



Insight Report – Cambodia: 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.

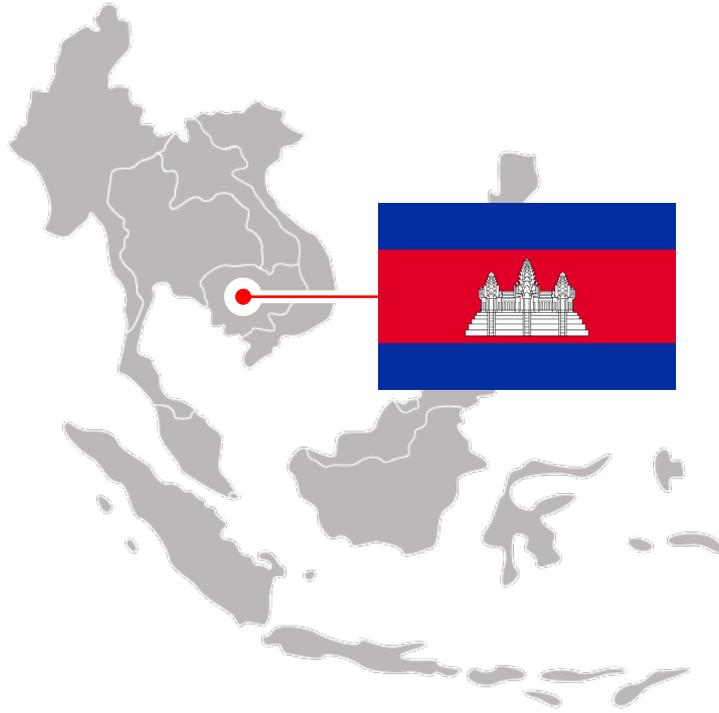


Scope of work

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:

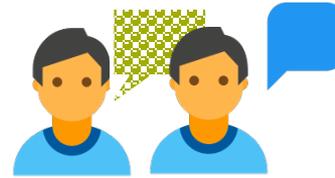
- Assess the impact of regulatory framework that impacted AH industry
- Evaluate the adoption of technology/innovation within the AH regulatory framework
- Gauge the extent of technical harmonization within each country, and across the region
- Evaluate the readiness of the AH regulatory framework for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

