



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

Issue date (updated): 11.June.2019



3	BACKGROUND & STUDY OBJECTIVES
5	EXECUTIVE SUMMARY
54	Detailed insights: No. of product registered 2016 - 2018
92	Detailed insights: Cost of AH product registration
164	Detailed insights: Time taken to achieve AH product registration
228	Detailed insights: Bringing new AH products to market – challenges faced
258	Detailed insights: Factors that impact registration achievement and maintaining registration of existing brands
327	Detailed insights: Hopes & expectations for the next 5 years



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 3rd 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 business context of the AH industry
- Understand the challenges faced in the product registration process
- Understand the challenges faced in the maintenance of the existing product registration
- Future outlook and hopes in the regulation in the next 5 years that could potentially impact AH business

This report was generated based on feedbacks from 62 regulatory managers across ASEAN



In addition to the above, we also interviewed 6 regional managers from MNC AH companies

Interviews were conducted via online surveys.

A few follow-up calls were also done to validate some answers with most of the respondents

Interviews were conducted between Feb – Apr 2019

Most respondents were recommended by AAHA and those sourced by Kynetec were agreed upon with AAHA before interviewing



Executive Summary

No. of products registered in 2016 – 2018, what are the trends?

Note: The information is only related to those who participate in the study, and not a reflection of national numbers

Feedbacks from 9 companies



Malaysia



Companion animals

- **Significant increase of no. of registration of new pharmaceutical products in 2018 (vs 2016 and 2017).** Of the 20 new products registered, two thirds were by non-MNC companies. This is likely due to fast track registration process initiated by the regulatory bodies in Malaysia.
- Also **significant increase of registration of minor variation for pharmaceuticals.** A total of 21 registrations, MNC companies had 17 registrations
- A total of 12 **renewals of biologicals** in 2018, of which 7 is done by non-MNC companies. This is a huge increase compared to 2016 (n=2) and 2017 (n=2).



Production animals

- No. of **new product registration for biologicals** have increased in 2017 (but remain stagnant in 2018). 80% of new registration for biologicals in 2017 were done by non-MNC. In 2018 however, 7 out of 16 registration done in this therapeutic area was done by MNC companies.
- Significant no. of **renewals** took place in 2018 – **a total of 116 products, mostly for biologicals.** Of the 99 renewals of biological products, 79 were done by MNC companies

Feedbacks from 12 companies



Indonesia



Companion animals

- No significant growth or change in the registration of different therapeutic area.



Production animals

- Some growth are observed in all therapeutic areas for **new product registrations.** The most significant ones are in biologicals (2017, n=16 new products vs. 2018, n=32 new products) and in-feed medications (2017, n=9 new products vs. 2018, n=23 new products). Both MNC and non-MNCs are active in registering new products.
- Similarly, **generic product registrations is also increasing in 2017 and 2018.** A total of 20 new registrations took place in 2018, which almost all (n=19) was done by non-MNC companies.

No. of products registered in 2016 – 2018, what are the trends?

Note: The information is only related to those who participate in the study, and not a reflection of national numbers

Feedbacks from 12 companies



Indonesia



Production animals

- There is a **sharp decreased in major variation registration** for all therapeutic areas in 2017 and 2018. In 2016, there is a total of n=109 registrations, whilst in 2018, only 15 major variation registrations took place.
- A for **minor variation registrations, a significant no, of registration for biologicals took place in 2018**. All 18 registrations in 2018 were done by MNC companies.
- With respect to **renewal of product registrations**, MNC companies seems to have gradual increase in product registrations, especially with pharmaceuticals and biologicals. In contrast, non-MNCs have decreased their registration of both therapeutic areas in 2017 and 2018

Feedbacks from 8 companies



Thailand



Companion animals

- **Most new product registrations in Thailand was done by MNC**. In 2018, a total of 13 new pharmaceuticals were registered and only 1 was done by non-MNC companies.
- **There are more minor variation product registrations compared to major variation product registrations in 2018**. Both MNCs and non-MNCs are active in minor variation of pharmaceuticals registrations, whilst only MNCs have done minor variation registrations for biologicals.



Production animals

- There are **increases in new product registrations for production animals in 2017 and 2018**. All new product registrations are done by MNC, with n=8 new biologicals and n=6 new in-feed medication products.
- Our findings had shown the there is some increase in registration of generic products in 2018, especially with pharmaceuticals.
- Similarly, in **2017 and 2018, the no. of major variation registration had decreased**, whilst for and **minor variation registrations had shown only marginal increased** (from n=65 products in 2017 to n=67 products in 2018)

No. of products registered in 2016 – 2018, what are the trends?

Note: The information is only related to those who participate in the study, and not a reflection of national numbers

Feedbacks from 6 companies



Vietnam



Production animals

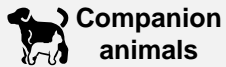
- There is **no major change in no. of new product registrations in 2016 – 2018**. A total of 17-20 products (for all different therapeutic areas) were registered annually.
- In 2018, a total of 5 new registration of generic products, an increase from 2016 and 2017 (n=2 respectively).
- There has been **an increase of minor variation product registrations in 2017 and 2018, primarily with biologicals**. A total of n=69 registrations took place in 2018 vs. n=40 registrations in 2017.
- **Renewal product registration had a sharp decreased in 2018**, especially for pharmaceuticals and biologicals

Feedback from Vietnam are only from MNC companies. No non-MNC companies participated in the study

Feedbacks from 8 companies



Philippines



Companion animals

- **More new products were registered in 2018 vs. 2017**. MNCs have registered 3 new products in pharmaceuticals and biologicals respectively, whilst non-MNC companies registered a total of n=5 new products (n=3 in pharmaceuticals, n=2 in in-feed medications).
 - There is a **decreased of registration of generic products in 2017 and 2018** compared to 2016.
 - MNC companies have increased their registration of minor variation in 2018 with n=26 registrations in pharmaceuticals and n=18 in biologicals
-
- A sharp **increase in registrations of new products and minor variations**, especially for pharmaceuticals for MNC companies.
 - We also found that MNCs were active in renewal product registrations in 2017 and 2018, especially with biologicals. A total of 88 renewal registrations took place for biologicals for MNC companies in 2018

No. of products registered in 2016 – 2018, what are the trends?

Note: The information is only related to those who participate in the study, and not a reflection of national numbers

Feedback from Vietnam is only from MNC companies. No non-MNC companies participated in the study

Feedbacks from 6 companies



Cambodia



Production animals

- Compared to 2016, **there is just a few registrations for new products in 2017 (n=9) and 2018 (n=10) in Cambodia.** Most are done by non-MNC companies.
- More and more generic products are registered in 2016-2018, especially by MNC companies.

Feedbacks from 6 companies



Myanmar

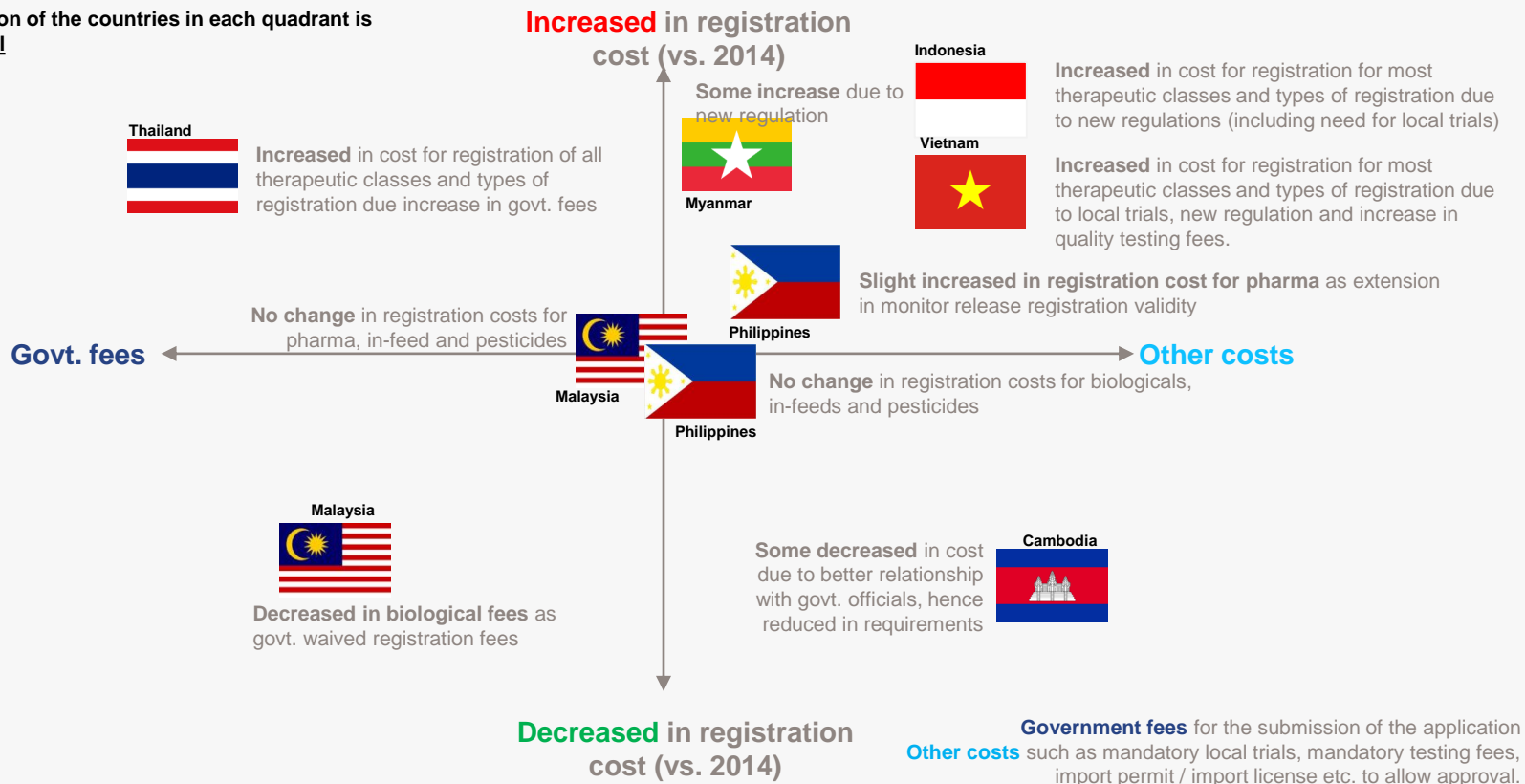


Production animals

- There has been **an increased of new product registrations in 2018, especially by MNCs for both pharmaceuticals and biologicals.**
- We have also observed an increased in generics import licenses by non-MNC companies, whilst MNC companies are doing more renewals import licenses in 2018 especially for pharmaceuticals and biologicals.

Have the product registration costs increased / decreased compared to 2014? What are the main component of the costs?
 Cost of registration in Myanmar, Indonesia, Vietnam and lesser extent in the Philippines have increased.
 A large amount of the registration costs in these countries are associated to other costs (e.g. local trials, testing fees, etc.). Product registration cost in Thailand has also increased, but it is primarily due to govt. fees.

NOTE: The position of the countries in each quadrant is not consequential



Which types of registration have increased/decreased in fees compared to 2014?

Malaysia: Generally no increase in product registration fees. Major & minor variation decreased in fees

Indonesia: Across the board, increased in product registration fees

Feedbacks from 9 companies



- The is **no change in registration costs for both new , generic products and re-registration** (vs. 2014) for pharmaceutical, in-feed and pesticide in Malaysia for both production and companion animals. For (new) **biologicals**, the govt. has waived the registration fees. Registration fees are primarily associated to govt. fees.
- For **major and minor variations**, slight decrease in costs (<10%) were observed vs. 2014 due to new regulation

Feedbacks from 12 companies

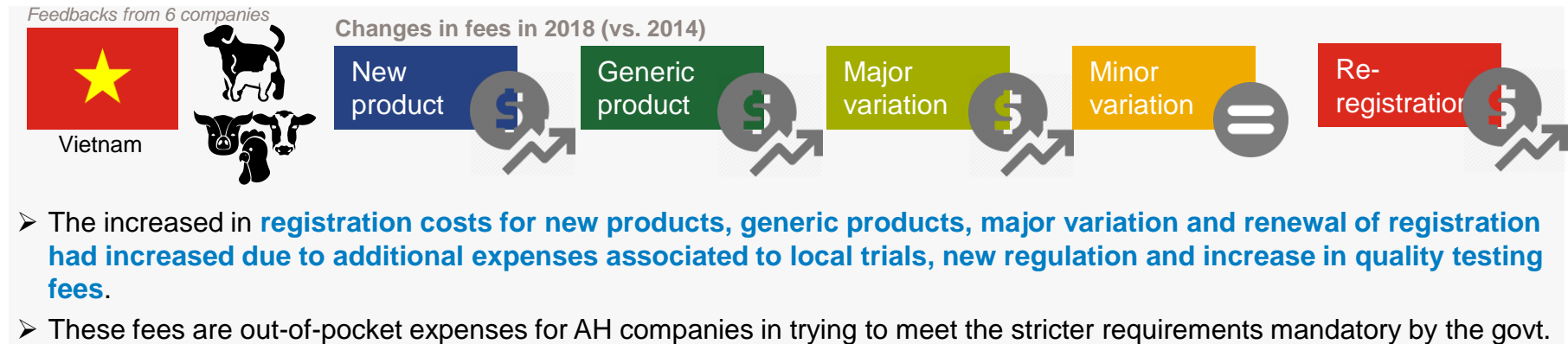
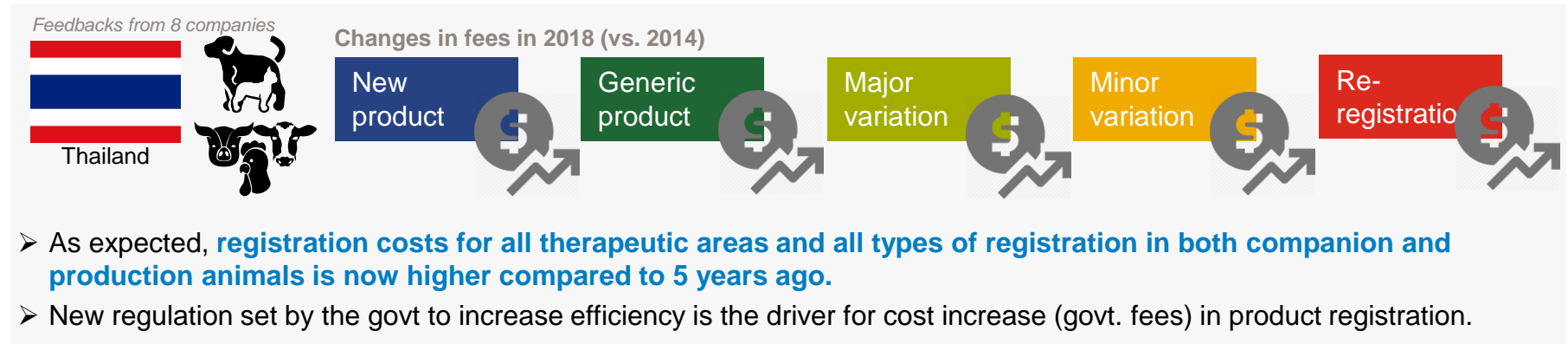


- Regulatory managers claimed **due to new regulation and local trials, registration fees for new products have increased a lot (>10%) for companion animals., and slightly increase (<10%) for production animals.** Govt. fees (for product registration) remains constant.
- The new regulation of requiring local trials also **impacted the cost for renewal registration of products.** Across the board, managers claimed that there had been **increase (>10%) in fees vs. 2014**

Which types of registration have increased/decreased in fees compared to 2014?

Thailand: Increased in govt. fees for all types of registration

Vietnam: Mostly increased in costs for different types of registration, with exception of minor variation



Feedbacks from Vietnam are only from MNC companies. No non-MNC companies participated in the study

Which types of registration have increased/decreased in fees compared to 2014?

Philippines: No change in product registration costs, with exception of pharma (increased)

Cambodia: Some types of registration, decreased in fees due to better rapport with regulatory bodies.

Feedbacks from 8 companies



- **Apart from pharmaceutical products, all other therapeutic classes have not experienced increase in costs for all types of registration in both companion and production animals.**
- Particularly for pharmaceutical products, registration fees has increased slightly (<10%) compared to 2014 as the result of extension in monitor release registration validity for new products. Legal fees have also increased registration fees for some generic products and major variation.

Feedbacks from 6 companies



- Generally no change in govt fees, and even other cost associated to product registration for major, minor and renewal product registration have not experienced increase nor decrease.
- However, for new and generic products' registration, regulatory managers professed they experienced slight decrease (<10%) due to better relationship with (regulatory) govt. officers

Which types of registration have increased/decreased in fees compared to 2014?

Myanmar: Increased in fees for some types of registration, others remain constant.

Feedbacks from 6 companies



Myanmar



Changes in fees in 2018 (vs. 2014)

New product



Generic product



Re-registratio



➤ Some increased in registration costs has been observed for new products and renewal of registration in Myanmar. New regulation had make bringing products to Myanmar more expensive.

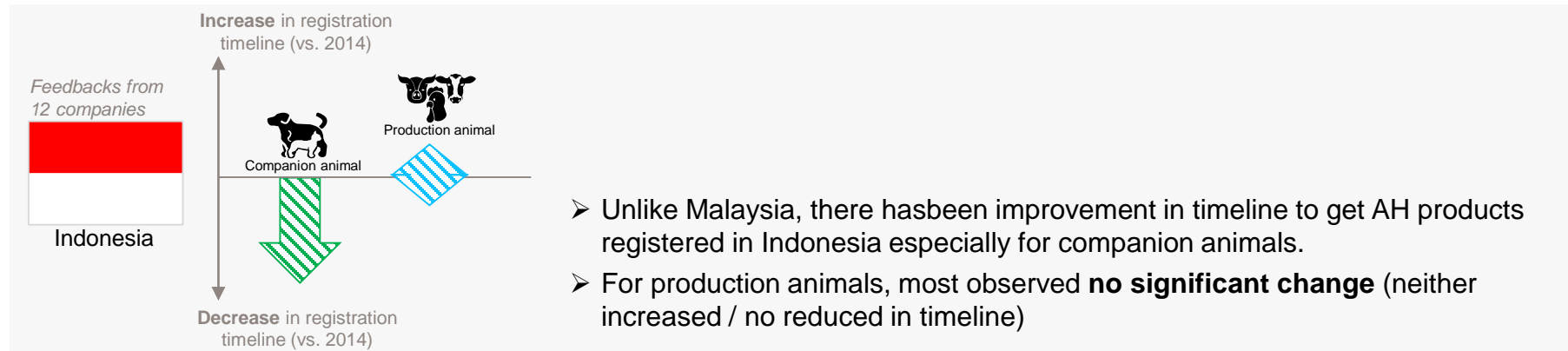
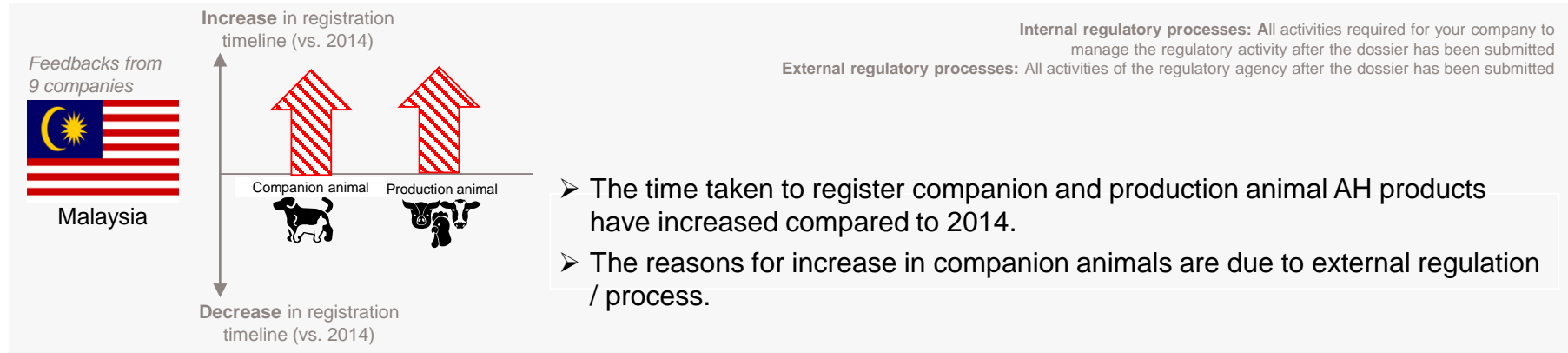
➤ For all the therapeutic class, no changes in fees now vs. in 2014

Myanmar does not require product registration. Hence, cost of registration fees to cost of import license

Registration timeline, compared to 2014, for which species has the time increased / decreased?

Malaysia: Increased in timeline for both companion and production animals

Indonesia: Decreased in timeline for companion animals.



Registration timeline, compared to 2014, for which species has the time increased / decreased?

Thailand: Reduction in timeline taken to get product registered due to increase in efficiency.

Vietnam: Increased in timeline due to external regulation, e.g. activities of regulatory bodies

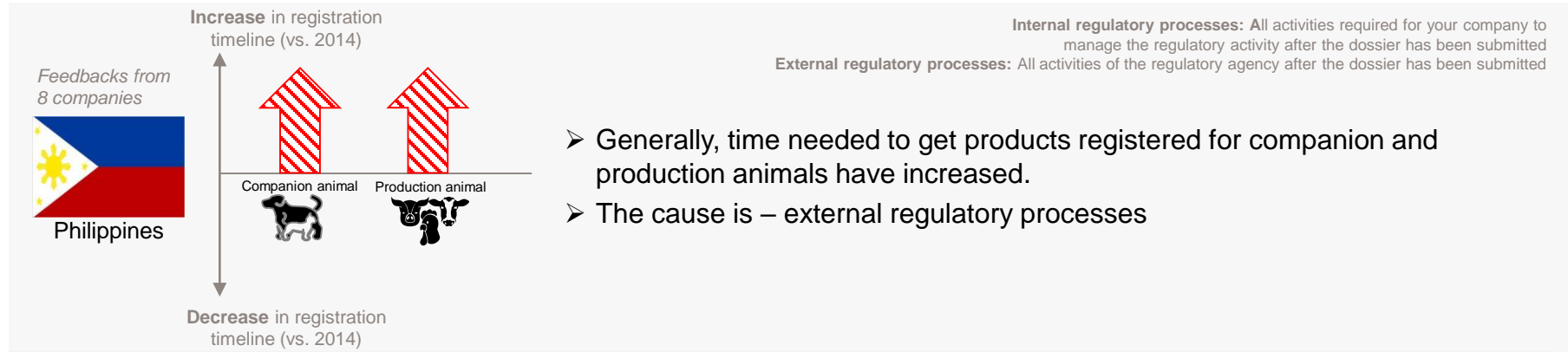


Feedbacks from Vietnam are only from MNC companies. No non-MNC companies participated in the study

Registration timeline, compared to 2014, for which species has the time increased / decreased?

