of veterinary drug



General requirements of veterinary drug registration



- Companies (manufacturers/importers) must have a veterinary drug business license which was issued by Ministry of Agriculture Republic of Indonesia.
- The applicant of imported products must have an appointment letter from its origin manufacturer, which states that the company as sole agent/registration holder of the registered product.
- The product to be registered has not been/is not registered by another applicant.
- The registration number of vet. drug is valid for ten years.
- The applicant must also submit a registration form and technical data from the registration of veterinary drug (pharmaceutical / vaccine) as attachment.

Future trend - raising awareness on anti-microbial resistance



News reported by FAO Indonesia...

In 2017, Indonesia has confirmed its commitment to advance [One Health collaboration](#), with five ministries namely MOH, MOA, MOEF, MMAF and Kemenko PMK issuing a joint communique recently on the implementation of One Health in the country, to respond to emerging disease threats and address global health challenges including Antimicrobial Resistance (AMR).

In 2018, **eleven faculties of veterinary medicine**, members of the Association of Veterinary Faculties of Indonesia (AFKHI) have **agreed to adopt the One Health approach** and associated best practices for zoonoses control, that have been developed by the MoA with the FAO ECTAD.

FAO ECTAD Indonesia, together with the MoA Indonesia and other related stakeholders successfully held several events which aimed to raise people's awareness of the danger of misusing antimicrobial agents during the World Antibiotic Awareness Week (WAAW) in 2017. Example of events are: Several journalists visited poultry farmers who, through mentoring by FAO, had implemented **3-zone biosecurity and good poultry farming practices** in Semarang and Karanganyar, Central Java. On both farms, the journalists were shown how the application of 3-zone biosecurity can reduce antibiotic and disinfectant usage by up to 40%. At the MoA, Jakarta, an **AMR Media Briefing** was hosted to which 70 journalists were invited. The briefing was held to enlighten the media on the subject of antimicrobial resistance and the use of antibiotics in Indonesia.

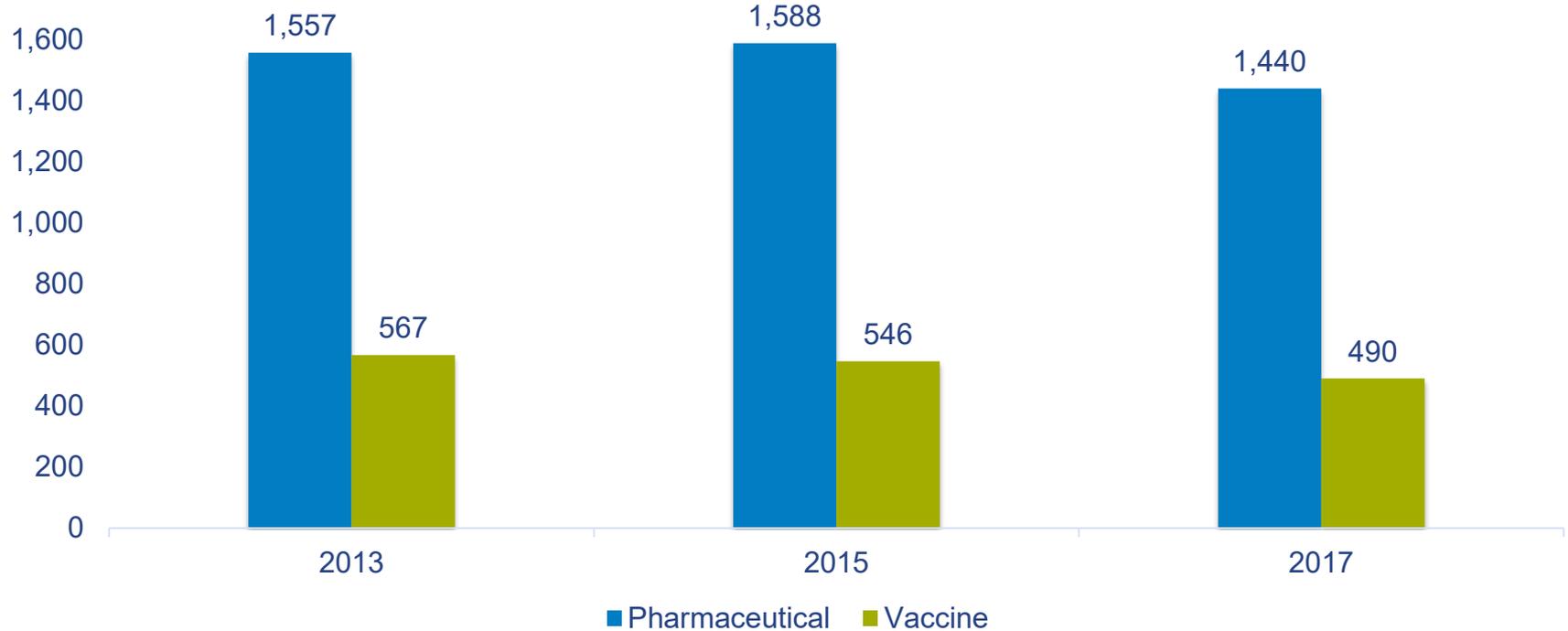
Future trend - stop depending on imported products and encouraging domestic production

News reported by news.cn...

In 2018, Indonesia's related institutions are now [formulating the needs of several industries to reduce imports](#) which have been increasing in the last few months, an Indonesian minister said. We would formulate the actual needs of the respective industry. The aim was to reduce imports in middle and long hauls, so as to make us less-dependend on imports and spurs exports as well,".

In 2017, Indonesian health ministry has [taken measures to find the source of raw material for pharmaceutical industry in domestic](#) that will reduce the country's high importation of the unprocessed materials, a senior official of the ministry disclosed. Indonesia's pharmaceutical industry is expected to manufacture raw materials in domestic, so that in 2025 Indonesia will be able to reduce reliance on imported raw materials" said Maura Linda Sitanggang, director general for pharmaceuticals and medical equipment of the ministry. High dependency on materials shipped from overseas has significantly hiked prices of drug in the country.

Number of pharmaceuticals and vaccines products registered in 2013 - 2017



Source: Indeks Obat Hewan Indonesia (IOHI)



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