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



Total interviews: N=3

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

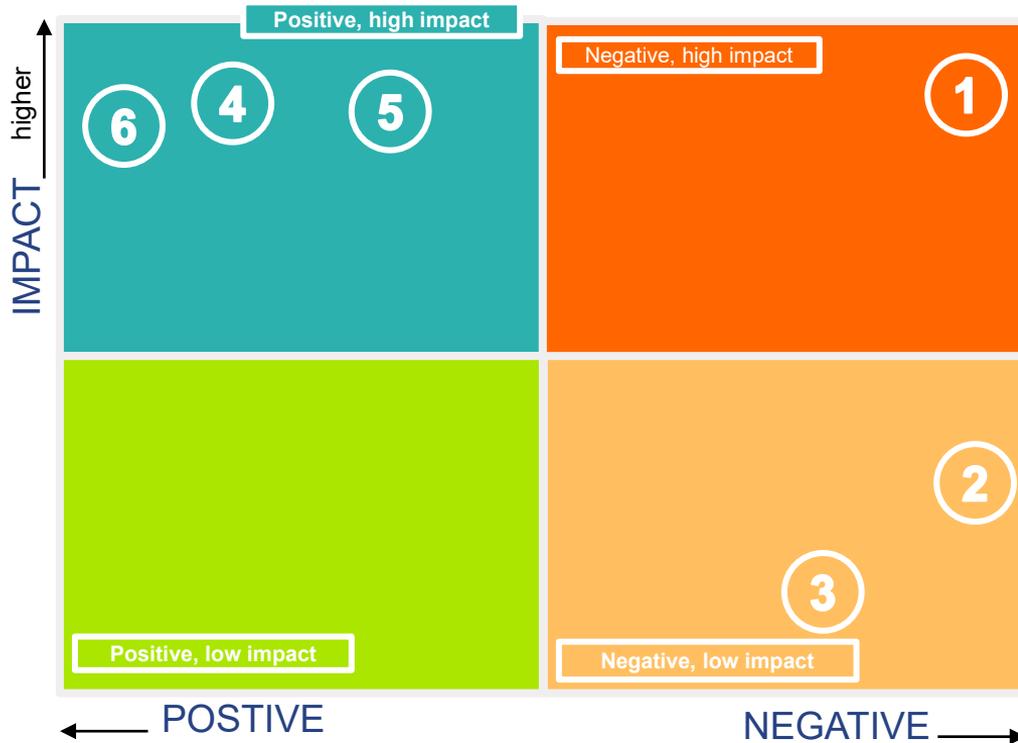


1- 1.5 hours face-to-face /
phone interviews with targeted
managers

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

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

AH regulations in Cambodia are somewhat lenient, and this is due to the fact that there is very few regulation in place. Enforcement is also relatively lacking....



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 Loose law enforcement
- ② Officers with limited AH knowledge (On innovative/new products)
- ③ Favoritism over local companies
- ④ Relatively easy & basic registration
- ⑤ Consolidation of regulatory units (only 1 units looking after AH product, now)
- ⑥ Predictable timeline

AH regulation in Cambodia is simple, and there is limited enforcement to ensure proper execution of these regulations.

Loose enforcement
of law

Negative, high impact

- >> The law and regulation in Cambodia is currently been poorly executed due to corruption. None companies will follow the guideline of product registration rigorously. Everyone mentioned (high) incidence of corruption in the country.
- 🔊 *The ministry of agriculture in Cambodia is dysfunctional. First of all, there's no import duties. They kill their own market, and their own benefits. It's completely corrupted. You can have 100% foreign owned company, you don't have to submit much documentation, it goes relatively fast and very easy. You don't have to have a partner. - Local*

Lack of knowledge of regulators is also a issue faced with AH regulatory agencies in Cambodia.

Negative, low impact

Officers with limited AH knowledge (on innovative/new products) **

>> The officers in MAFF do not have much knowledge or understanding on the AH industry. Thus manufacturers need to explain or educate the officers by arranging discussions with the authorities before their new product gets approval.

If the officer do not understand the innovative product, they will tend to put the product's approval aside then delayed the timeline for approval.

- 🔊 *There is one product with A.I. of an anticoagulant in class 1B which is forbidden for registration under WHO standard but it was diluted to 1% in this product. No matter how we explained they still do not get it. So the product couldn't get in. That's why, I mean, it's very hard to reason with them – Local*
- 🔊 *Meeting the authorities is challenging because it's a new product, they don't know it , so to bring the technical dossiers with all our technical data from Europe or US is challenging. The regulatory is making an impact for me when we meet the authorities and convince the authorities to have a look at the dossier. They don't know much about the new product so they need someone to help them to understand. In this case it is good to bring technical data to show them. - MNC*

Favoritism over local companies

>> The foreign companies cannot register products by themselves. They will need to collaborate with local companies or hire a third party to submit the application for product registration.

- 🔊 *....even though you are selling the brand in the country, you still have no right to submit application on your own to get the license. They are trying to prevent the foreigners and support or promote the local. We have to hire the third party - MNC*

** Most of the time, Khmer gov. do not treat the registration for generic and innovative products much different, hence registration is easy and fast. BUT if for selective innovative products whereby the a.i. is controversial / new (e.g. approved in EU, not in US or vice versa) regulators might follow the decision from developed countries and might choose not to register the products. Companies might need to provide more convincing evidences / training / explanations.

On the positive side, Cambodia regulatory agencies are taking (right) actions to improve the country's AH regulatory framework.