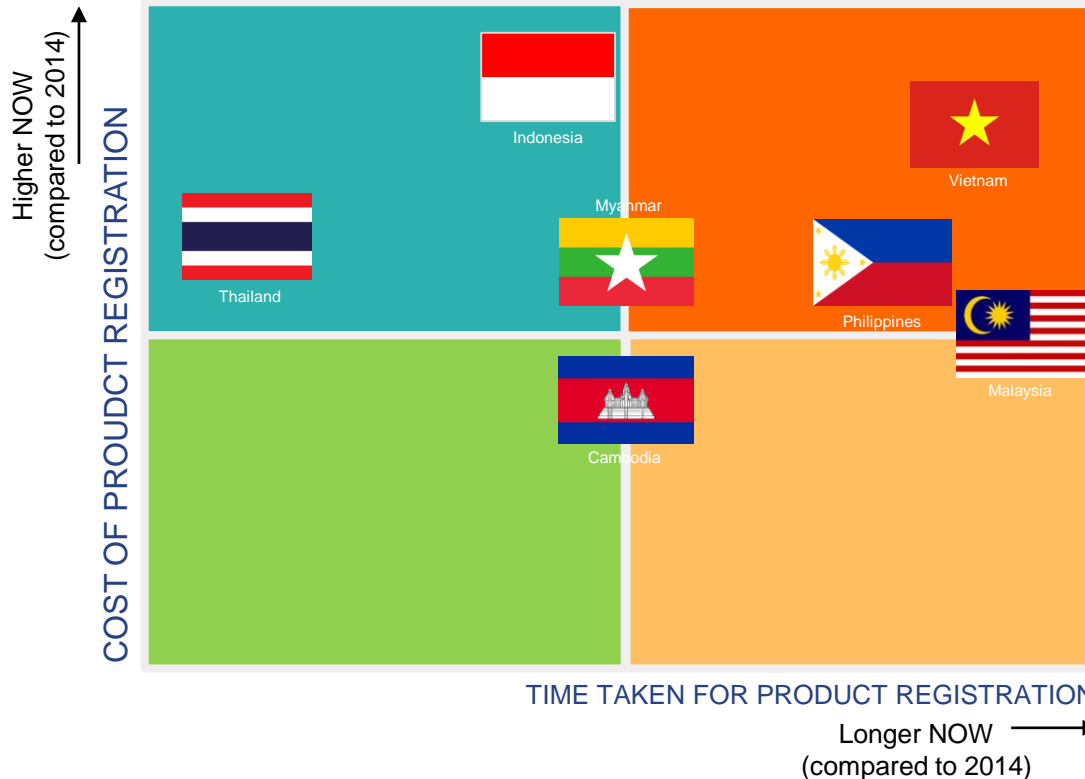
Philippines: Increased in product registration timeline for both species.

Cambodia & Myanmar: No change in registration timeline.



Compared to 2014, which country takes longer and more costly to get AH product registered?

Vietnam and Philippines have been voted to be the 2 ASEAN countries that is now performing worst compared to 5 years in cost (more expensive) and timeline (takes longer) for product registration.



Vietnam: Worst performing country. The time taken and cost of registration had increased compared to 5 years ago.

Philippines: Some increased in cost of registration, and time needed to register AH products have increased.

Malaysia: No increased in cost of registration for products, but the duration needed to get registration had lengthen.

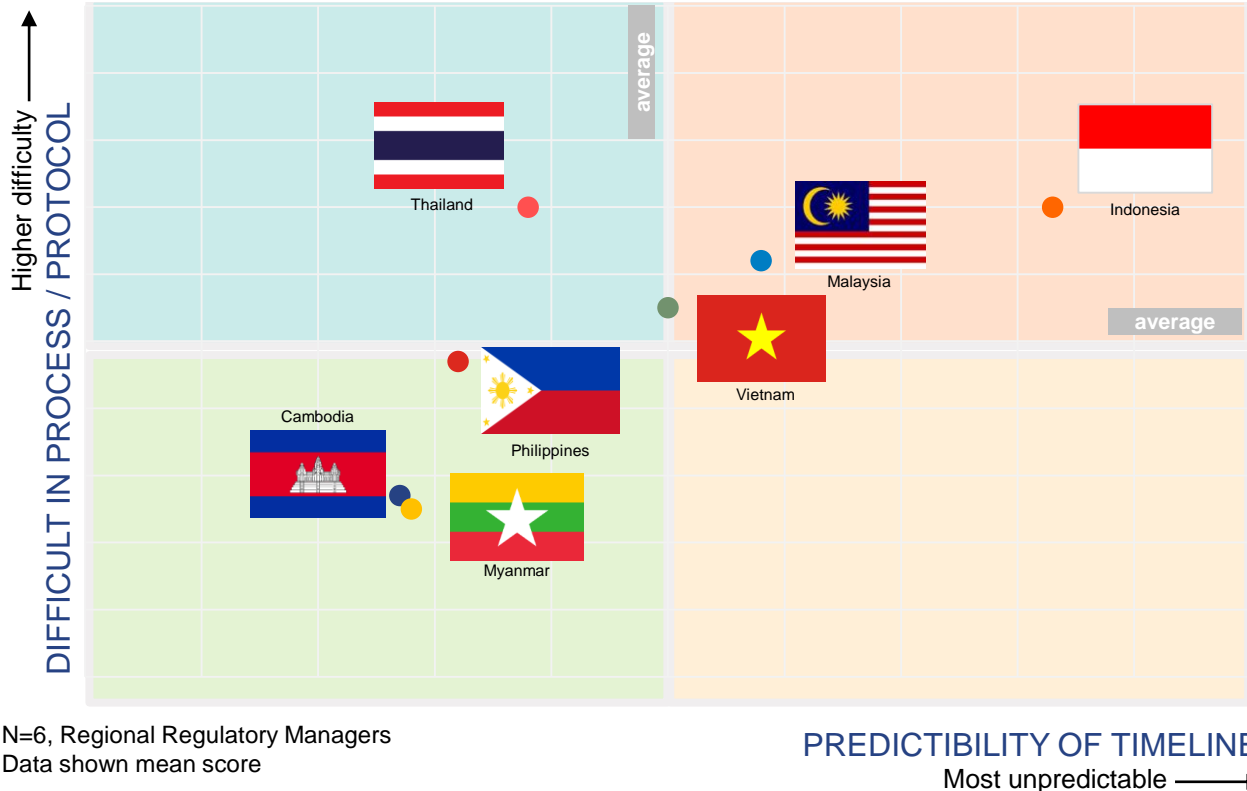
Indonesia: Significant increase in cost of product registration, but the time taken to get products registered perceived to have improved

Thailand: Relatively most expensive for AH product registration, but significant improvement in timeline for product registration.

Myanmar & Cambodia: No change in timeline to get products registered. Having said that managers have experienced some reduction in registration cost in Cambodia, whilst an increased in Myanmar

Level of difficulty of AH product registration – in terms of process / protocol & timeline across ASEAN

Indonesia is the toughest country to get product registered. Although the timeline is relatively predictable in Thailand, due to the strict requirements, it is rated by regional managers to be difficult in product registration process/protocol



N=6, Regional Regulatory Managers
Data shown mean score

Thailand & Indonesia: Regional regulatory managers have scored both Thailand and Indonesia at the same level of difficulty in registration process / protocol. However, the predictability of timeline between the 2 countries are vastly different.

Malaysia: Still considered to be a little unpredictable in timely and somewhat difficult in registration process/protocol

Vietnam: Average in predictability of timeline, but slightly difficult in registration process / protocol.

Philippines: Somewhat predictable in registration timeline, and not difficult in the registration process / protocol.

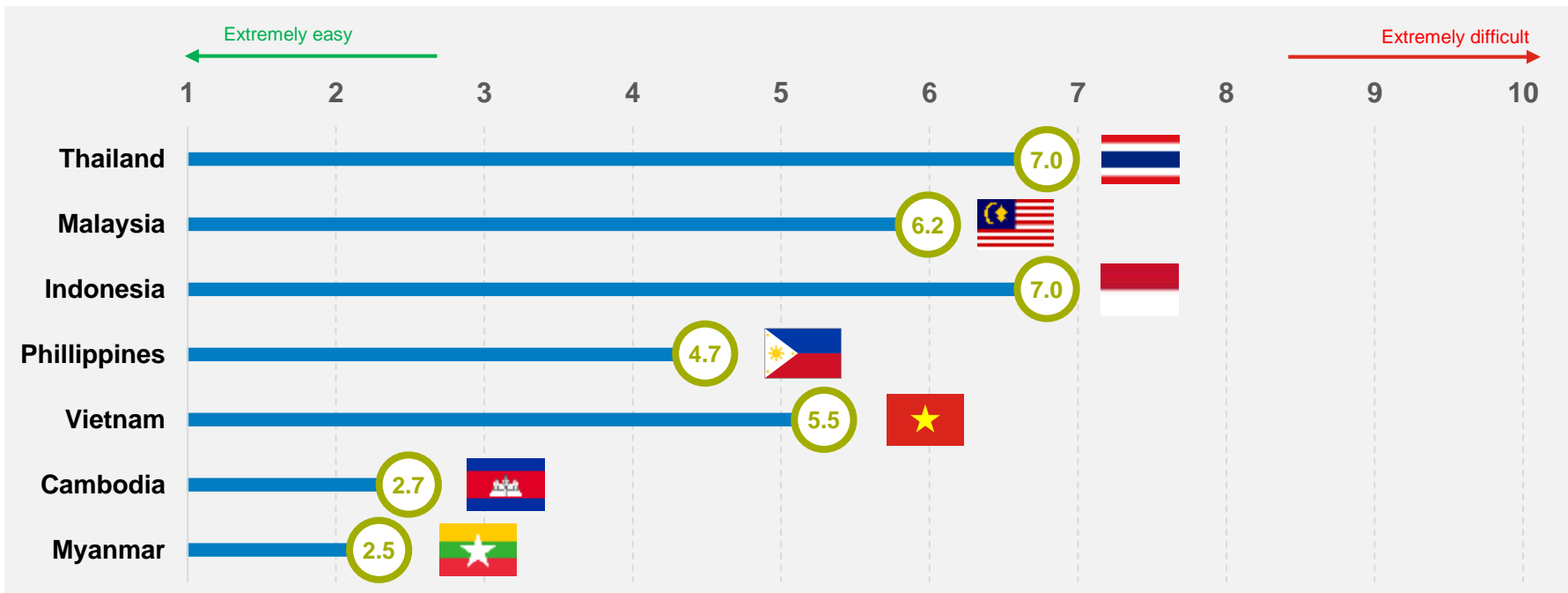
Cambodia & Myanmar: Perceived to be easy in registration process and predictable in registration timeline.

Thailand and Indonesia are considered most difficult in terms of process/protocol compared to other ASEAN countries

Level of difficulty of AH product registration – in terms of **process / protocol** across ASEAN

N=6, Regional Regulatory Managers

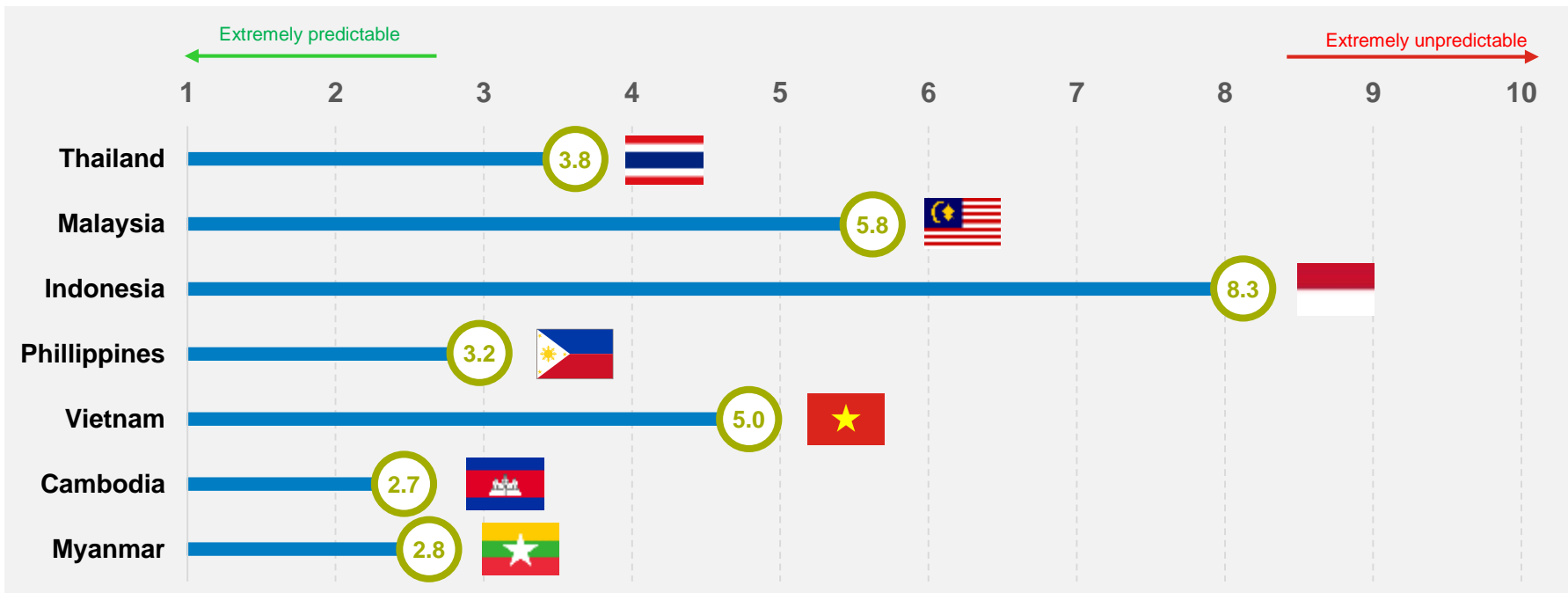
Data shown mean score



In terms of timeline, Indonesia is considered the most unpredictable for AH product registration. Malaysia is in the 2nd spot, followed by Vietnam in terms of unpredictability of timeline for product registration.

Level of predictability of AH product registration – in terms of timeline across ASEAN

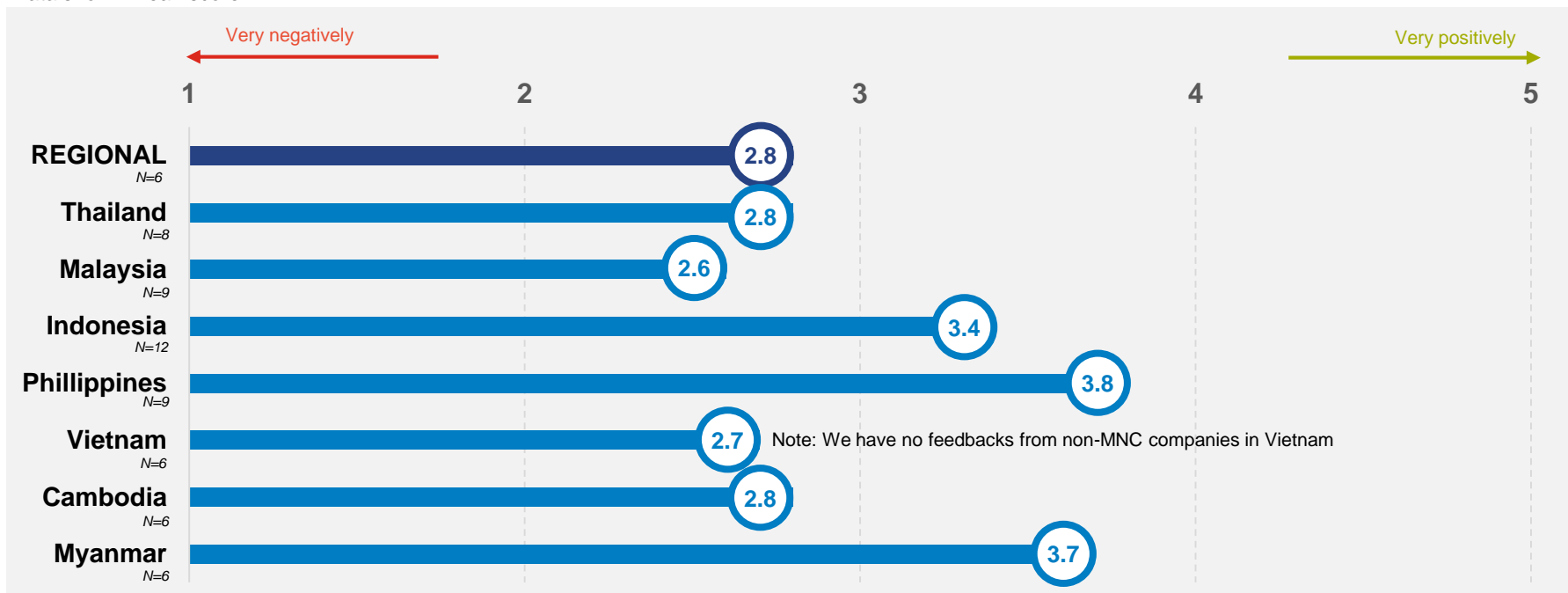
N=6, Regional Regulatory Managers
Data shown mean score



Based on the feedbacks for their country/region, regulatory managers in Thailand, Malaysia, Vietnam and to some extent Cambodia felt that the current regulatory environment is not advantages in bringing new AH products to market.

Overall impact of current regulatory environment in bringing new AH product to market

Data shown mean score

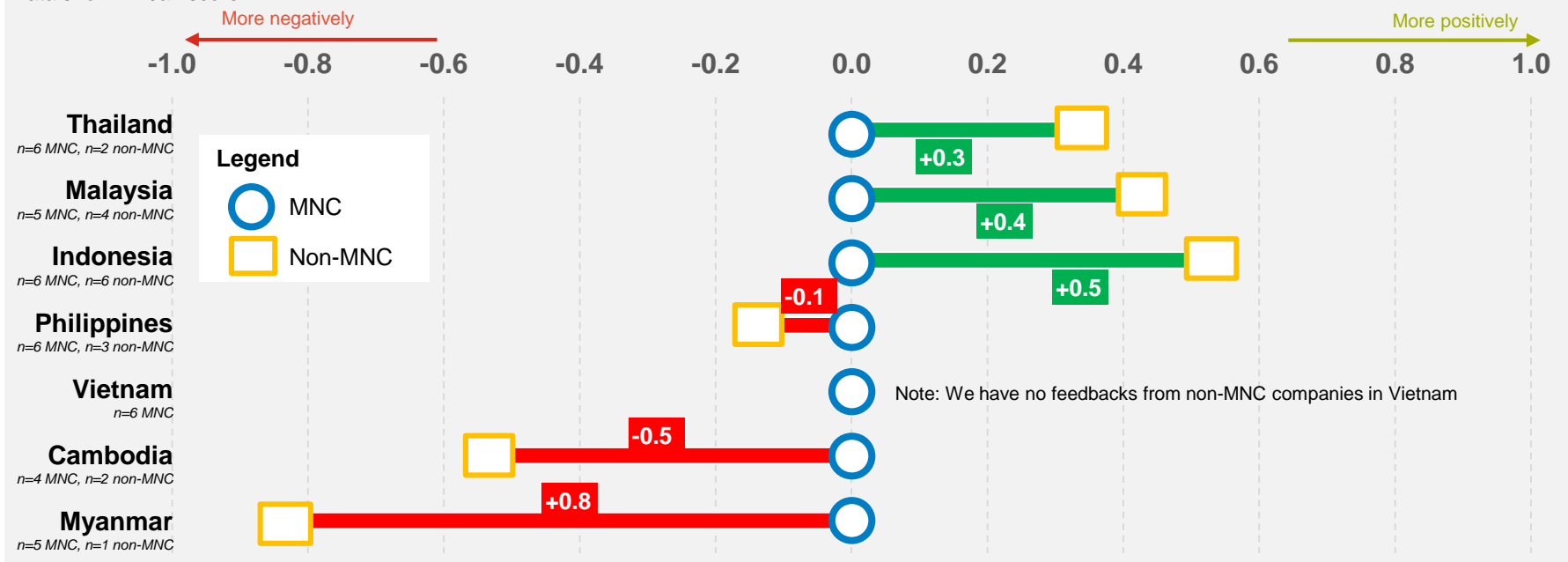


In Thailand, Malaysia and Indonesia, the non-MNC have a more positive view on the impact of regulatory environment in bringing new AH products to market.

In contrast, MNC companies found the regulatory environment in the Philippines, Cambodia and Myanmar to be more positive in bringing new products compared to non-MNC companies.

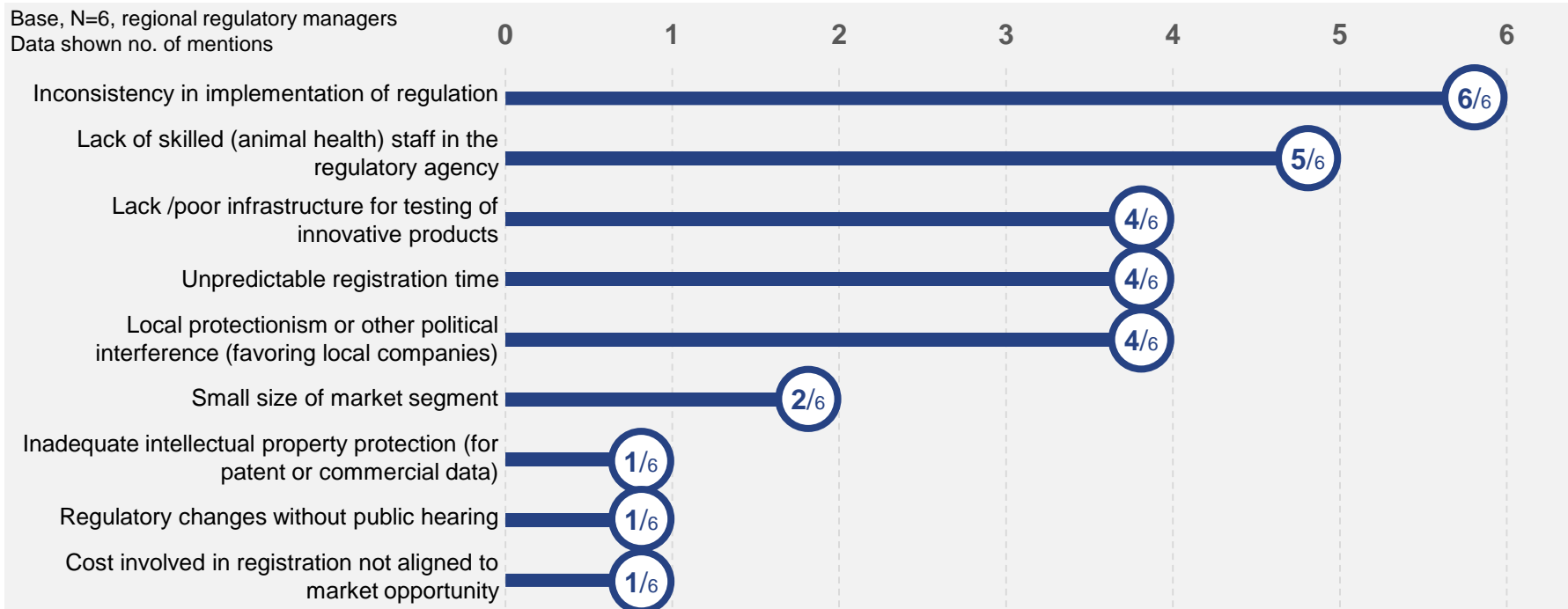
Overall impact of regulatory environment in bringing new AH product to market: feedbacks from MNC vs. non MNC

Data shown mean score



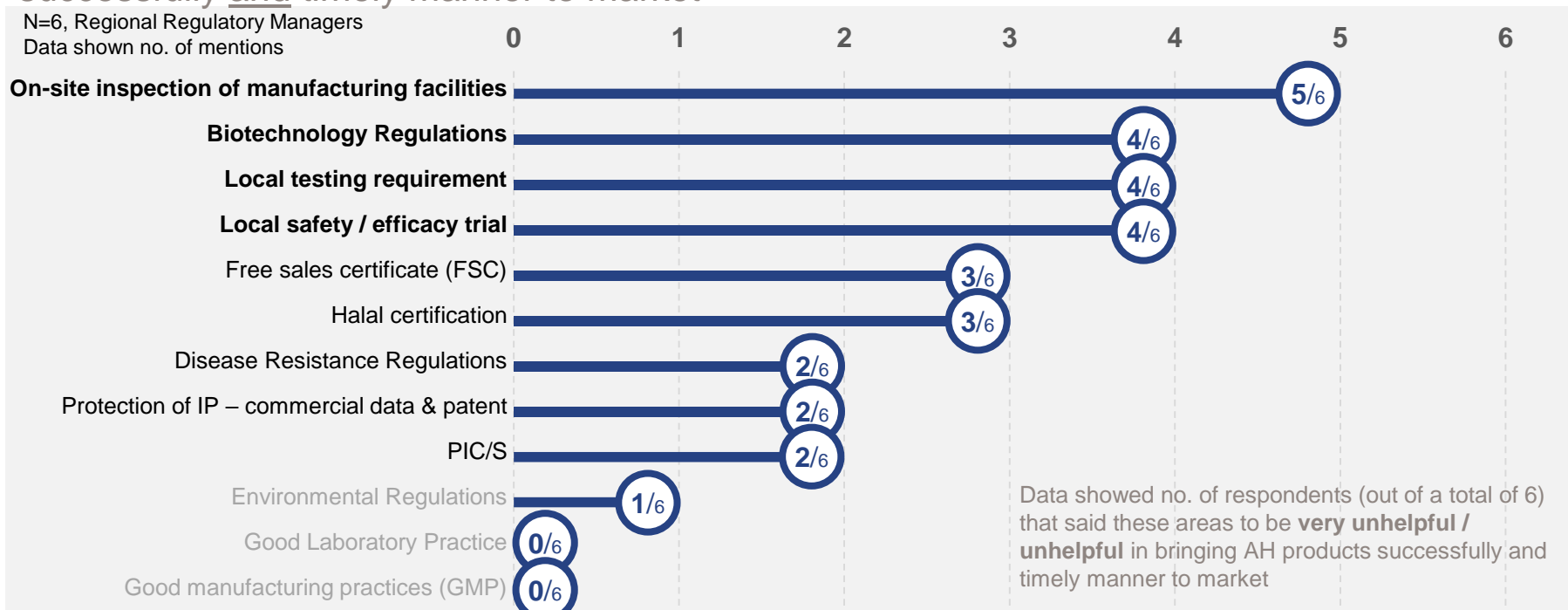
Feedbacks from the regional regulatory managers are: inconsistency in implementation of regulation and lack of skilled (animal health) staff in regulatory bodies in ASEAN countries are the main ‘culprit’ for the factors that have significant impact in preventing companies bringing new products.

Factors / challenges that are significant in preventing companies bring [new AH products](#)



Apart from on-site inspection of manufacturing facilities, biotechnology regulation, local testing requirement and local safety/efficacy are aspects of regulation that have negative impact in bring new AH products successfully and timely manner to market

(Negative) Impact on different areas of regulation on ability to bring new AH product successfully and timely manner to market

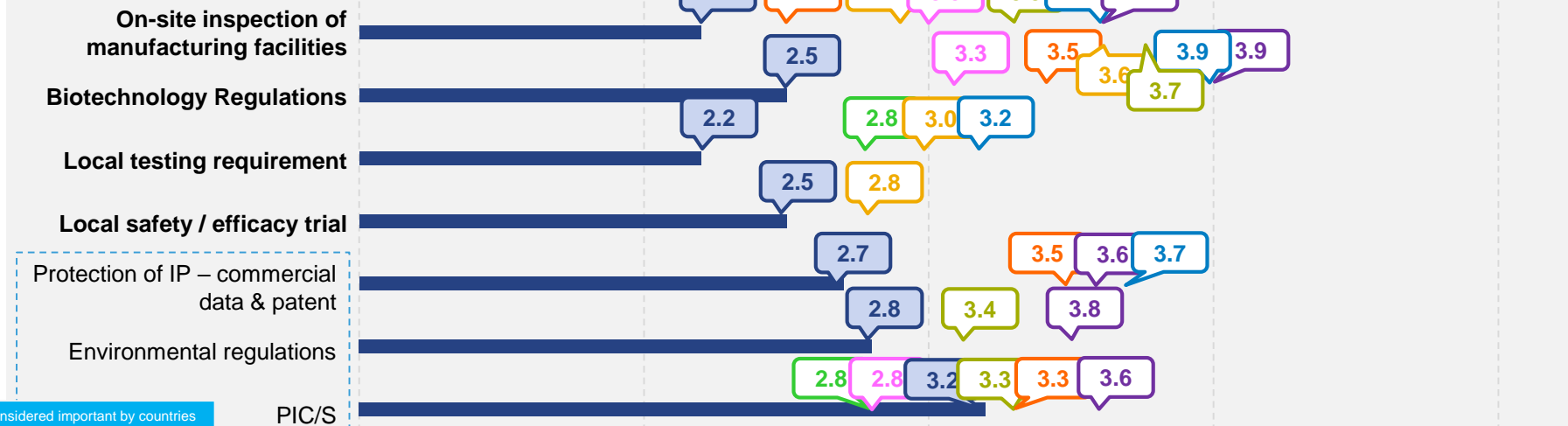
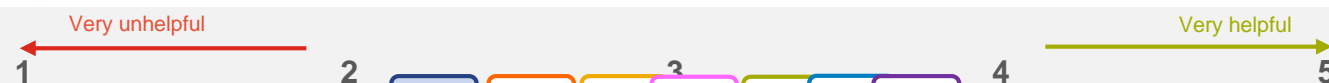


Across the 7 ASEAN countries, these 7 areas of regulations are considered by local regulatory managers to be least helpful in bringing new AH products successfully & timely manner to the market.

(Negative) Impact on different areas of regulation on ability to bring new AH product successfully and timely manner to market

Base, N=62

Data shown means score



Considered important by countries

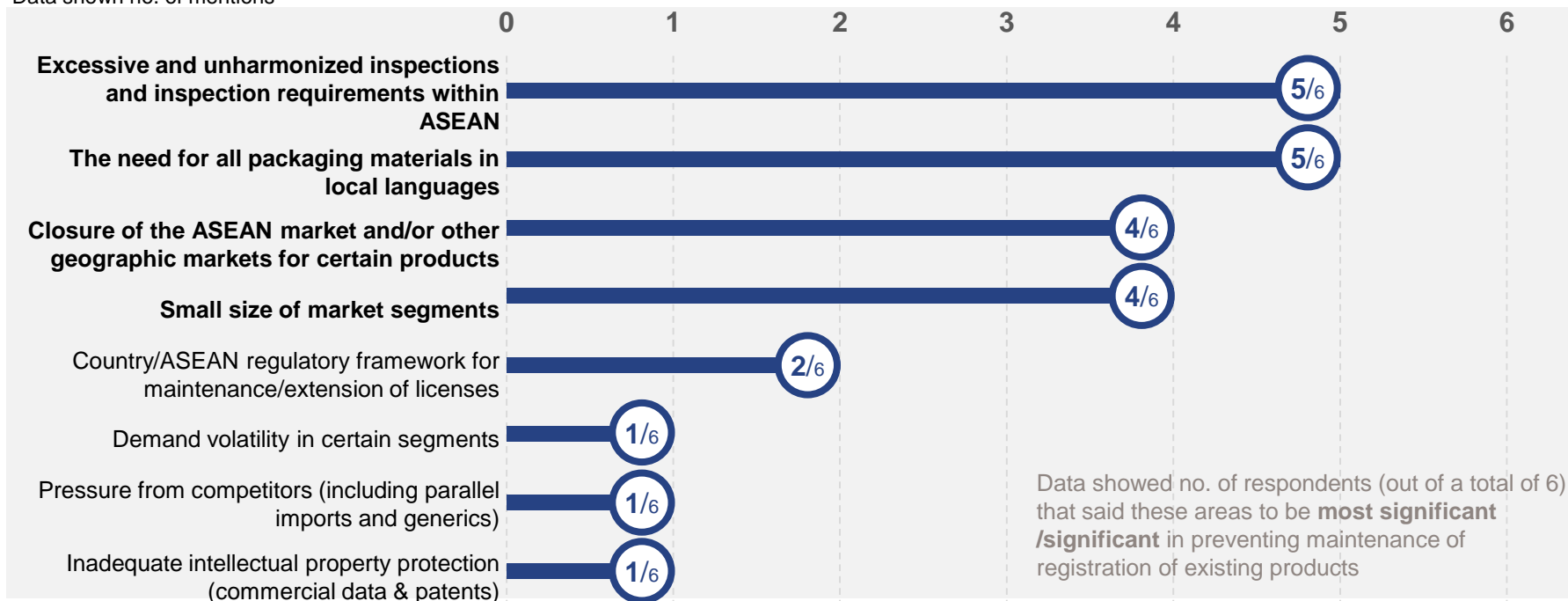


▪ Apart from these 6 regulatory areas, Malaysia regulatory managers also found disease resistance regulation and halal certification to be unhelpful

Feedbacks from the regional regulatory managers are: excessive and unharmonized inspections and requirements, need for all packaging materials in local languages are the hurdles faced in the maintenance of registration of existing products

Factors preventing maintenance of registration of existing AH products

Base, N=6, regional regulatory managers
Data shown no. of mentions

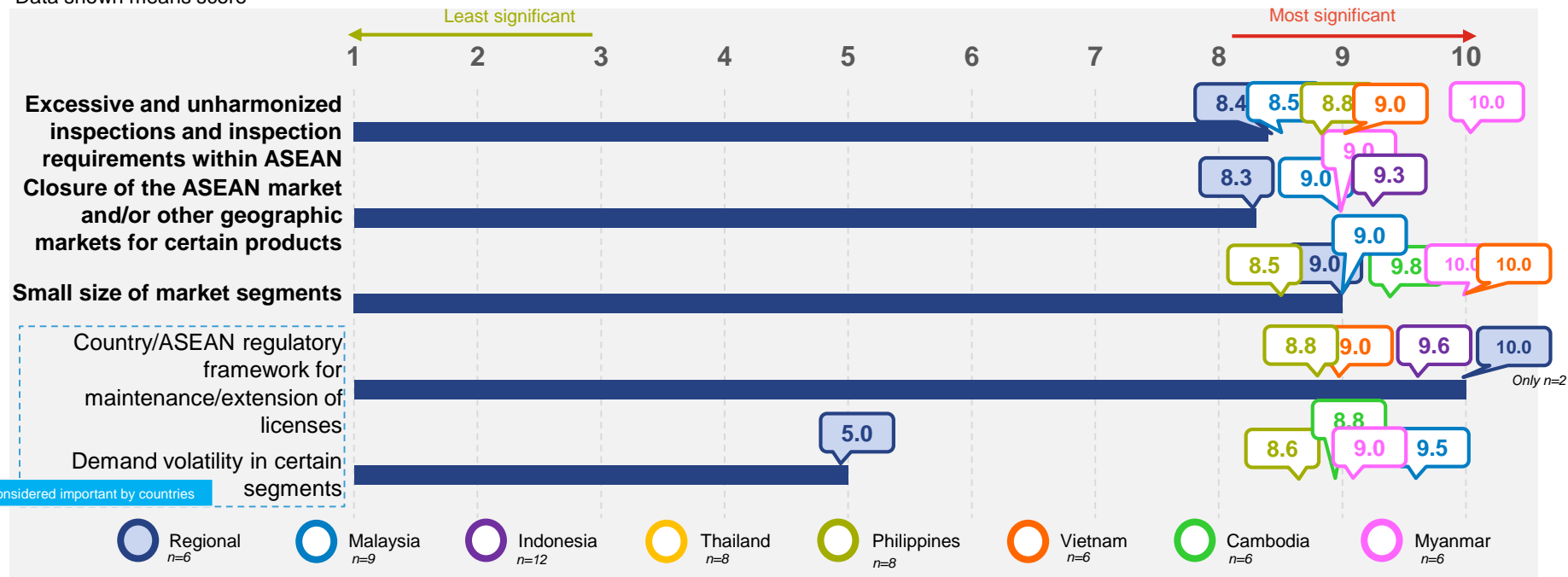


Across the 7 ASEAN countries, these 6 areas of regulations are considered by local regulatory managers to be most significant in preventing the maintenance of registration of existing AH products. For Thailand, the factors are different – lack of skilled regulatory staff, difficulty in GMP clearance and lack of IP protection

Factors preventing maintenance of registration of existing AH products

Base, N=62

Data shown means score

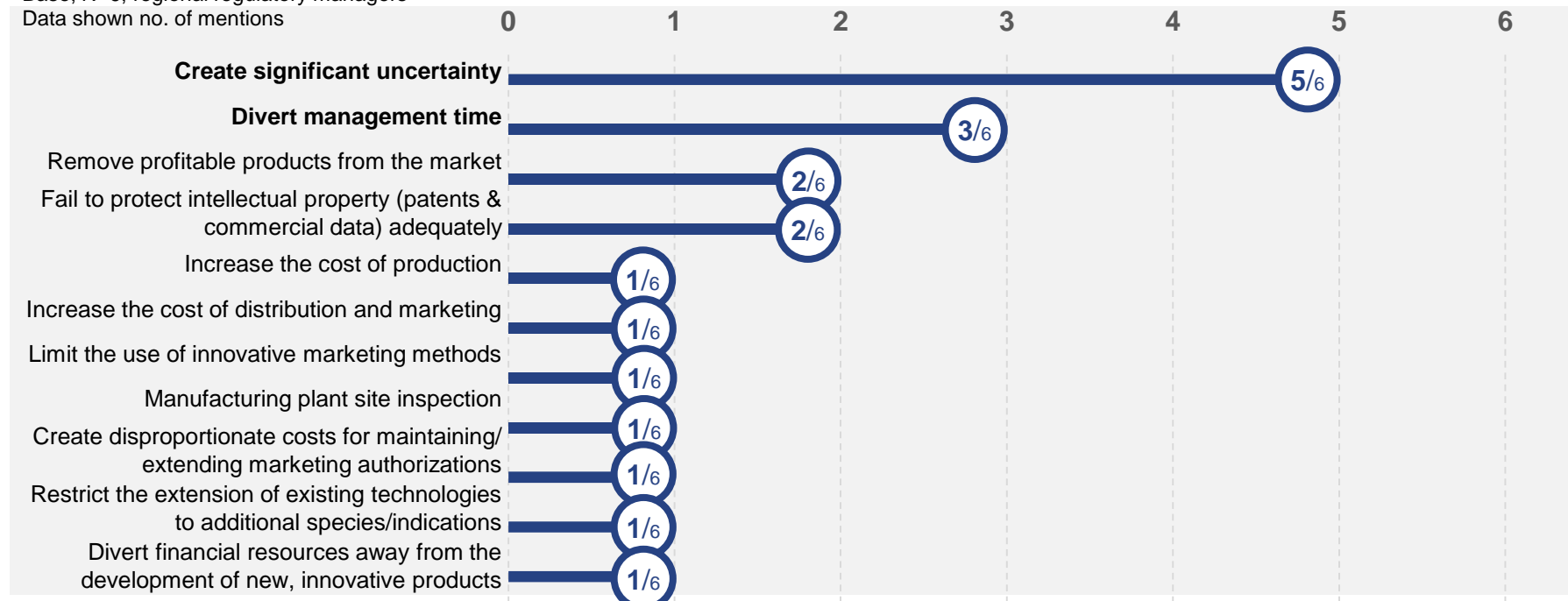


According to regional regulatory managers, govt regulations create significant uncertainty, divert management time and remove profitable products for the market and failed to protect IP, which have negative impact on the AH business

(Negative) effect on the AH business due to govt. regulations

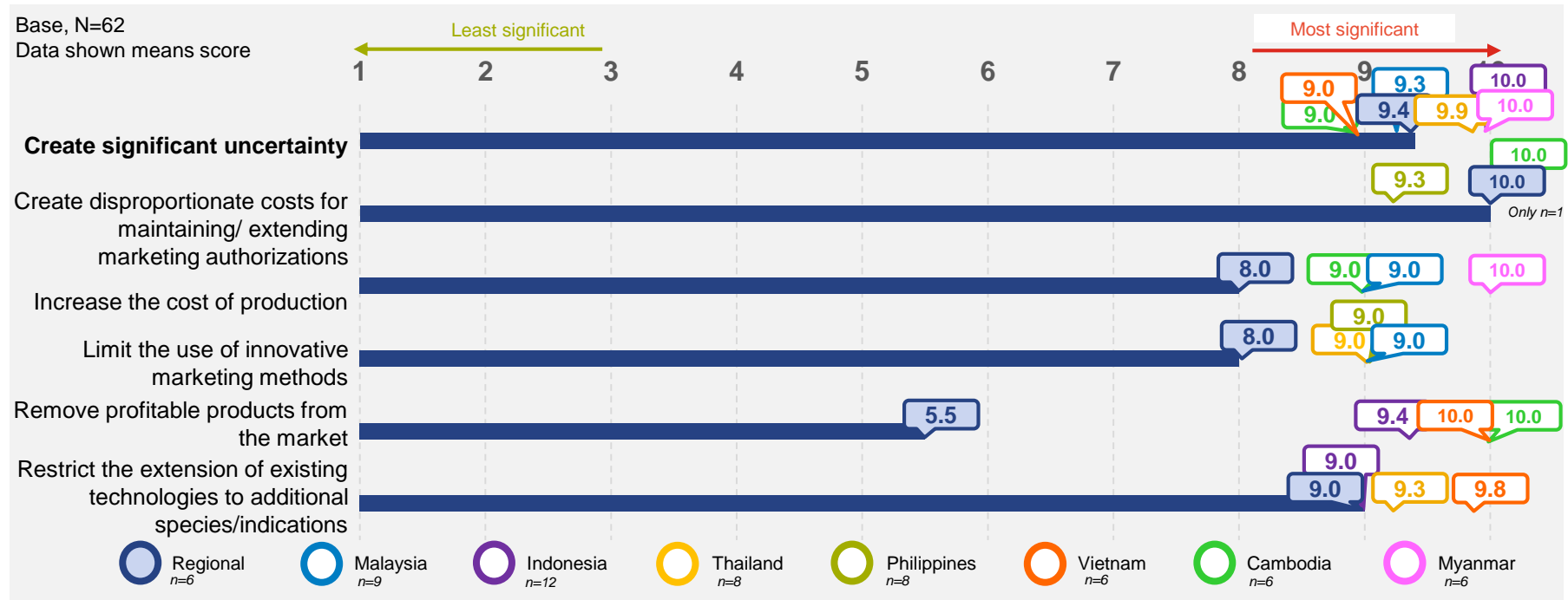
Base, N=6, regional regulatory managers

Data shown no. of mentions

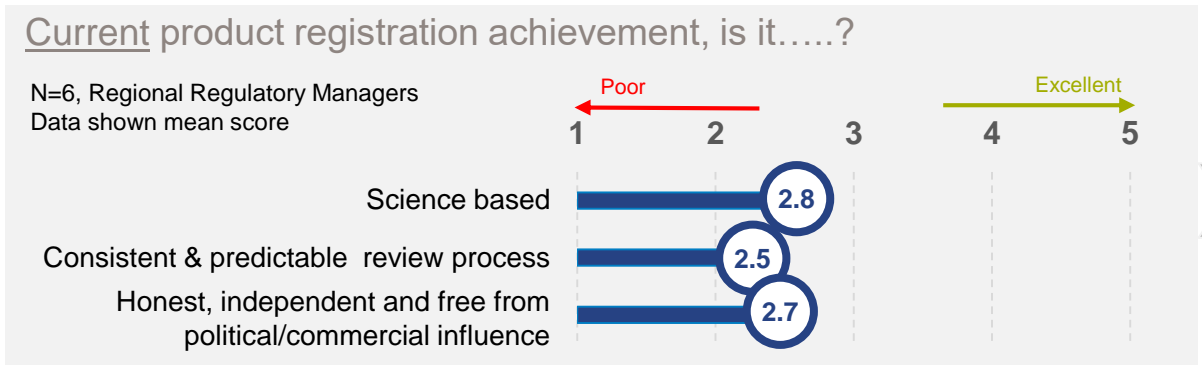


Across the 7 ASEAN countries, these are the key (negative) impact of government regulations on AH business. Feedbacks are captured from local regulatory managers

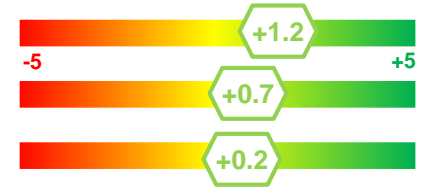
(Negative) effect on the AH business due to govt. regulations



Regional regulatory managers considered that current product registration achievement is slightly better on 3 criteria: science based, consistent & predictable review process and honest, independent and free from political / commercial influence compared to 5 years ago. But complexity level had increased.