Positive, high impact

Relatively easy & basic registration

- >> The product registration for AH products in Cambodia is very basic and simple. The requirement for the registration is usually very easy to fulfill for the companies (not many additional checklists). Moreover, the registration for both generic and innovative product is the same. Thus there is not much major issues faced by the companies in terms of providing the checklist requested by the authority.

Consolidation of regulatory bodies (New PRAKAS)

- >> A new directive, Prakas 208 on “Procedures and standard requirements for the registration of drugs in the veterinary industry” was signed on 4th May 2018. Previously, AH companies need to gone through two departments will now go though only 1 department.
On positive side, this will increase the efficiency of AH product registration. Additionally, the IP protection in Cambodia will be better for the companies by preventing the illegal products from getting into the market easily.
In contrast, the companies worried that this new directive will set higher requirements or extra procedures. This will lead to delay or burden the registration process.

On the positive side, Cambodia regulatory agencies are taking (right) actions to improve the country's AH regulatory framework.

Positive, high impact

Predictable timeline

>> Both MNC and local companies agreed that the timeline for product registration is relatively much shorter than the other countries. The usual timeline would take around 2 – 6 months. Delay is not common!

🔊 *We have one case, we have one product that I told you that I have to interfere with other department because it is longer than we expect. Usually one department needs to take three months, but the case stay longer than three months. Yes, we use three to six months for two departments. However, one department already took more than three month, it is not normal. That's why we interfered. Normally products get registered very quickly.... Within 6 months...– MNC*

Expected, getting AH products into this marketplace is not difficult. The only obstacle could be – the need to pay off (as bribe) officer with a huge amount of money to obtain import license.



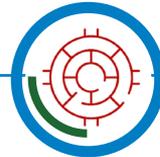
Most expensive

▪ Import license

Companies mentioned import license being the most expensive part in the product registration.

Local companies mentioned that the official fee should be 50 – 100 USD per product but could end up paying 3k – 5k USD for the import license, depending on the rapport/payment needs to be make to the officers....

The MNC normally pay 1,000 USD to their distributor for each import license



Most challenging

- There is no major challenges in the product registration of AH products in Cambodia for both MNC and local companies.
- A minor issue faced by the MNC is to bring the innovative product with new chemical into the country. As the officers have very little knowledge on AH, the companies will need to explain the innovative product to the regulators to obtain the approval.
- In future, local companies foresee the regulations will stay the same whereas the MNC believe the law will have higher requirement and stricter as the international inter-government (e.g.: OIE, WHO and FAO) will put more emphasis on AMR issue. However, weak border is a concern for MNC since unregistered products get into the market easily

There is no challenges or issues with marketing or selling products. Having said that due to lack of proper monitoring and control, there has been issue with unregistered AH products due to weak border control.

Negative development

No public hearing

MNC concerned about the new laws because there is no public hearing or decision making involving key players in the industry. Thus this can be restrictive for companies as the draft might be very unrealistic.

Influx of unregistered AH product due to poor border control

Past 2 years, the weak border between Vietnam and Cambodia 'promote' unregistered AH products enter the Cambodian market easily. This impact the sales of premium product as the huge price difference

Positive development

None....

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

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



Safety

- All companies do not have any problem with the safety as the regulation in Cambodia is very simple and straightforward.
- MNC mentioned the needs to have the technical trial in order to make sure the product do not pass down residue to human after consuming the meat treated with the product.
- 🔊 *I believe if the pharmaceutical is scientifically proved already, when we want to release the product, we try many times to ensure it is safe, however I afraid of the social rumour which may not be the correct information. Misunderstanding. For example, for a safe product, if the rumour says that it is not safe and might cause cancer, even though it is rumour, I think it is not under control. Currently no, I mean for safety. – MNC*

Manufacture/Quality

- Again, none faced challenges with the manufacture or quality for the product registered and selling in Cambodia.
- They agreed that MAFF actually follows the framework on developed countries for product approval. They usually do not test on the product for quality check.
- 🔊 *I think the safety of low potency. Once there is one consumer report that the product is not safe or there is an adverse effect after consume it, I think this is the issue. – MNC*



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



Efficacy

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

R&D activities

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



None faced issue with GMP. FSC however is a different picture. Companies do faced issue with this certification!