AND comparison with 2014 (benchmark), is current product registration achievement better or worst?
(-5 = A lot worse, 0 = No change; +5=A lot better)



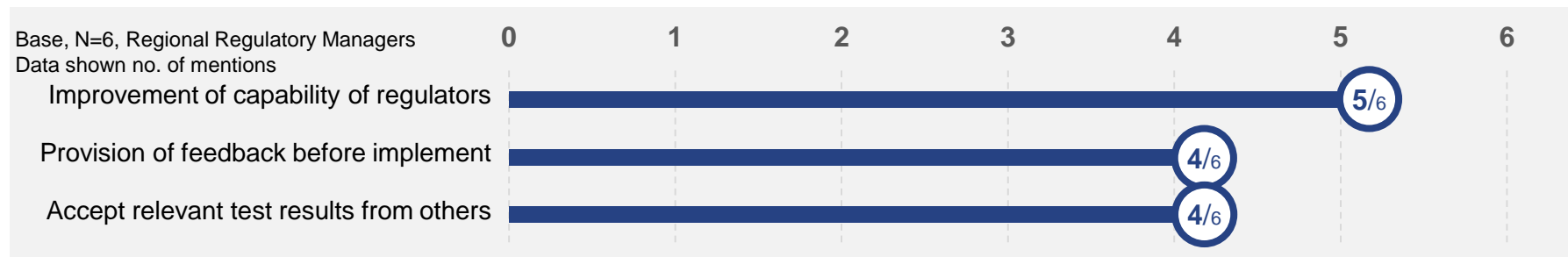
AND comparison with 2014 (benchmark), is current product registration complexity better or worst?
(-5 = A lot worse, 0 = No change; +5=A lot better)



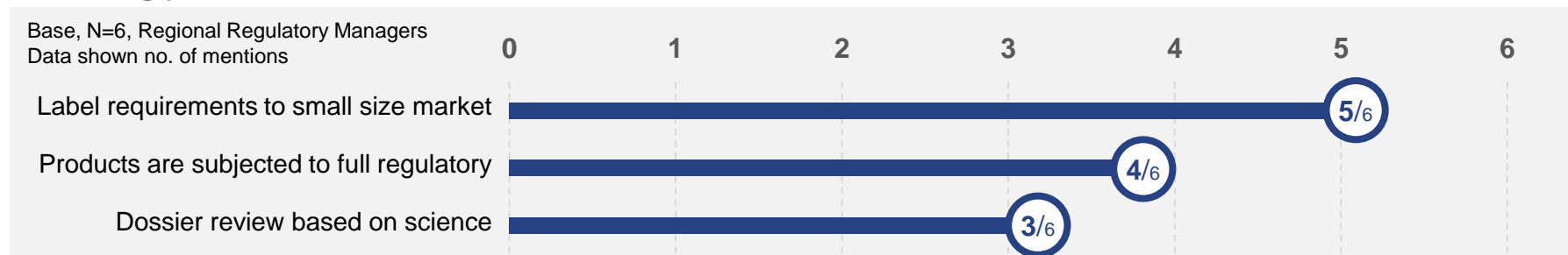
Managers had said that there has been some improvement in capability of regulators, provision of feedbacks before implementation and accept relevant test results from others had improve product registration achievement.

Some implementation such as label requirement, full regulatory of product and science based dossier review also have positive impact in maintaining of registration of existing products.

(KEY) Issues that have occurred, and would have (positive) impact product registration achievement



(KEY) Issues that have occurred, and would have (positive) impact performing maintenance of registration of existing products



Product registration complexity has reduced now compared to 2014. But some managers are of the view that the review process is less consistent & predictable, and also less honest, independent and free from political / commercial influence

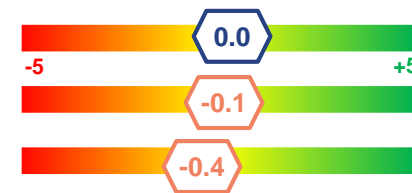


Current product registration achievement, is it.....?



AND comparison with 2014 (benchmark), is current product registration achievement better or worst?

(-5 = A lot worse, 0 = No change; +5=A lot better)



Current product registration complexity, is it.....?



AND comparison with 2014 (benchmark), is current product registration complexity better or worst?

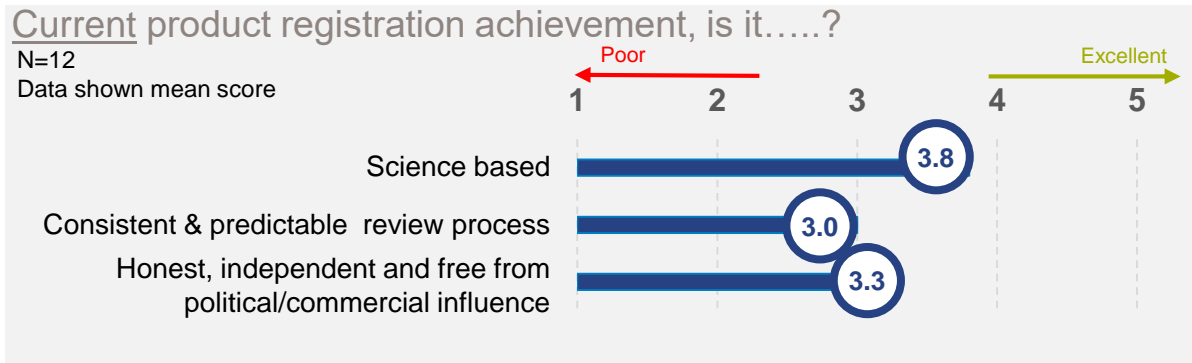
(-5 = A lot worse, 0 = No change; +5=A lot better)



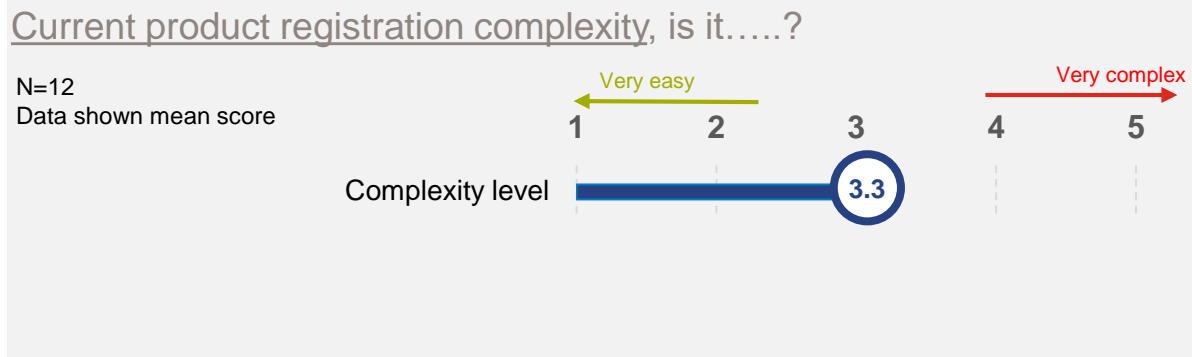
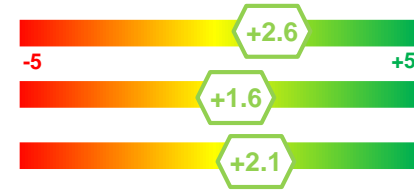
In Indonesia, there has been significant improvement in product registration achievement and also reduced complexity to 2014



Indonesia



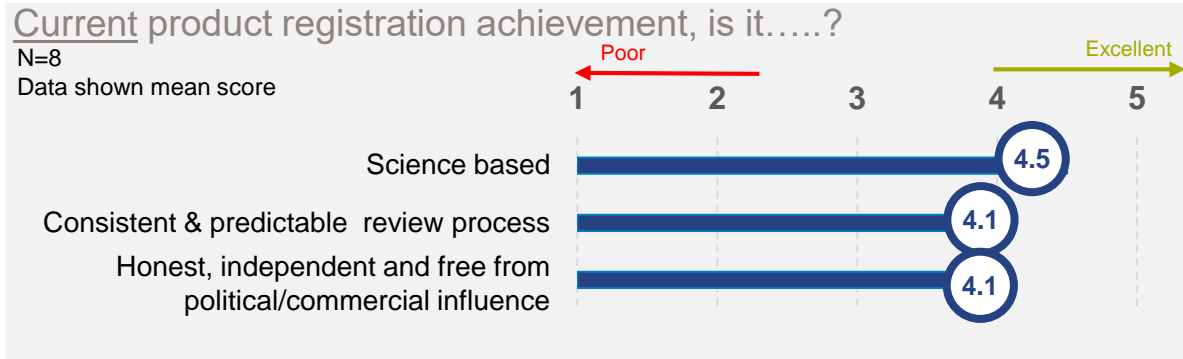
AND comparison with 2014 (benchmark), is current product registration achievement better or worst?
(-5 = A lot worse, 0 = No change; +5 = A lot better)



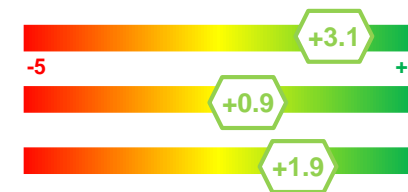
AND comparison with 2014 (benchmark), is current product registration complexity better or worst?
(-5 = A lot worse, 0 = No change; +5 = A lot better)



Thailand has also experienced improvement in product registration achievement since 2014, although some do complained the complexity of product registration remains high.



AND comparison with 2014 (benchmark), is current product registration achievement better or worst?
(-5 = A lot worse, 0 = No change; +5=A lot better)



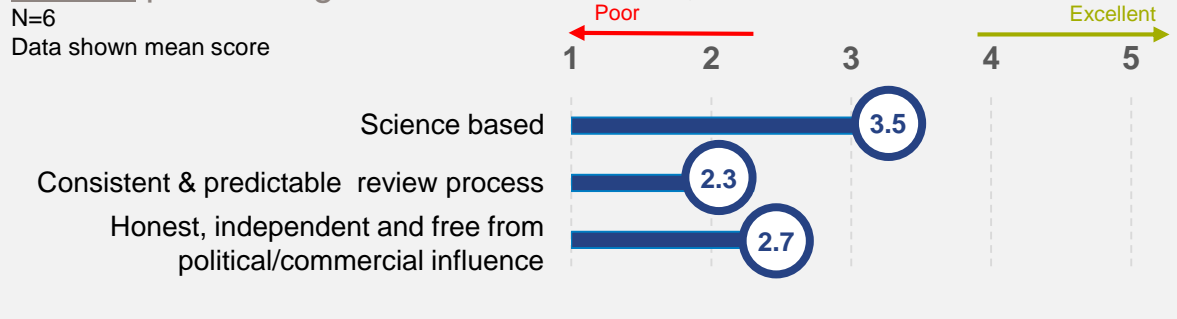
AND comparison with 2014 (benchmark), is current product registration complexity better or worst?
(-5 = A lot worse, 0 = No change; +5=A lot better)



Although the product registration achievement is more science based, there has not been improvement on consistency and predictability of review process and (still) lacking in honest, independent and free from political / commercial influence. Complexity in product registration has also increased compared to 2014

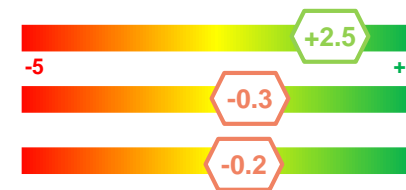


Current product registration achievement, is it.....?

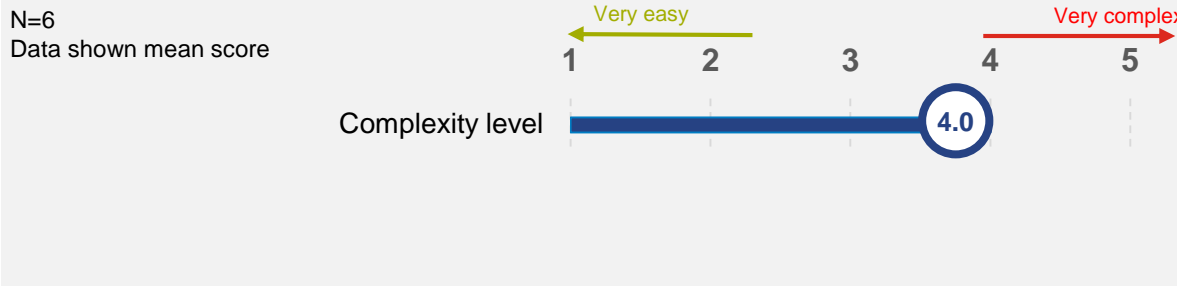


AND comparison with 2014 (benchmark), is current product registration achievement better or worst?

(-5 = A lot worse, 0 = No change; +5 = A lot better)



Current product registration complexity, is it.....?



AND comparison with 2014 (benchmark), is current product registration complexity better or worst?

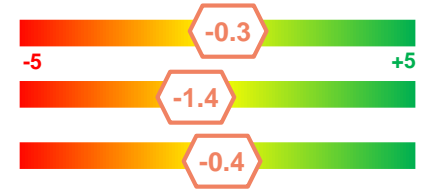
(-5 = A lot worse, 0 = No change; +5 = A lot better)



Even though local managers felt that the current product registration achievement in the Philippines is above average in terms of science based, consistent & predictable review process and honest, independent and free from political / commercial influence, they claimed that it was (even) better in 2014. Complexity of product registration has also increased somewhat significantly.



AND comparison with 2014 (benchmark), is current product registration achievement better or worst?
(-5 = A lot worse, 0 = No change; +5 = A lot better)



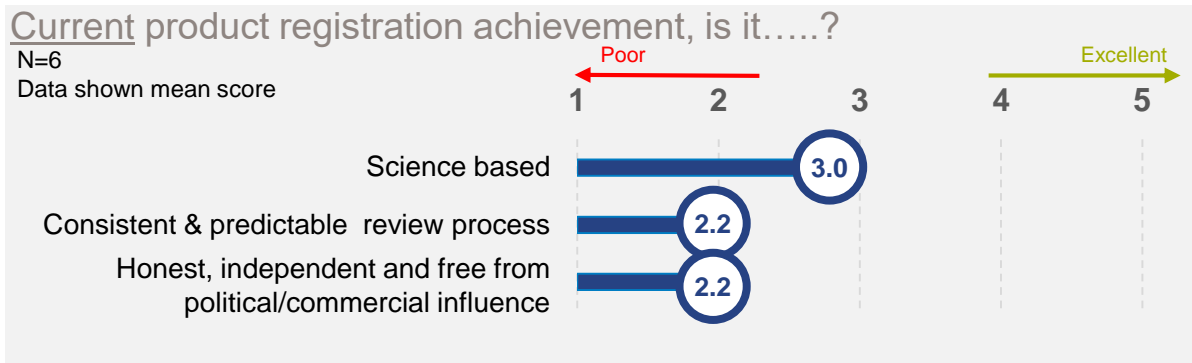
AND comparison with 2014 (benchmark), is current product registration complexity better or worst?
(-5 = A lot worse, 0 = No change; +5 = A lot better)



Expectedly, the product registration achievement in Cambodia is still poor and not science based, not consistent nor predictable in review process, and not independent and free from political / commercial influences

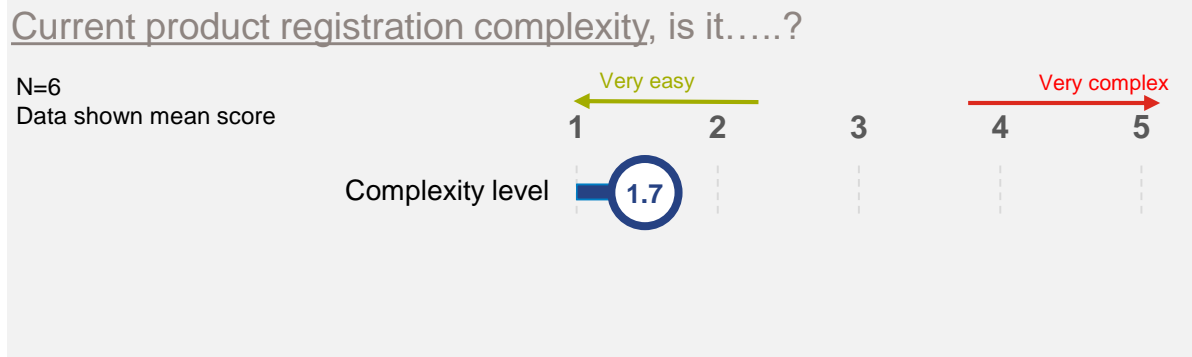
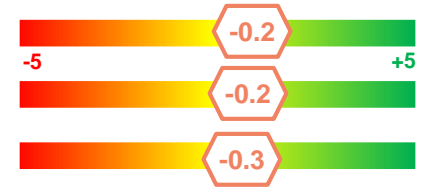


Cambodia



AND comparison with 2014 (benchmark), is current product registration achievement better or worst?

(-5 = A lot worse, 0 = No change; +5=A lot better)

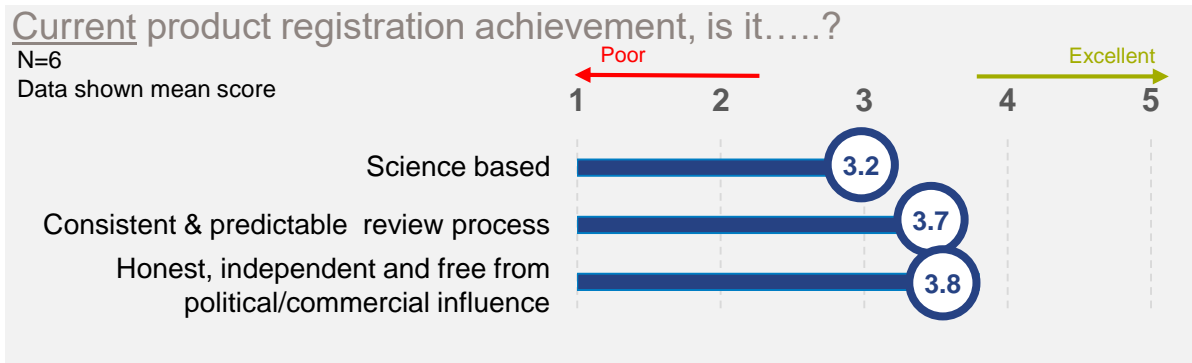


AND comparison with 2014 (benchmark), is current product registration complexity better or worst?

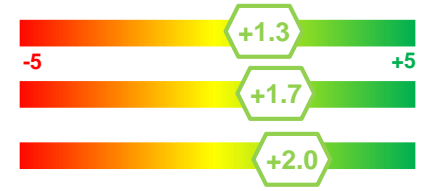
(-5 = A lot worse, 0 = No change; +5=A lot better)



Local regulatory managers claimed that current product registration achievement is more science based, consistent & predictable review process, honest, independent and free from political / commercial influence. It is also perceived the level of registration complexity has reduced slightly compared to 2014



AND comparison with 2014 (benchmark), is current product registration achievement better or worst?
(-5 = A lot worse, 0 = No change; +5=A lot better)

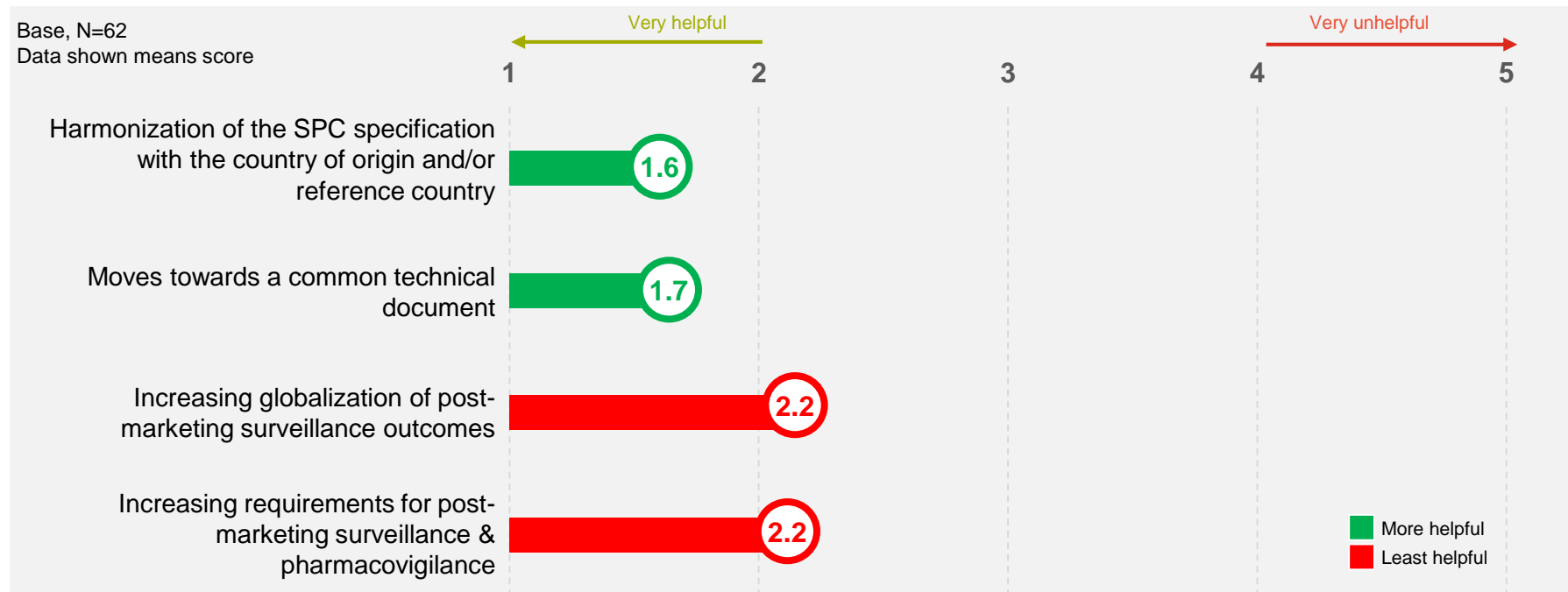


AND comparison with 2014 (benchmark), is current product registration complexity better or worst?
(-5 = A lot worse, 0 = No change; +5=A lot better)



Regulatory managers in ASEAN agreed that harmonization of the SPC specification with the country of origin and/or reference country and move toward a common technical documents are 2 aspects that will be most helpful for AH business. In contrast, increase globalization and requirements in post marketing surveillance are going to make business more challenging.

Top trends that more and least helpful in the next 5 years that can impact your business



TOTAL: Trends that will occur in the next 5 years that will impact the AH business

Both MNC and non-MNC agreed that harmonization of the SPC specification will have significant impact on the AH business in the future. Furthermore, MNC also felt that moves towards a common technical document will help too.

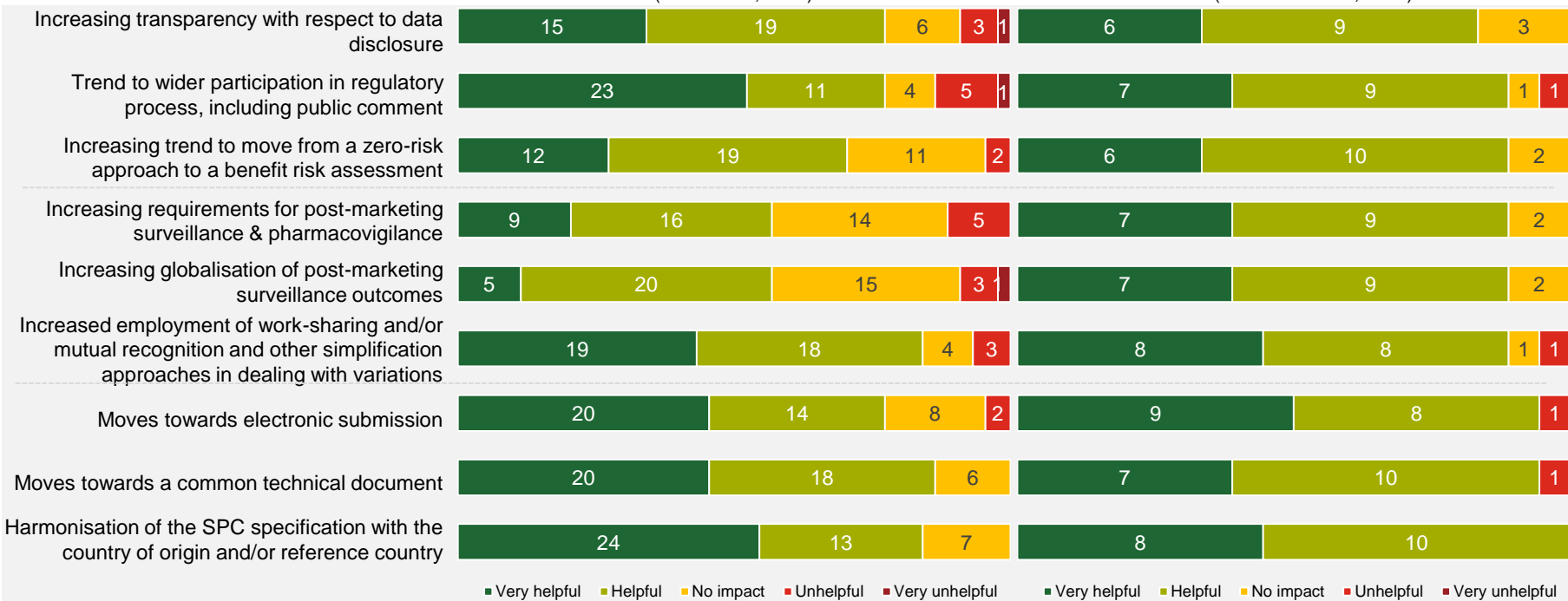
Base, N=62 (combined both MNC & Non-MNC)
Data shown no. of mentions

MNC

Number of mentions (Base: MNC, n=44)

Non-MNC

Number of mentions (Base: Non-MNC, n=18)



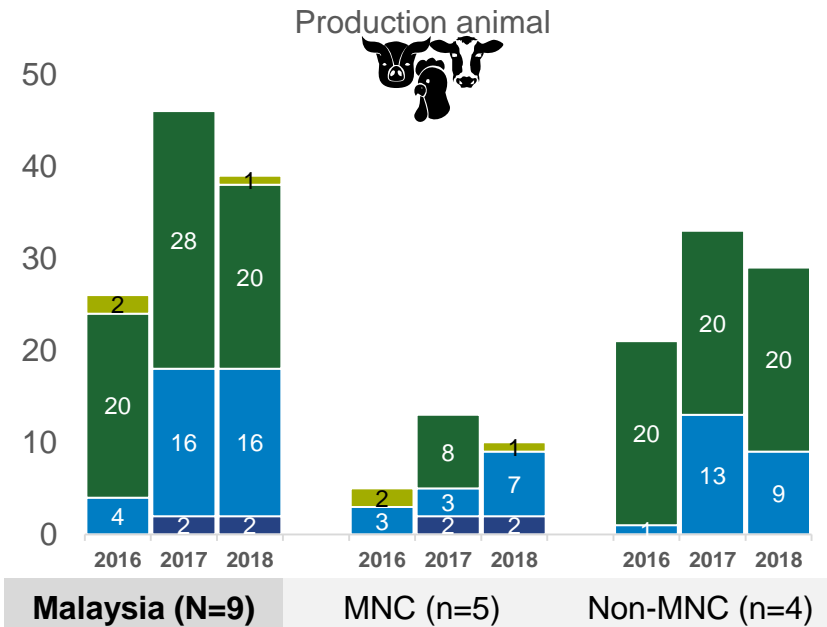
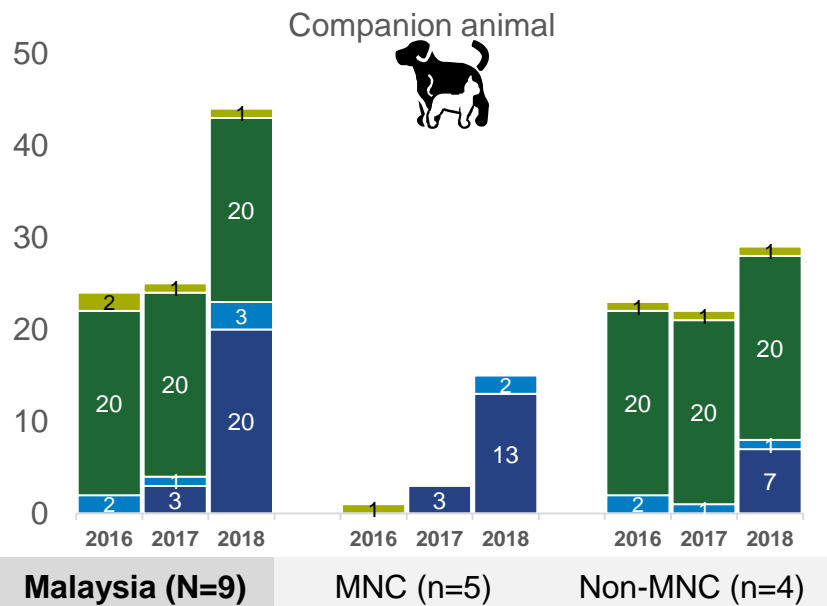
G1. The following trends or changes in regulatory approach have been taking place recently and may well have an impact in future. What trend(s) do you expect to occur in the next 5 years that will affect your business?

A glowing lightbulb is centered on the right side of the slide, set against a dark blue background. The lightbulb is illuminated from within, casting a bright blue glow. A semi-transparent white horizontal bar is positioned across the middle of the slide, containing the text.

No. of product registered 2016 - 2018

MALAYSIA: New Animal Health Product Registration for each therapeutic area by species in 2016 – 2018

Data shows no. of products registered in each year by different therapeutic areas and species



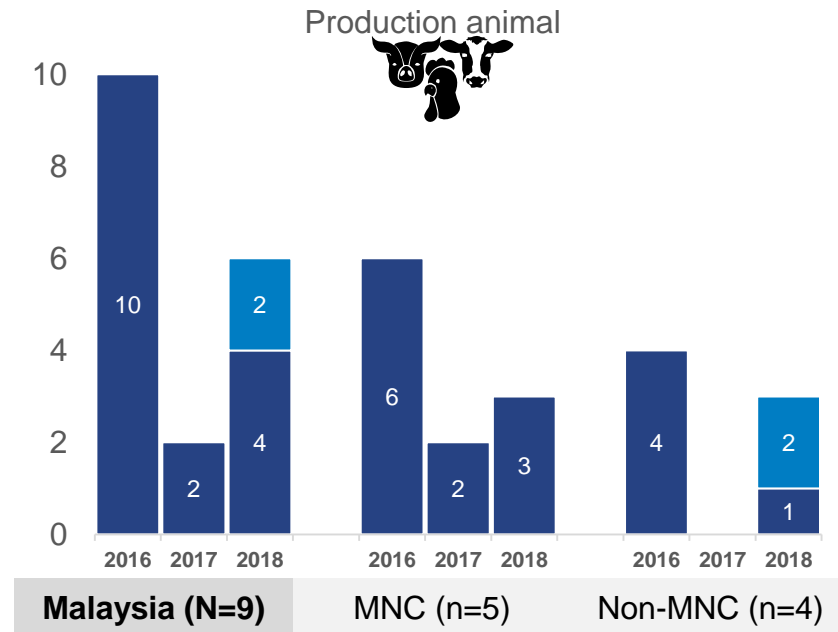
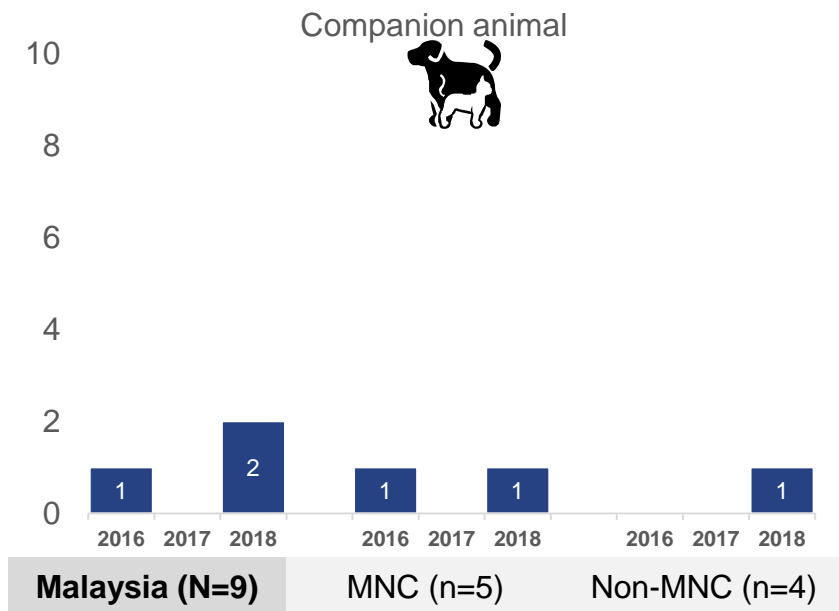
For species – **Aqua and others**, only 1 MNC company registered 1 product in 2018. No product was registered in previous years

A1a: Thinking about registration of new AH products for your country/ASEAN, can you tell me how many products did your company register in 2016, 2017 and 2018?

MALAYSIA: Generic Animal Health Product Registration for each therapeutic area by species in 2016 – 2018



Data shows no. of products registered in each year by different therapeutic areas and species



A1b: Thinking about registration of generic AH products for your country/ASEAN, can you tell me how many products did your company register in 2016, 2017 and 2018?

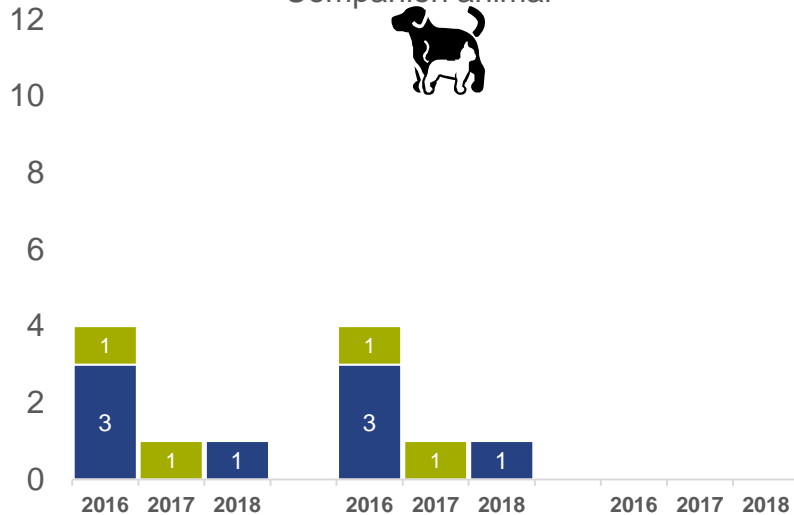
MALAYSIA: Major Variation Animal Health Product Registration for each therapeutic area by species in 2016 – 2018



Data shows no. of products registered in each year by different therapeutic areas and species



Companion animal

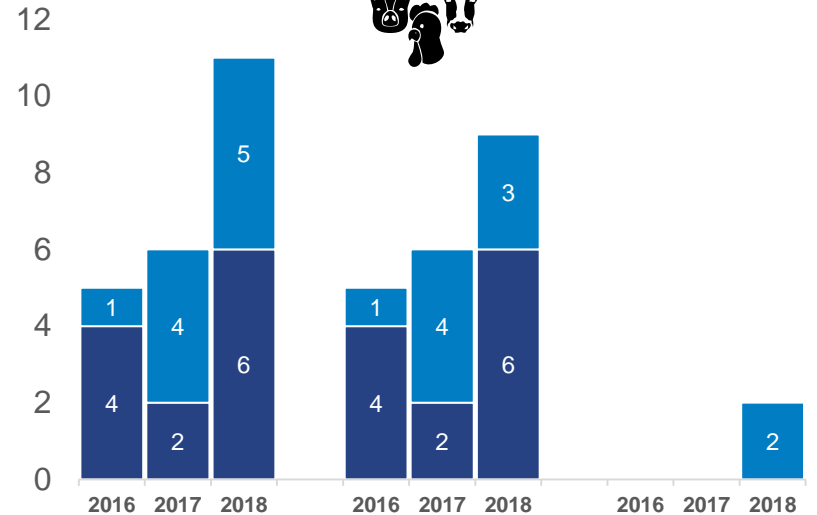


Malaysia (N=9)

MNC (n=5)

Non-MNC (n=4)

Production animal



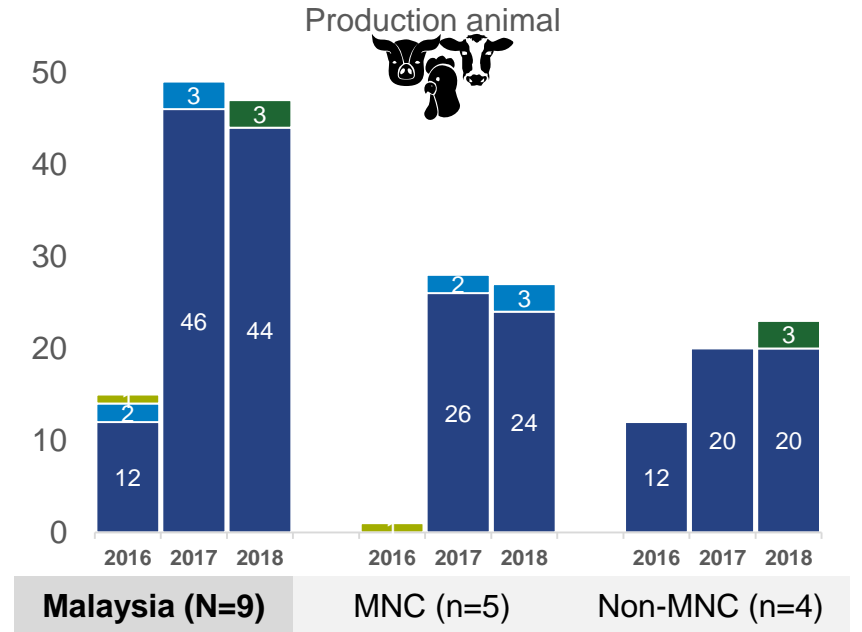
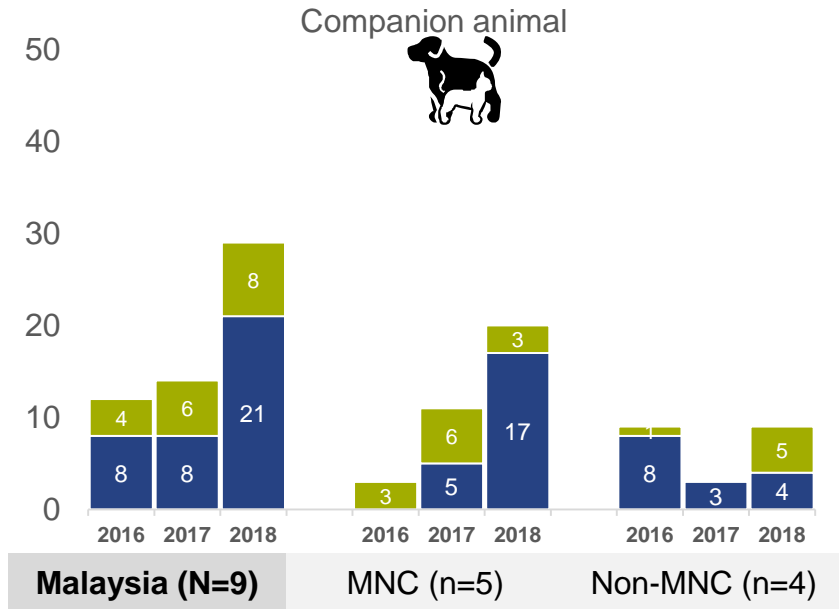
Malaysia (N=9)

MNC (n=5)

Non-MNC (n=4)

MALAYSIA: Minor Variation Animal Health Product Registration for each therapeutic area by species in 2016 – 2018

Data shows no. of products registered in each year by different therapeutic areas and species

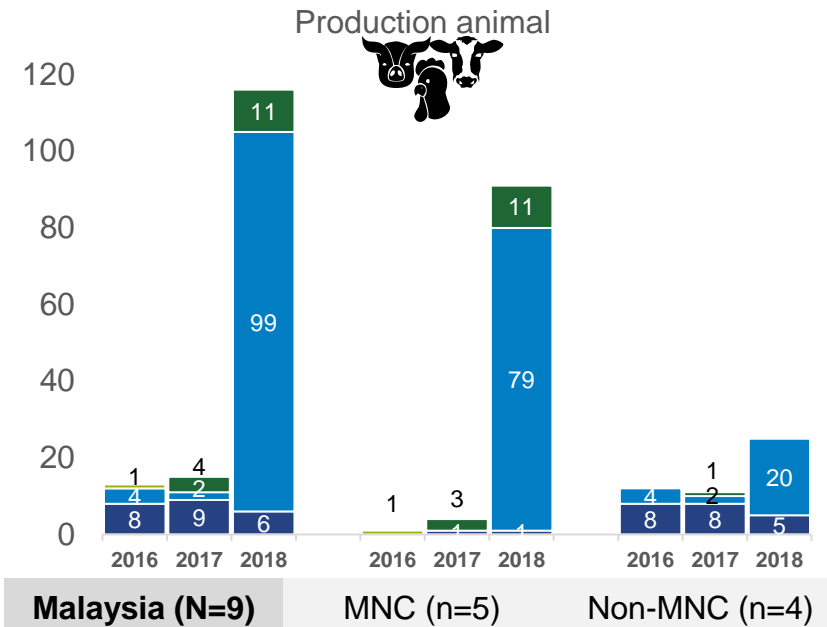
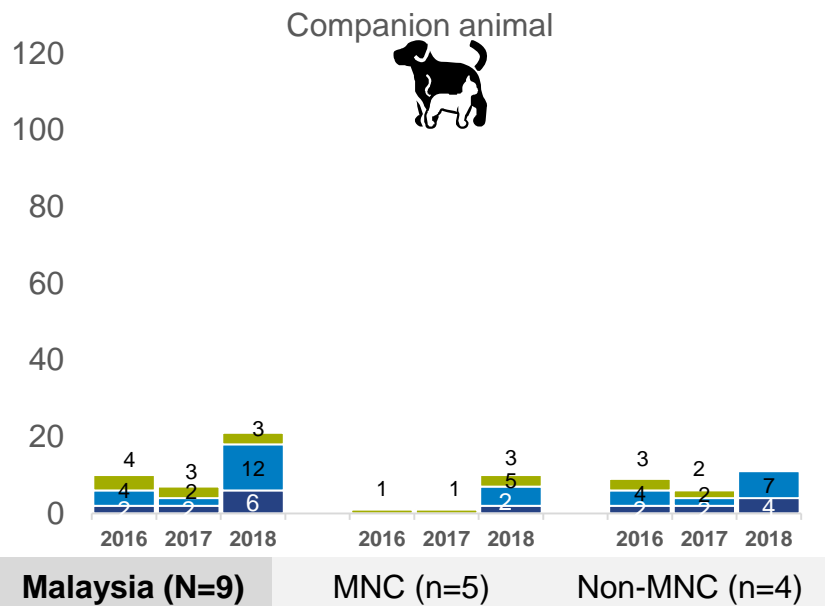


A2b: Thinking about regulatory approval of a minor variation of AH products for your country/ASEAN, can you tell me how many products did your company in 2016, 2017 and 2018?

MALAYSIA: Renewal Animal Health Product Registration for each therapeutic area by species in 2016 – 2018



Data shows no. of products registered in each year by different therapeutic areas and species



For species – Aqua and others, only 1 MNC company renewed 3 products in 2018. No product was renewed in previous years

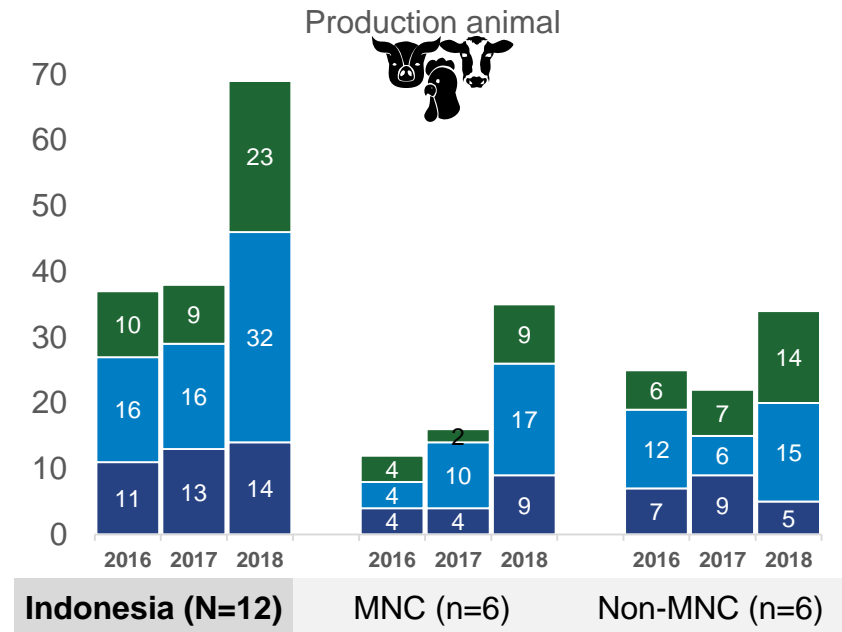
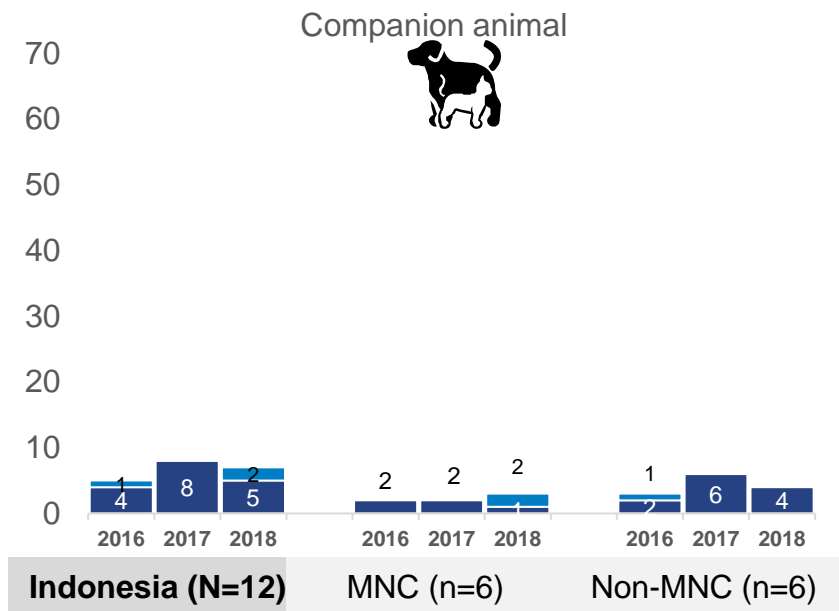
A3: Thinking about approval of AH products re-registration for your country/ASEAN, can you tell me how many products did your company register in 2016, 2017 and 2018?