- A few companies mentioned that the MAFF needed GMP for product registration.
- Others said their 3rd party or distributors only ask for Certificate of Analysis (CoA) rather than GMP.
- None however said they will faced issue if the regulatory bodies WANT GMP certification



- All imported products need FSC for product registration.
 - FSC certification is an issue for some companies. Some time regulators asked for FSC of old products...and they do not have FSC for the product. This will caused delay in bring products to market as they need to 'create' this FSC from the Origin country.
 - Local companies said authority sometimes asked about the manufacturing process or Certificate of Origin (CoO) instead of FSC. CoO is manageable for most...
-  *They asked free sales certificates from the country where are producing the product and sometimes we are producing for a very long time in US and we have a very old free sales certificate or even not , so it's an issue for us to find free sales certificate. Sometimes it's old product and we don't have free sales certificate statement from the authorities and we have to ask it and we have to wait 2 months for the American authorities to answer so it's an issue - MNC*

Importance & feasibility of ASEAN technical harmonization

ASEAN technical harmonization is welcomed by MNC companies. Local companies agreed it will improve the regulatory standard for Cambodia, but some are concern that such action might make it more difficult for them to do business.

Progress

- Both MNC and local agreed that the harmonization in AH registration currently does not happen in Cambodia. The regulatory requirements in Cambodia currently is different from most ASEAN countries.

Challenges & benefits to the industry

- Each country has very different culture, making it hard for these different countries to compromise with each other.
- The weak law enforcement in Cambodia will be a challenge to ensure the regulations are followed after harmonization.
- If harmonization is implemented, it will benefits MNCs as they are already aligned with the regulation/practices of other ASEAN countries.
- The local companies agreed that authority will pay more attention on AH industry after harmonization. They might develop a better regulations by bringing in safe and quality AH products at the same time prevent illegal products from entering the market.

🔊 *All country wants to be safe and sufficient so this is very political. If every country follow the same regulation, it will be standardize and easy to follow. In principal, I think it's a good thing, again, I don't really know if they're going to make it simpler, or more difficult for Cambodia AH industry.... - Local*

ASEAN Harmonization



AAHA is not known to ...and their influence or activities in Cambodia is not existence....



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

Future outlook of ASEAN regulatory framework

APPENDIX: Desk Research

GDAHP of MAFF is the regulatory body involves in the registration and approval of animal health products

MINISTRY OF AGRICULTURE,
FORESTRY AND FISHERIES
(MAFF)

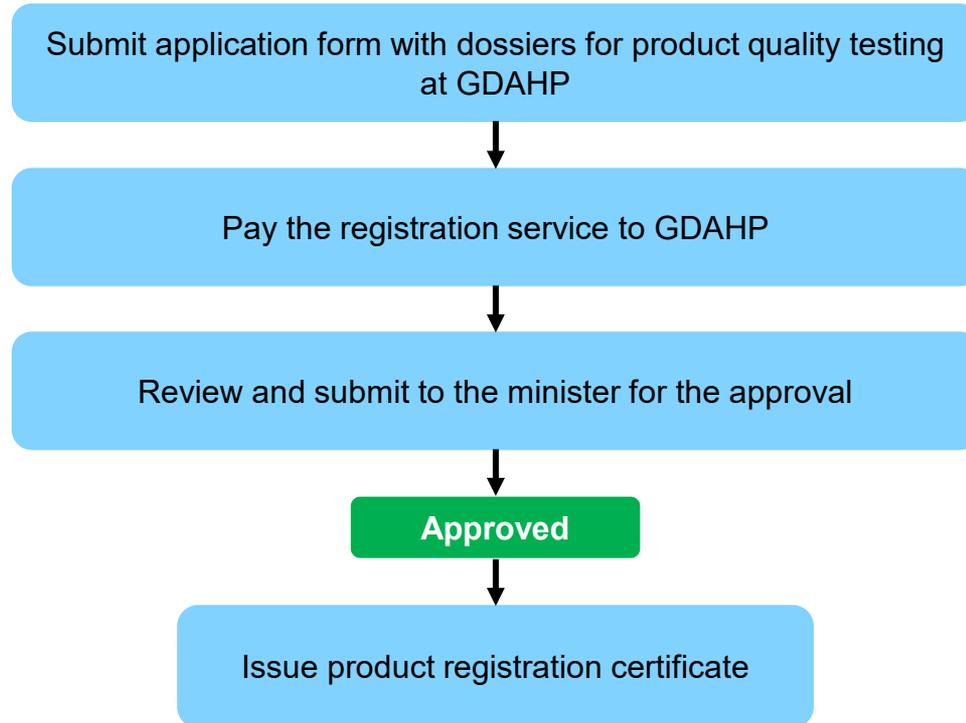
GENERAL DIRECTORATE
OF ANIMAL HEALTH AND
PRODUCTION (GDAHP)