INDONESIA: New Animal Health Product Registration for each therapeutic area by species in 2016 – 2018



Indonesia

Data shows no. of products registered in each year by different therapeutic areas and species

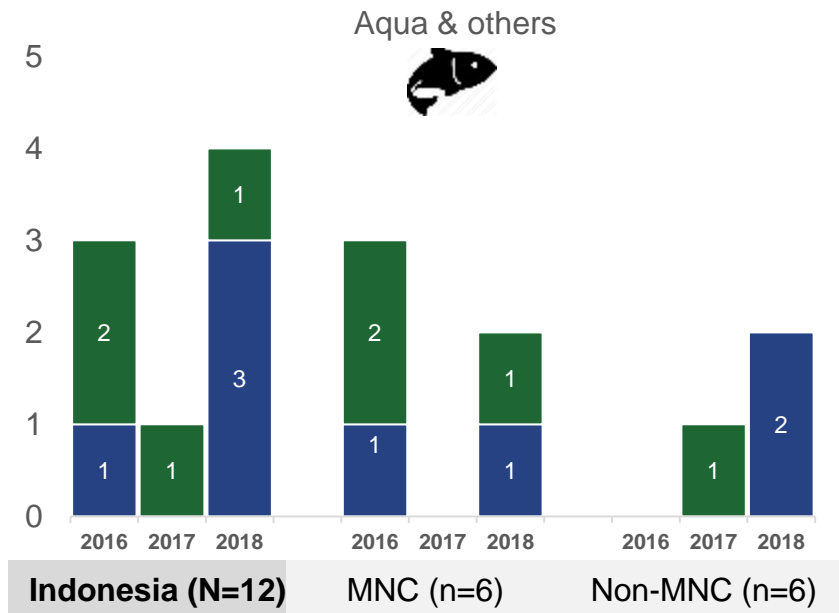


A1a: Thinking about registration of new AH products for your country/ASEAN, can you tell me how many products did your company register in 2016, 2017 and 2018?

INDONESIA: New Animal Health Product Registration for each therapeutic area by species in 2016 – 2018



Data shows no. of products registered in each year by different therapeutic areas and species



For **species – Aqua and others**, only 1 MNC company has **major variation** registration in 2018. No product was recorded in previous years

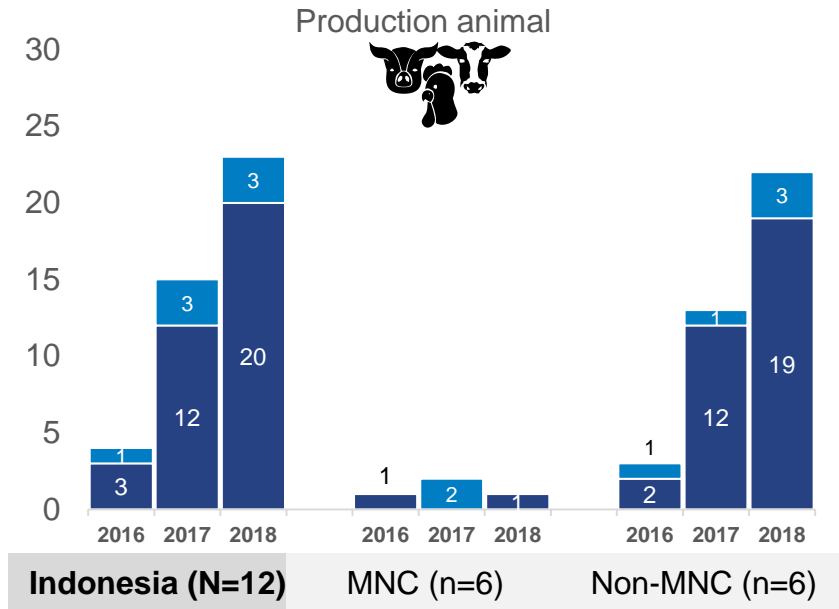
For **species – Aqua and others**, only 1 non MNC company has **renewal of product registration** in 2016 and 2018. No product was recorded in 2017.

INDONESIA: Generic Animal Health Product Registration for each therapeutic area by species in 2016 – 2018



Indonesia

Data shows no. of products registered in each year by different therapeutic areas and species



A1b: Thinking about registration of generic AH products for your country/ASEAN, can you tell me how many products did your company register in 2016, 2017 and 2018?

INDONESIA: Major Variation Animal Health Product Registration for each therapeutic area by species in 2016 – 2018

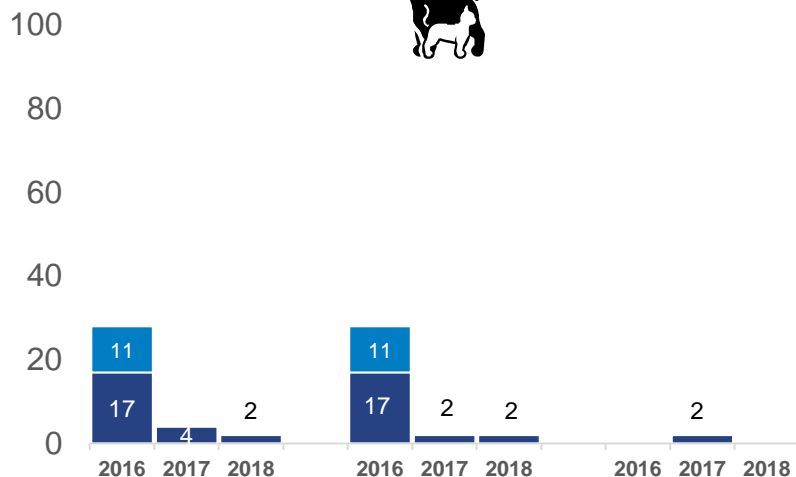


Indonesia

Data shows no. of products registered in each year by different therapeutic areas and species

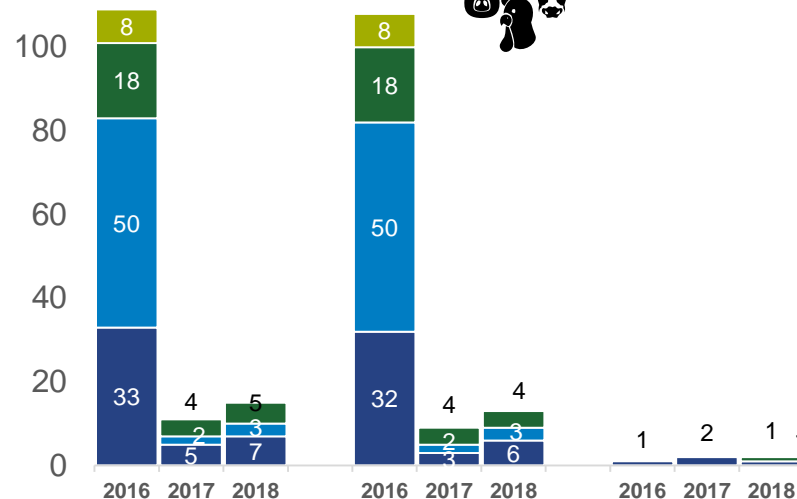


Companion animal



Indonesia (N=12) MNC (n=6) Non-MNC (n=6)

Production animal



Indonesia (N=12) MNC (n=6) Non-MNC (n=6)

For species – Aqua and others, only 1 MNC company registered 1 in-feed medication in 2018

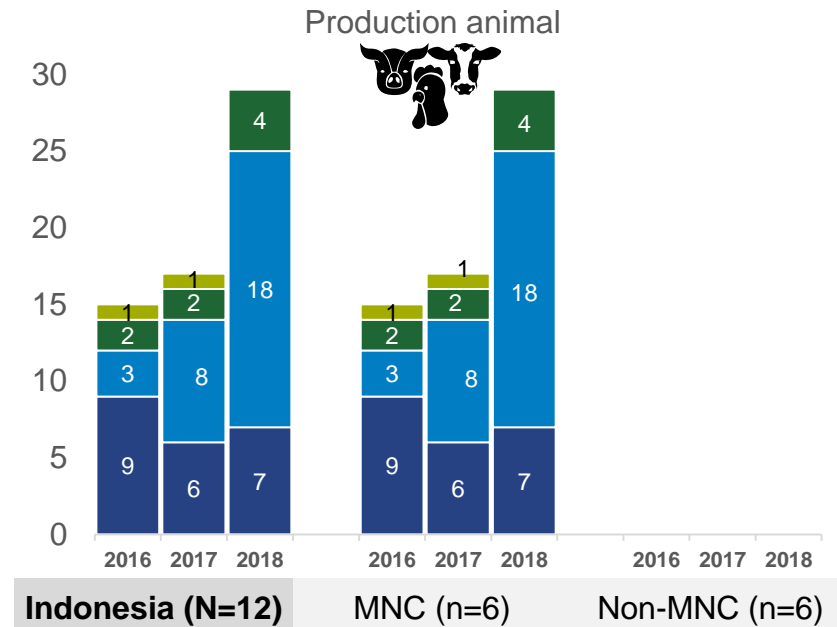
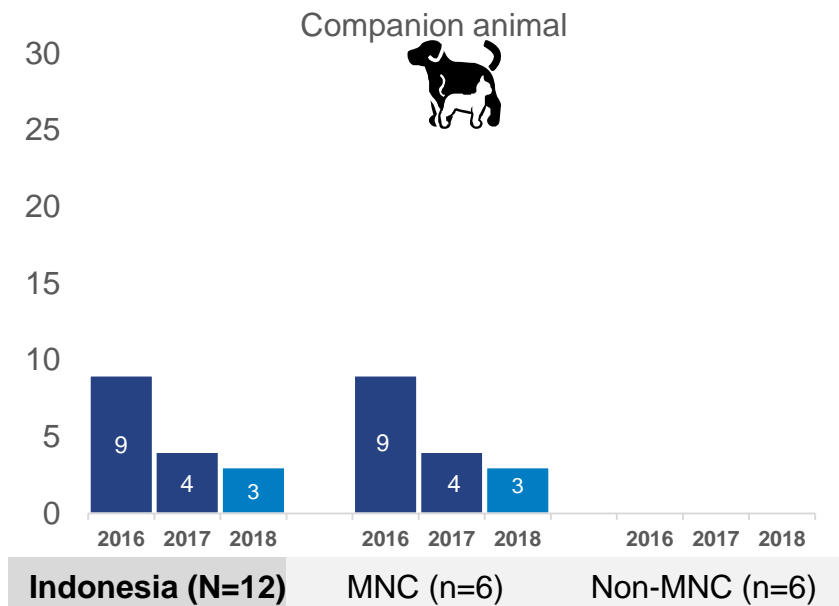
A2a: Thinking about regulatory approval of a major variation of AH products for your country/ASEAN, can you tell me how many products did your company register in 2016, 2017 and 2018?

INDONESIA: Minor Variation Animal Health Product Registration for each therapeutic area by species in 2016 – 2018



Indonesia

Data shows no. of products registered in each year by different therapeutic areas and species



A2b: Thinking about regulatory approval of a minor variation of AH products for your country/ASEAN, can you tell me how many products did your company in 2016, 2017 and 2018?

INDONESIA: Renewal Animal Health Product Registration for each therapeutic area by species in 2016 – 2018

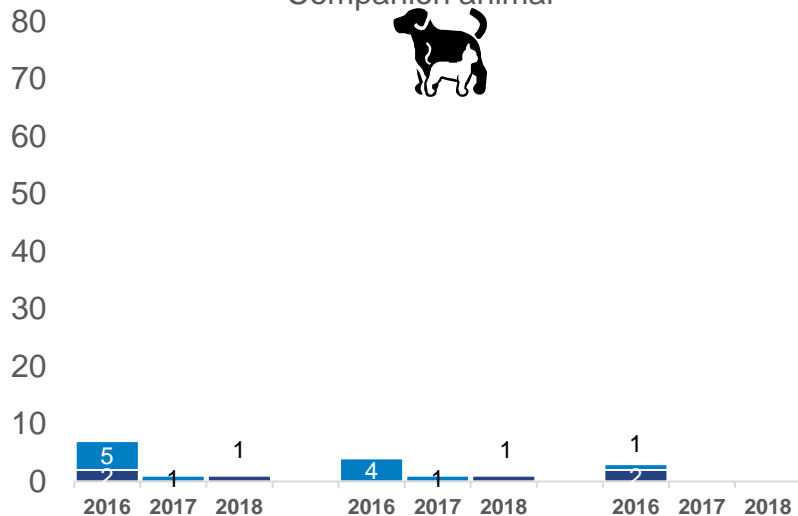


Indonesia

Data shows no. of products registered in each year by different therapeutic areas and species

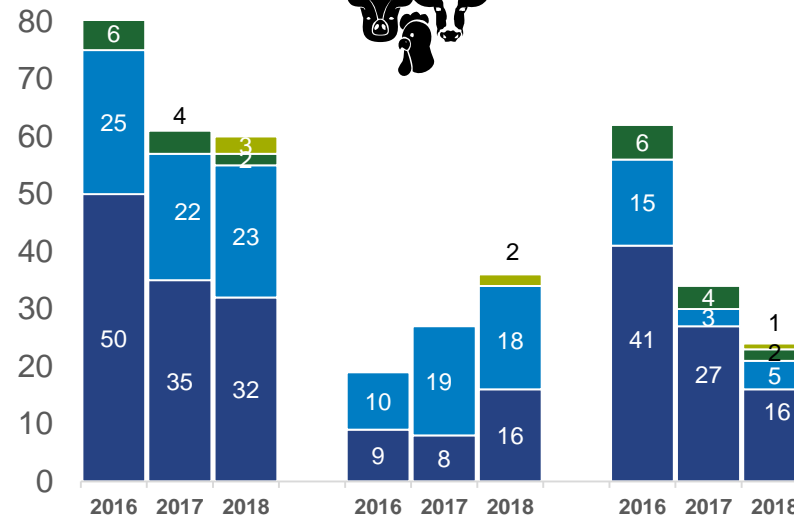


Companion animal



Indonesia (N=12) MNC (n=6) Non-MNC (n=6)

Production animal



Indonesia (N=12) MNC (n=6) Non-MNC (n=6)

A3: Thinking about approval of [AH products re-registration](#) for your country/ASEAN, can you tell me how many products did your company register in 2016, 2017 and 2018?

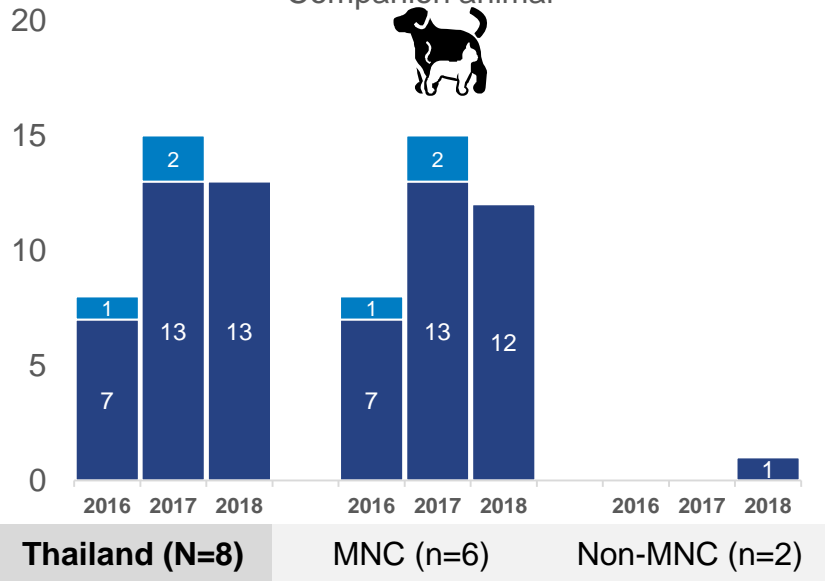
THAILAND: New Animal Health Product Registration for each therapeutic area by species in 2016 – 2018

Data shows no. of products registered in each year by different therapeutic areas and species

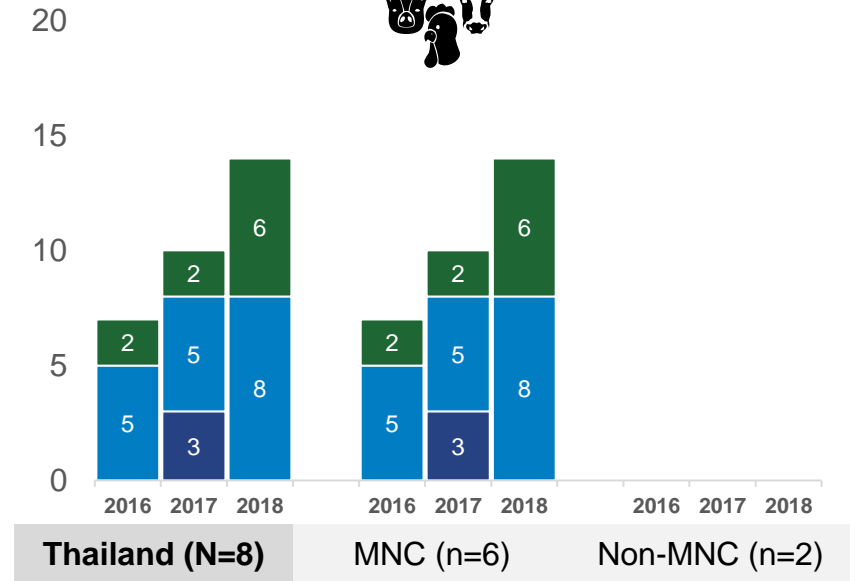


Pharmaceuticals
 Biologicals
 In-feed medications
 Pesticides

Companion animal



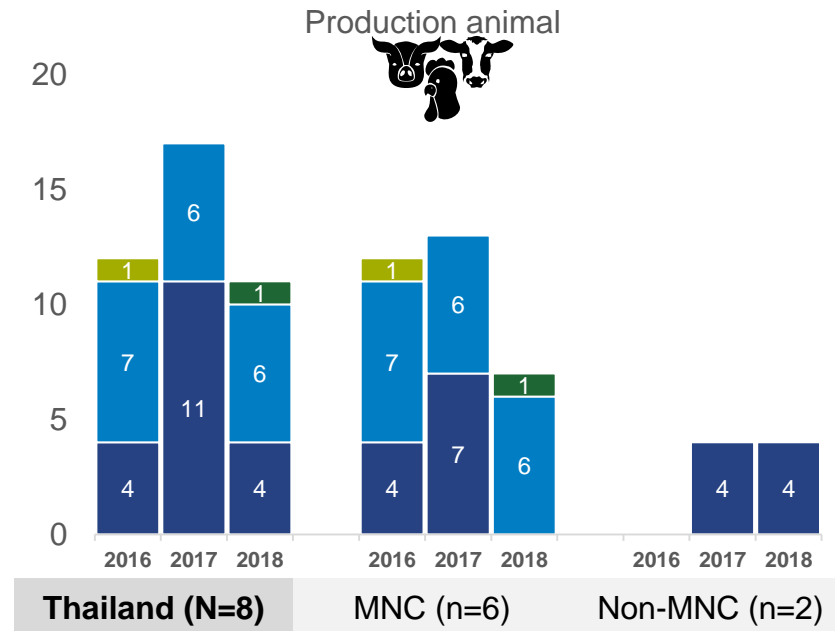
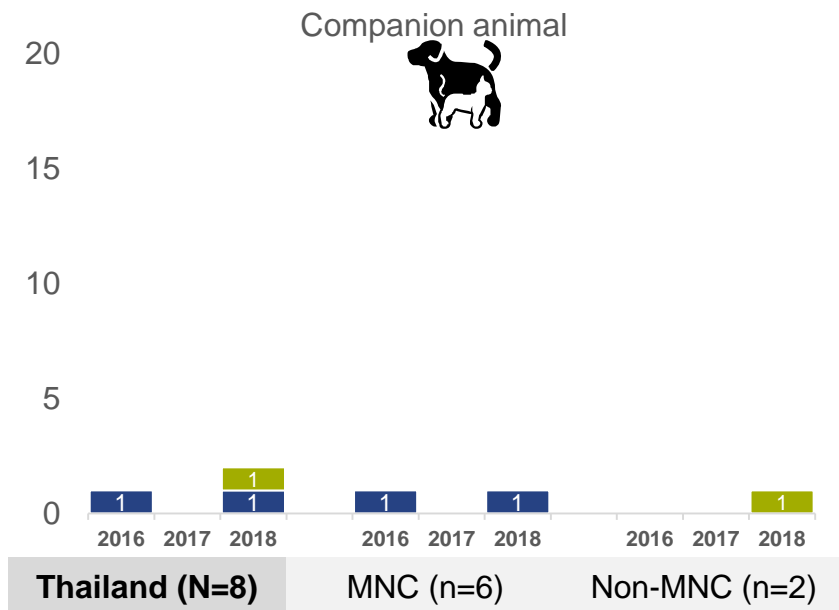
Production animal



A1a: Thinking about registration of new AH products for your country/ASEAN, can you tell me how many products did your company register in 2016, 2017 and 2018?

THAILAND: Generic Animal Health Product Registration for each therapeutic area by species in 2016 – 2018

Data shows no. of products registered in each year by different therapeutic areas and species



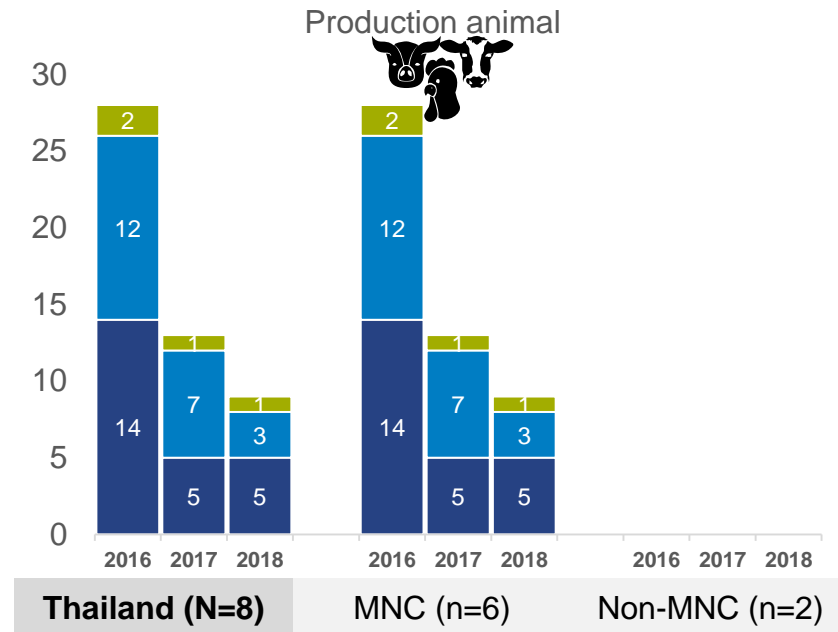
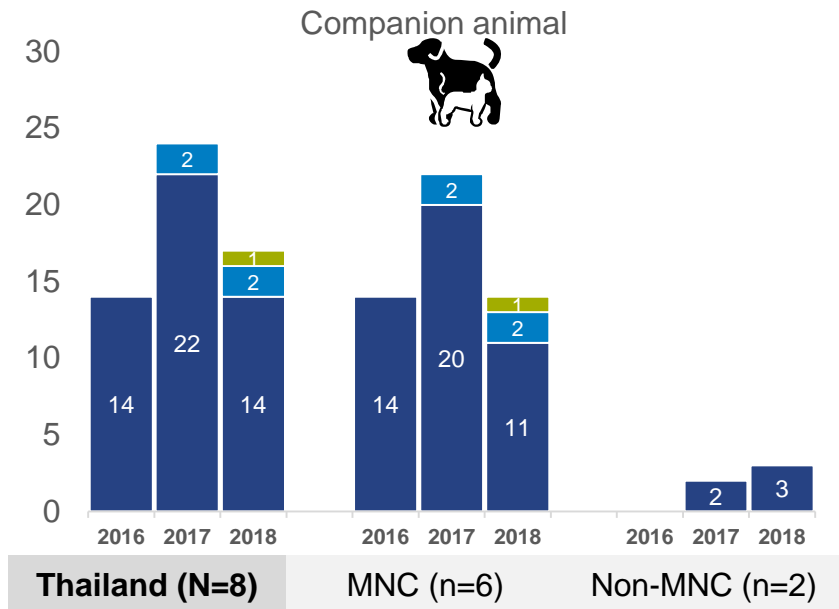
A1b: Thinking about registration of generic AH products for your country/ASEAN, can you tell me how many products did your company register in 2016, 2017 and 2018?

THAILAND: Major Variation Product Registration for each therapeutic area by species in 2016 – 2018

Data shows no. of products registered in each year by different therapeutic areas and species



■ Pharmaceuticals
 ■ Biologicals
 ■ In-feed medications
 ■ Pesticides



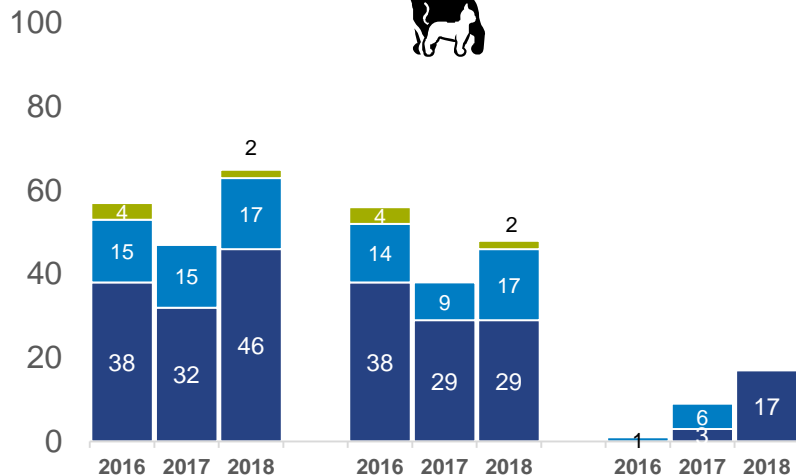
THAILAND: Minor Variation Product Registration for each therapeutic area by species in 2016 – 2018

Data shows no. of products registered in each year by different therapeutic areas and species



■ Pharmaceuticals
 ■ Biologicals
 ■ In-feed medications
 ■ Pesticides

Companion animal

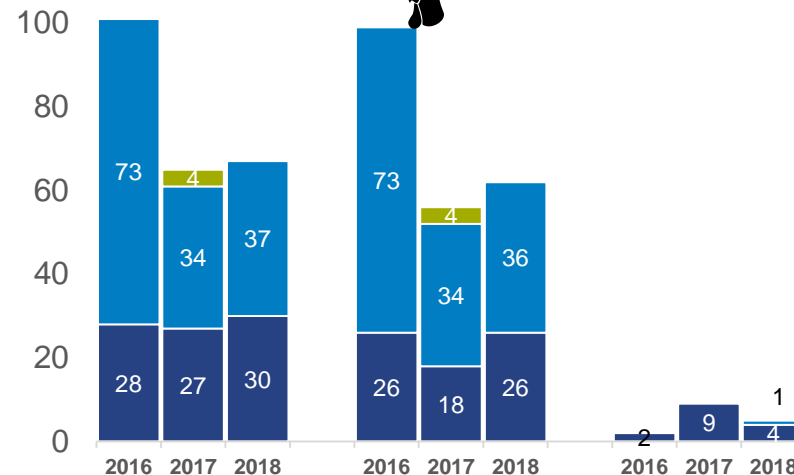


Thailand (N=8)

MNC (n=6)

Non-MNC (n=2)

Production animal



Thailand (N=8)

MNC (n=6)

Non-MNC (n=2)

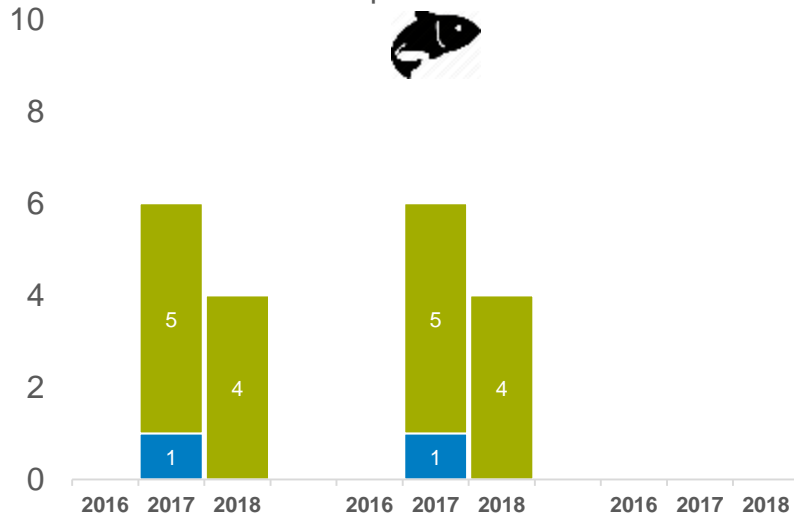
A2b: Thinking about regulatory approval of a minor variation of AH products for your country/ASEAN, can you tell me how many products did your company in 2016, 2017 and 2018?

THAILAND: Minor Variation Product Registration for each therapeutic area by species in 2016 – 2018

Data shows no. of products registered in each year by different therapeutic areas and species



Aqua & others



For species – Aqua and others, only 1 non MNC company has renewal of product registration in 2018. No product was recorded in previous years

Thailand (N=8)

MNC (n=6)

Non-MNC (n=2)

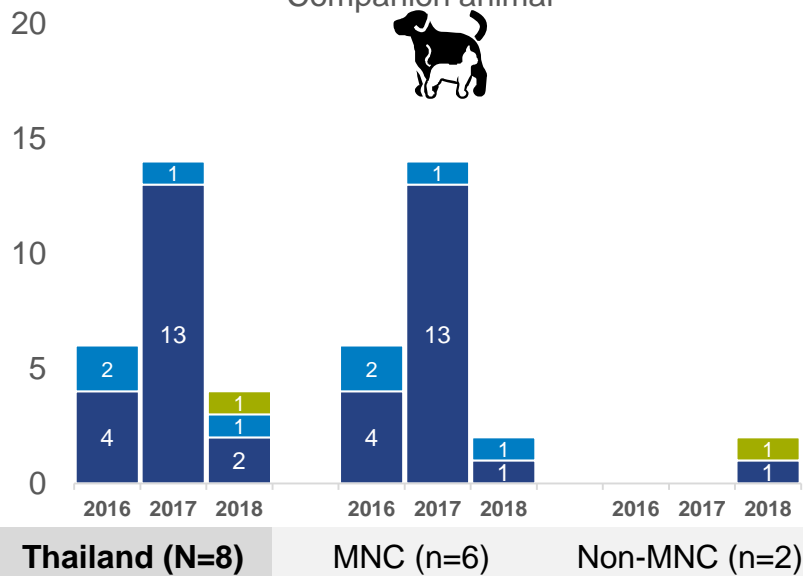
THAILAND: Renewal Product Registration for each therapeutic area by species in 2016 – 2018

Data shows no. of products registered in each year by different therapeutic areas and species

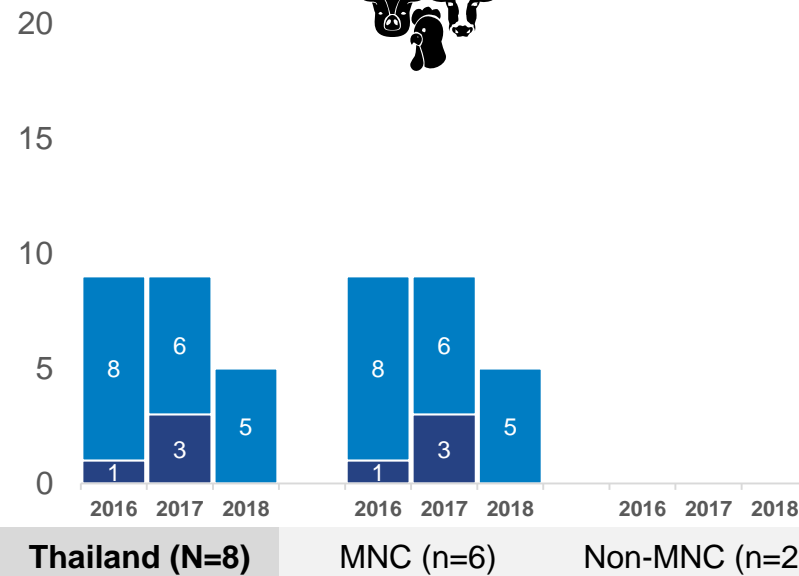


Pharmaceuticals Biologicals In-feed medications Pesticides

Companion animal



Production animal



A3: Thinking about approval of [AH products re-registration](#) for your country/ASEAN, can you tell me how many products did your company register in 2016, 2017 and 2018?



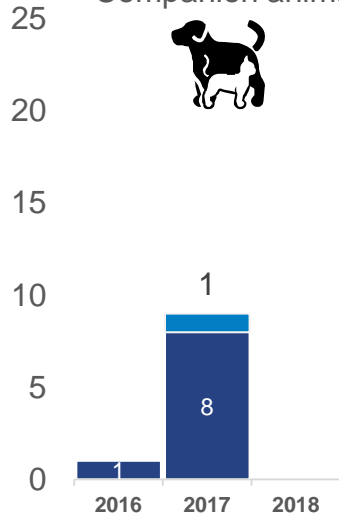
VIETNAM: New & Generic Animal Health Product Registration for each therapeutic area by species in 2016 – 2018

Data shows no. of products registered in each year by different therapeutic areas and species



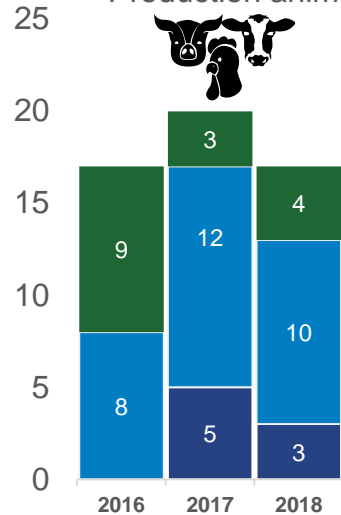
New Animal Health Product Registration

Companion animal



Vietnam (N=6)

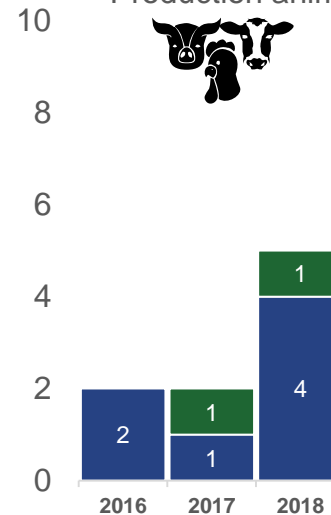
Production animal



Vietnam (N=6)

Generic Animal Health Product Registration

Production animal



Vietnam (N=6)

A1a: Thinking about registration of new AH products for your country/ASEAN, can you tell me how many products did your company register in 2016, 2017 and 2018?

A2b: Thinking about registration of generic AH products for your country/ASEAN, can you tell me how many products did your company register in 2016, 2017 and 2018?

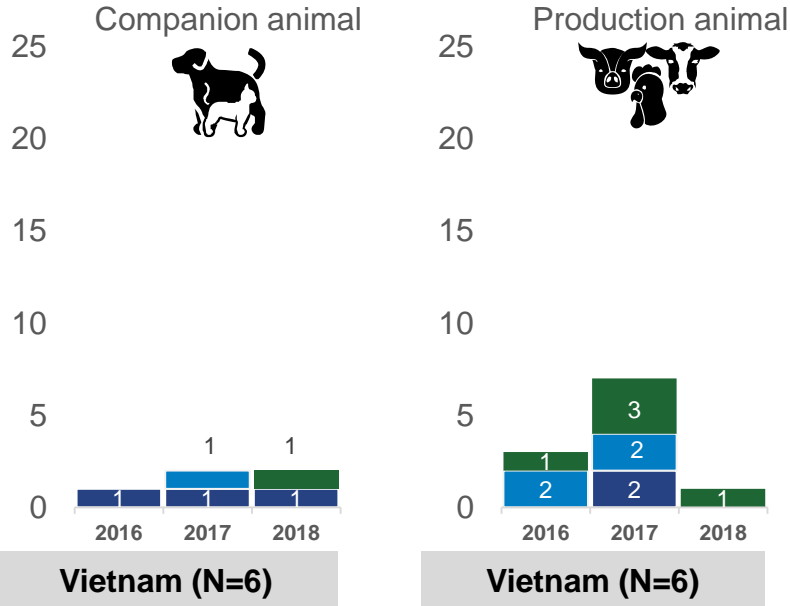


VIETNAM: Major & Minor Animal Health Product Registration for each therapeutic area by species in 2016 – 2018

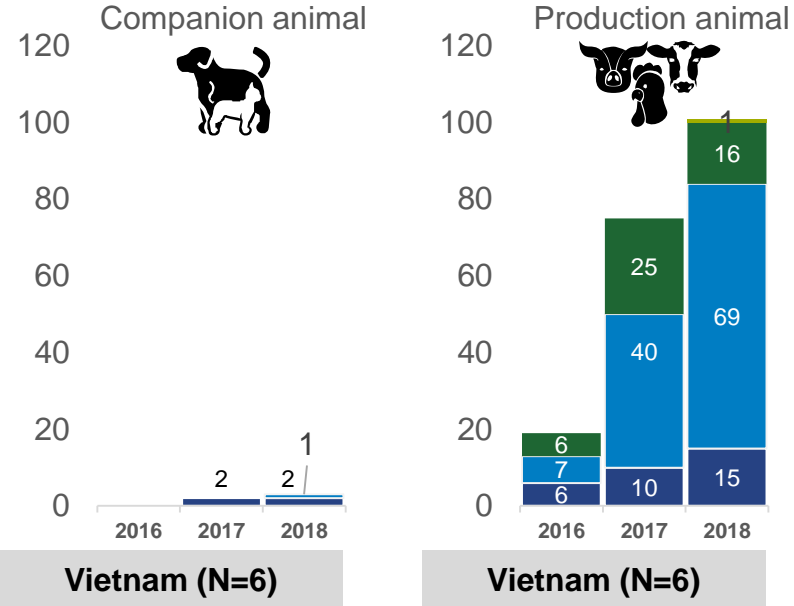
Data shows no. of products registered in each year by different therapeutic areas and species



Major Variation Animal Health Product Registration



Minor Variation Animal Health Product Registration



A2a: Thinking about regulatory approval of [a major variation of AH products](#) for your country/ASEAN, can you tell me how many products did your company register in 2016, 2017 and 2018?
A2b: Thinking about regulatory approval of [a minor variation of AH products](#) for your country/ASEAN, can you tell me how many products did your company in 2016, 2017 and 2018?

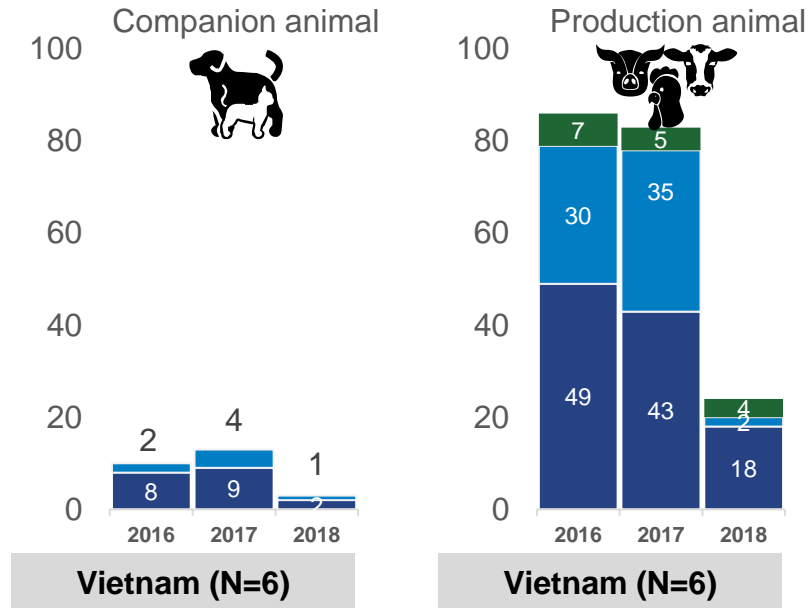


VIETNAM: Renewal Animal Health Product Registration for each therapeutic area by species in 2016 – 2018

Data shows no. of products registered in each year by different therapeutic areas and species



Renewal Animal Health Product Registration



A3: Thinking about approval of [AH products re-registration](#) for your country/ASEAN, can you tell me how many products did your company register in 2016, 2017 and 2018?

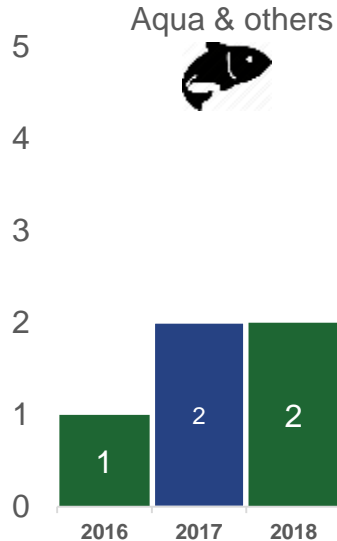


VIETNAM: New, Minor & Renewal Animal Health Product Registration for each therapeutic area by species in 2016 – 2018

Data shows no. of products registered in each year by different therapeutic areas and species

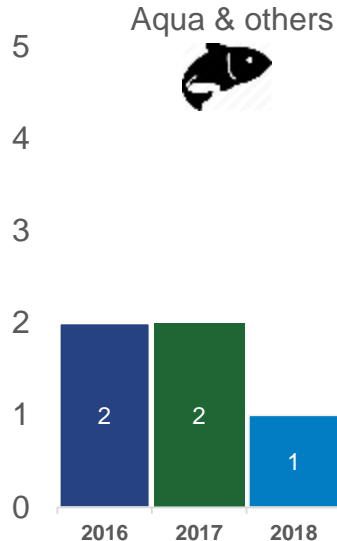
■ Pharmaceuticals
 ■ Biologicals
 ■ In-feed medications
 ■ Pesticides

New Animal Health Product Registration



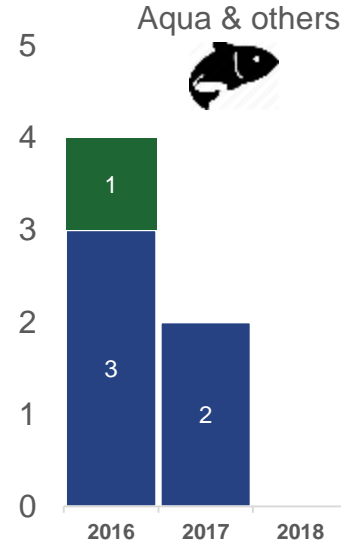
Vietnam (N=6)

Minor Variation Animal Health Product Registration



Vietnam (N=6)

Renewal Animal Health Product Registration



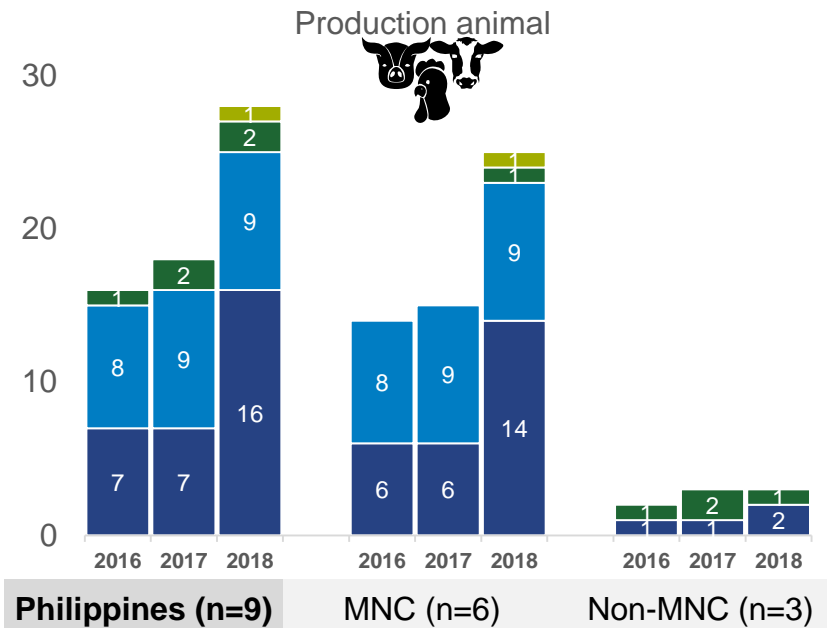
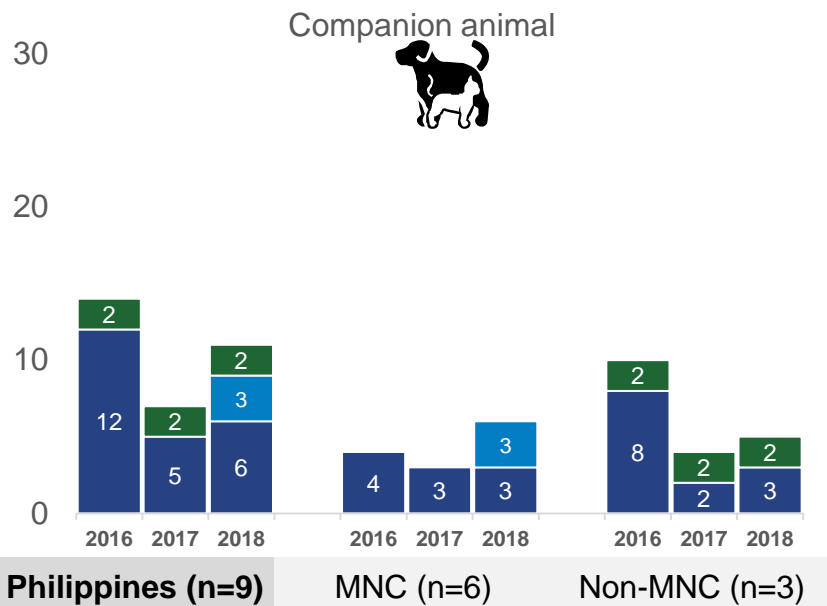
Vietnam (N=6)

A1a/A2b/A3: Thinking about registration of new AH products/ a minor variation/ renewal for your country/ASEAN, can you tell me how many products did your company register in 2016, 2017 and 2018?