- Dept. of Administrative, Planning, Accounting and cooperation
- Dept. of Animal Health and Production
- Dept. of Animal Health and Veterinary Public Health
- Dept. of Technical Extension and Legislation
- National research of Animal Health and Production Institute

General Directorate of Animal Health and Production (GDAHP)

- Accept dossiers and review documents for product quality testing
- Grant approval for AH products

The Regulation framework for Veterinary Drug Registration in Cambodia



Future trend - National multi-sectorial action plan to combat AMR planned to be established in 2018

Antimicrobial resistance (AMR) has been a concerning topic for Cambodia since 2009. That was when the resistance was reported to the anti-malarial drug Artemisinin on the Cambodia-Thailand border in that year. Consequently, a National Policy (2014) and Strategy (2015-2017) was developed and endorsed by the MoH, followed by the drafting of a national action plan on AMR for food and agriculture by the MAFF.

The three leading ministries on antimicrobial resistance (AMR), the Ministry of Health (MoH), Ministry of Agriculture, Forestry and Fisheries (MAFF), and the Ministry of Environment (MoE) came together in Phnom Penh for a high level meeting. The meeting, co-organized by the tripartite collaboration on AMR between the Food and Agriculture Organization of the United Nations (FAO), the World Health Organization (WHO) and the World Organization for Animal Health (OIE) was the first national meeting to be supported by the tripartite collaboration on AMR, and involved experts from regional and national institutions. The main goal of this high level meeting was to outline the process for developing a Multi-Sectoral Action Plan to Combat AMR in Cambodia.

1) PRAKAS 208 (Signed but yet to be implemented)

The new directive, Prakas 208 on 'Procedures and standard requirements for the registration of drugs in the veterinary industry', was signed on Friday (4th May 2018) by Minister of Agriculture Veng Sakhon. As per the new law, companies must conclude the registration process before they are allowed to sell their products in the local market. "Companies that import, export, buy, sell, manufacture or package pharmaceuticals for the veterinary or husbandry industries must register their products in advance to comply with the law," the Prakas said. The new directive aims to standardize procedures in the industry and manage the drug registry in order to increase efficiency in trade and enhance safety for consumers by "preventing risks and protecting the lives of humans and animals", as stated in the official document.

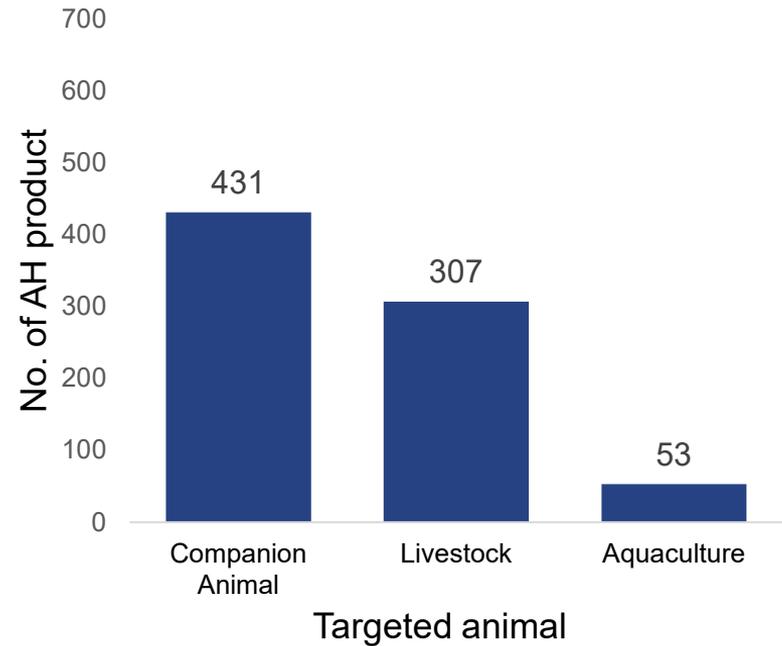
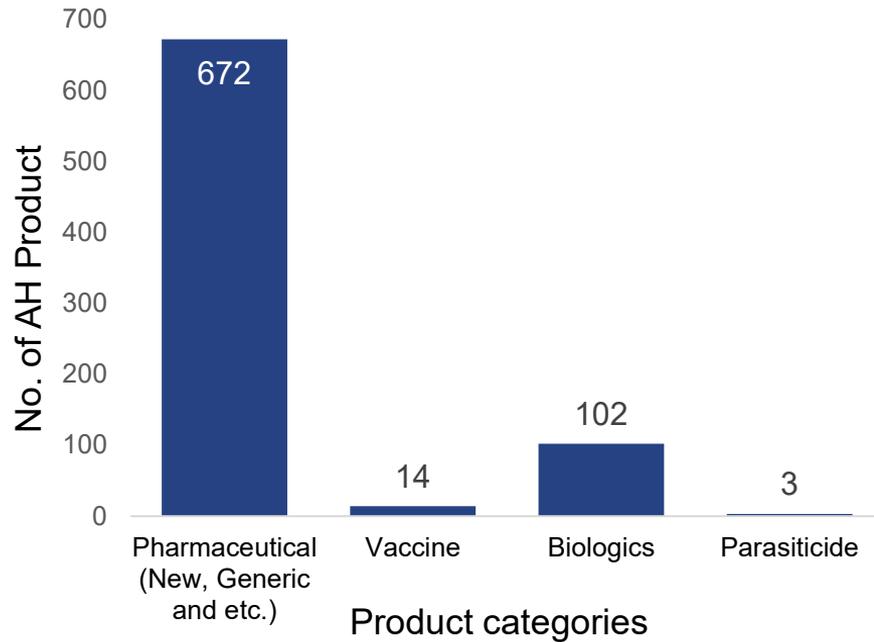
2) Strategic Planning Framework for Livestock Development (2016-2025)

The strategic planning identified strategic issues affecting the Cambodian livestock sub-sector during the next ten years. These include issues related to animal production, animal health, expanding markets, food safety and public health, poverty alleviation and food security, role of the private sector, farmer groups/ associations, the Village Animal Health Workers (VAHWs), the regional economic integration and important cross cutting issues such as gender and climate change.

Objectives

1. Strengthen animal production, including the promotion of animal management and breeding
2. Strengthen animal health, veterinary public health and animal welfare
3. Promote law dissemination and law enforcement and policies
4. Promote and conduct research and development on animal health and animal production
5. Improve institutional and human resource development in the field of animal health and animal production
6. Promote partnership between the public and private sectors in the field of animal health and animal production
7. Strengthen media services on animal health and animal production and marketing development
8. Strengthen national and international economic and technical cooperation in animal health and production

Number of product registered in 2013 – 2018 (5 years)





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