PHILIPPINES: New Animal Health Product Registration for each therapeutic area by species in 2016 – 2018



Data shows no. of products registered in each year by different therapeutic areas and species



For species – Aqua and others, only 1 MNC company registered 1 product in 2018. No product was registered in previous years

A1a: Thinking about registration of new AH products for your country/ASEAN, can you tell me how many products did your company register in 2016, 2017 and 2018?

PHILIPPINES: Generics Product Registration for each therapeutic area by species in 2016 – 2018

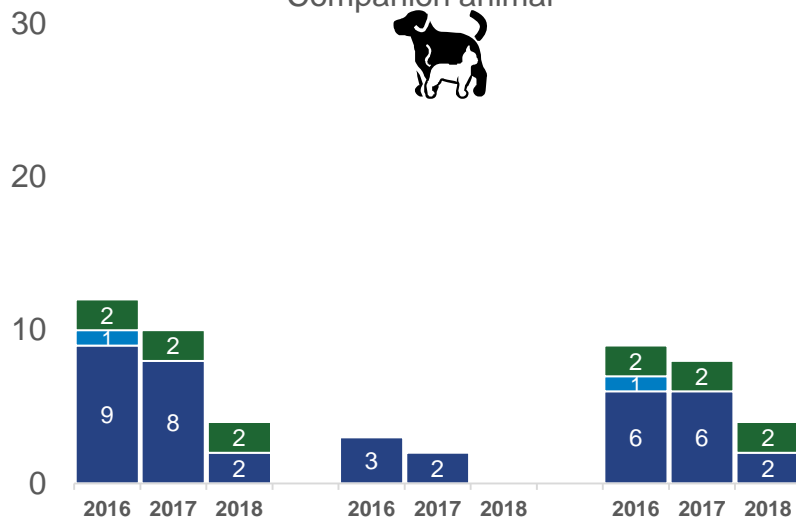
Data shows no. of products registered in each year by different therapeutic areas and species



Philippines



Companion animal

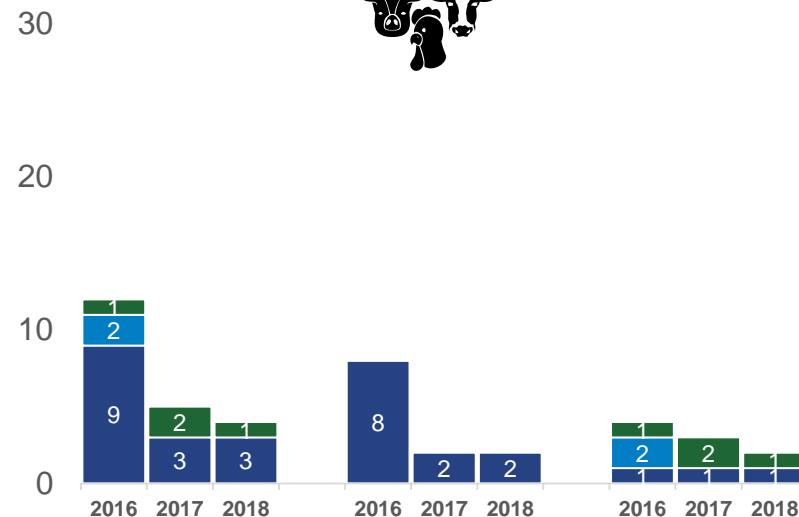


Philippines (n=9)

MNC (n=6)

Non-MNC (n=3)

Production animal



Philippines (n=9)

MNC (n=6)

Non-MNC (n=3)

For species – Aqua and others, only 1 MNC company registered 1 product in 2018. No product was registered in previous years

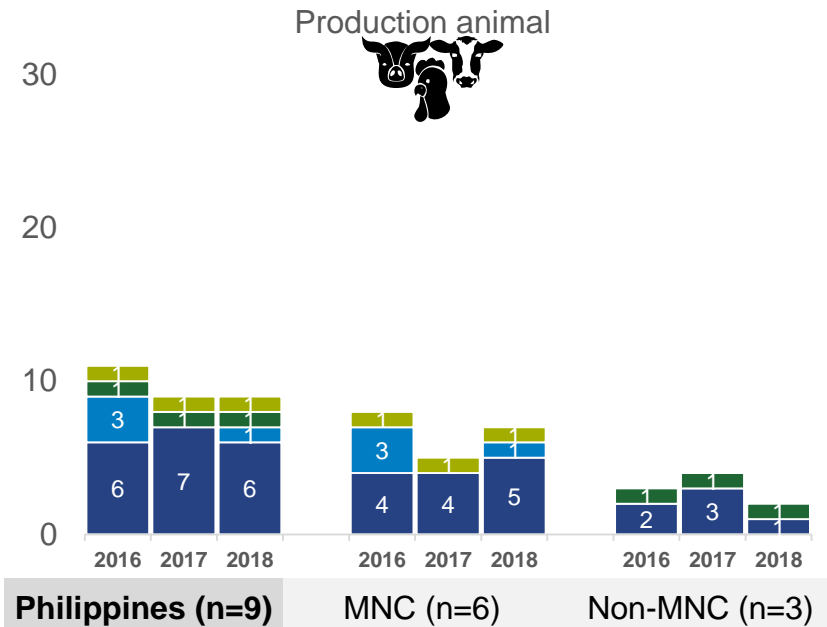
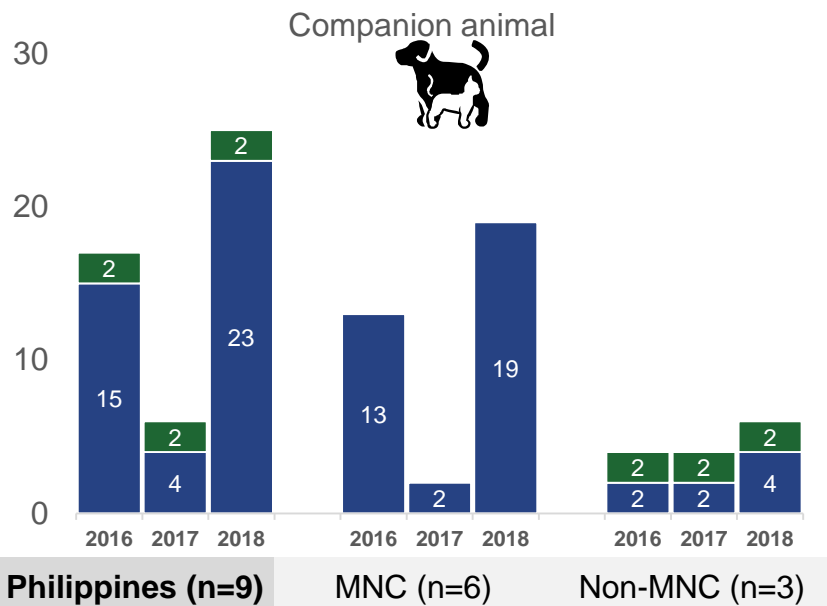
A1b: Thinking about registration of generic AH products for your country/ASEAN, can you tell me how many products did your company register in 2016, 2017 and 2018?

PHILIPPINES: Major Variation Product Registration for each therapeutic area by species in 2016 – 2018

Data shows no. of products registered in each year by different therapeutic areas and species



Philippines



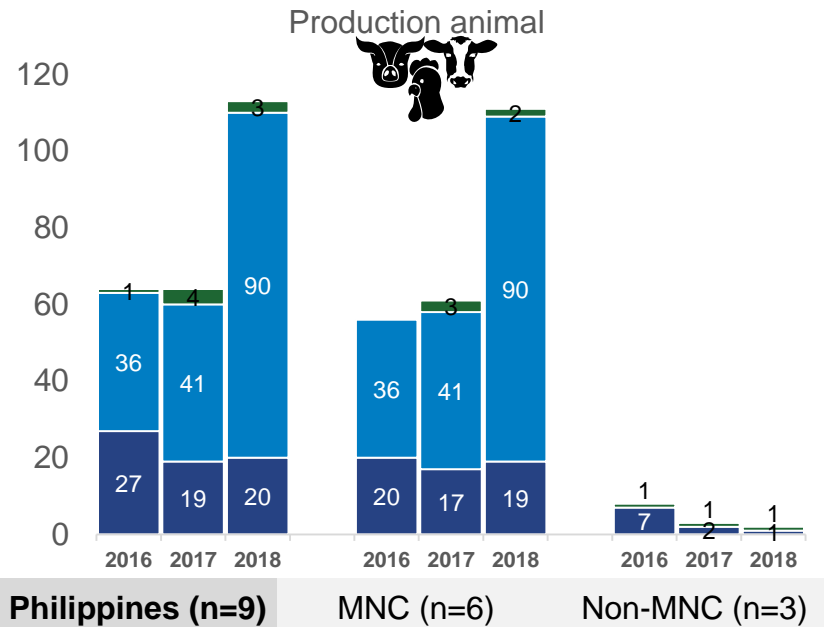
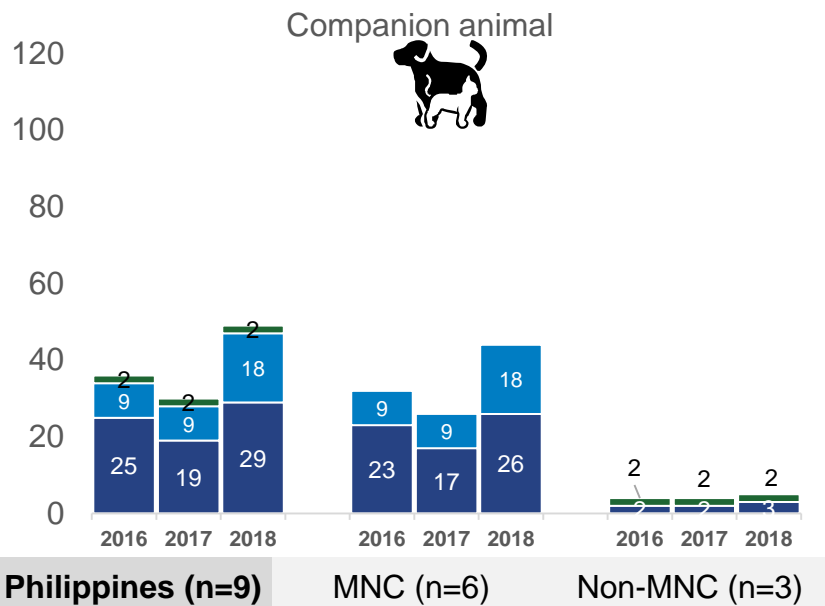
For species – Aqua and others, only 1 MNC company registered 1 product in 2018. No product was registered in previous years

A2a: Thinking about registration of a major variation of AH products for your country/ASEAN, can you tell me how many products did your company register in 2016, 2017 and 2018?

PHILIPPINES: Minor Variation Product Registration for each therapeutic area by species in 2016 – 2018



Data shows no. of products registered in each year by different therapeutic areas and species



For species – Aqua and others, only 1 MNC company registered 1 product in 2018. No product was registered in previous years

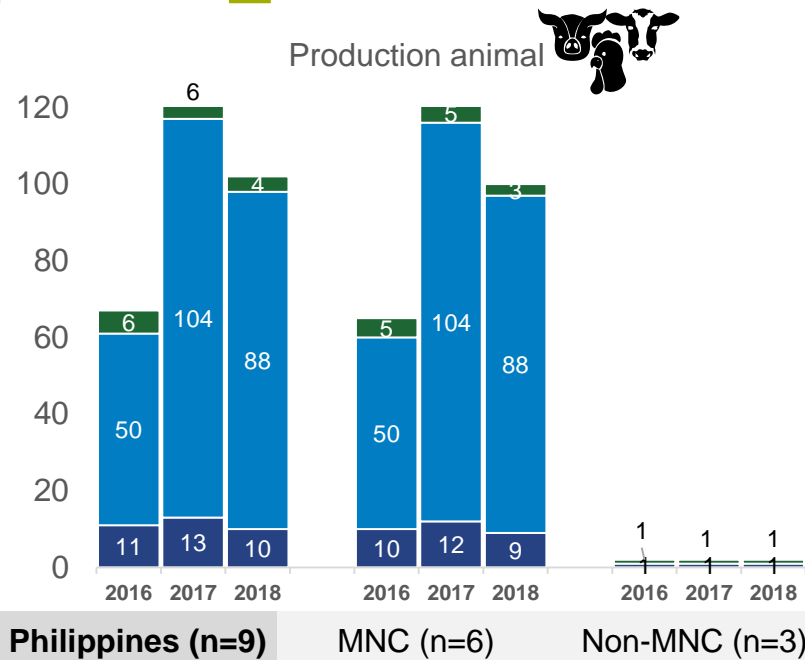
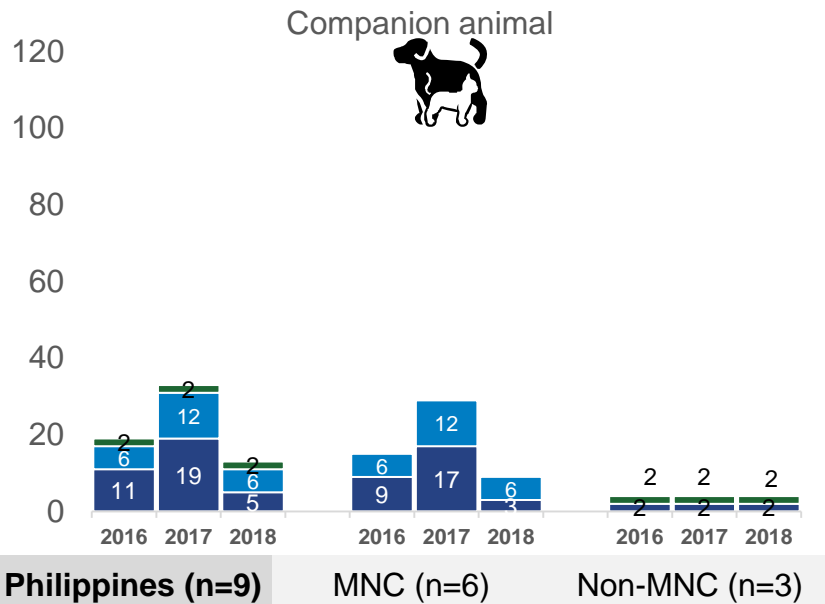
A2b: Thinking about registration of a minor variation of AH products for your country/ASEAN, can you tell me how many products did your company register in 2016, 2017 and 2018?

PHILIPPINES: Renewal Product Registration for each therapeutic area by species in 2016 – 2018

Data shows no. of products registered in each year by different therapeutic areas and species



Philippines



For species – Aqua and others, only 1 MNC company registered 1 product in 2018. No product was registered in previous years

A3: Thinking about approval of [AH products re-registration](#) for your country/ASEAN, can you tell me how many products did your company register in 2016, 2017 and 2018?

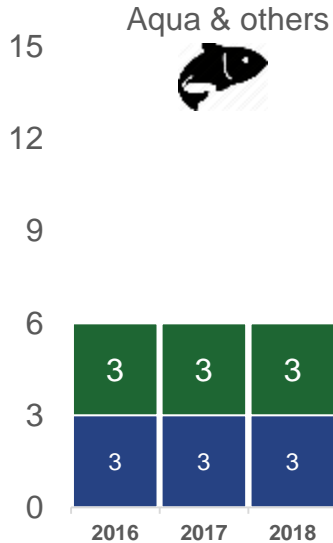
PHILIPPINES: New, Generic and Major Variation Product Registration for each therapeutic area by species in 2016 – 2018



Data showed no. of products registered in each year by different therapeutic areas and species

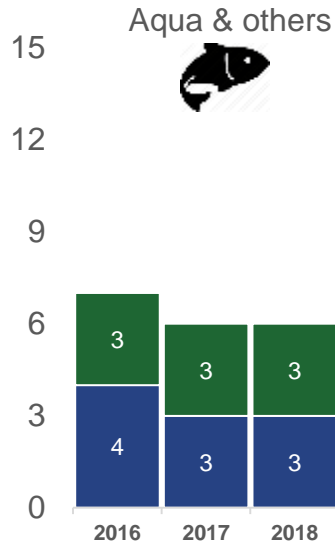


New Animal Health Product Registration



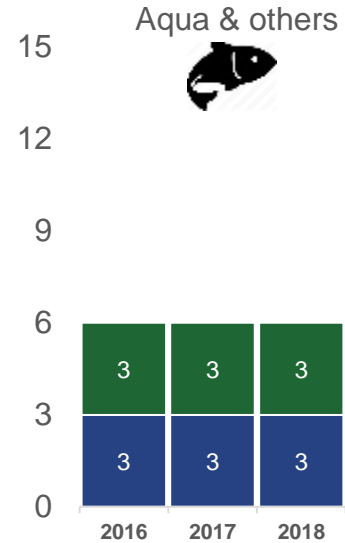
Philippines: Non-MNC (n=3)

Generic Animal Health Product Registration



Philippines: Non-MNC (n=3)

Major Variation Animal Health Product Registration



Philippines: Non-MNC (n=3)

A1a/b/A2a: Thinking about registration of new AH products/ major/minor variation for your country/ASEAN, can you tell me how many products did your company register in 2016, 2017 and 2018?

PHILIPPINES: Minor Variation & Renewal of Product Registration for each therapeutic area by species in 2016 – 2018



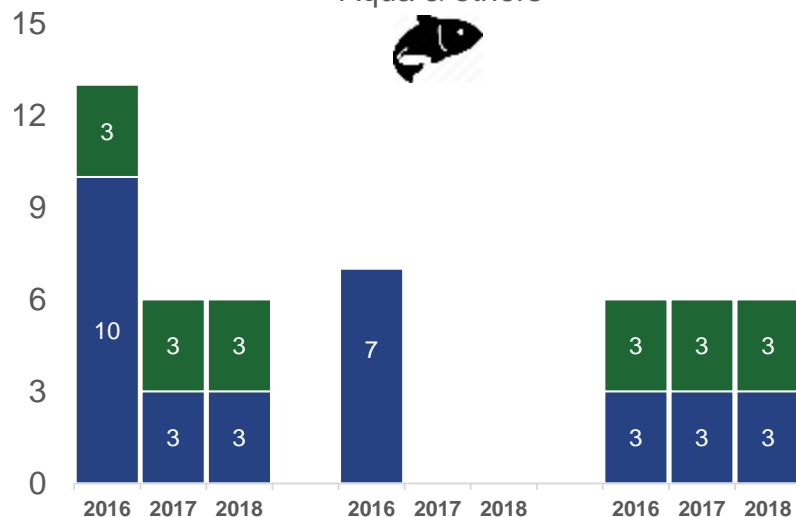
Philippines

Data showed no. of products registered in each year by different therapeutic areas and species



Minor Variation Animal Health Product Registration

Aqua & others



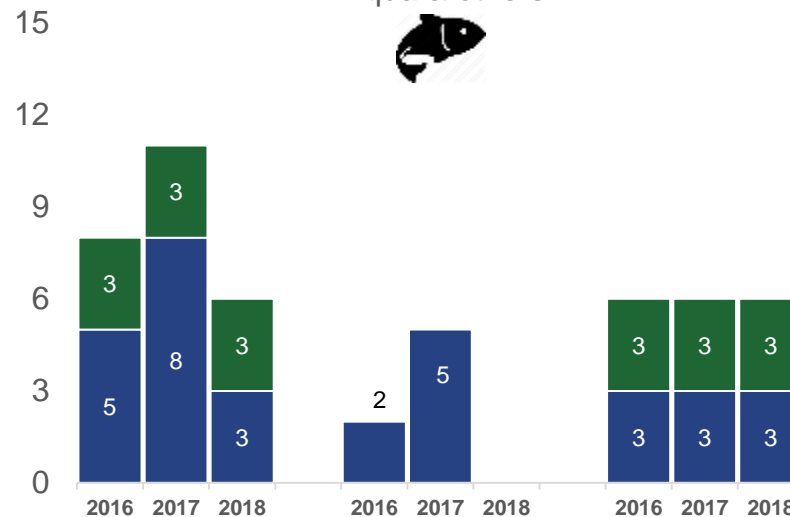
Philippines (n=9)

MNC (n=6)

Non-MNC (n=3)

Renewal Animal Health Product Registration

Aqua & others



Philippines (n=9)

MNC (n=6)

Non-MNC (n=3)

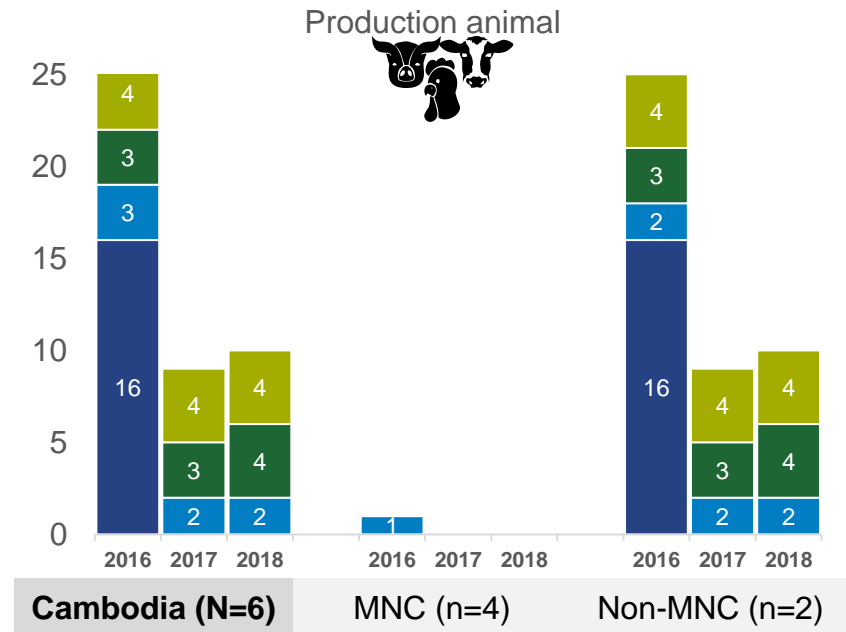
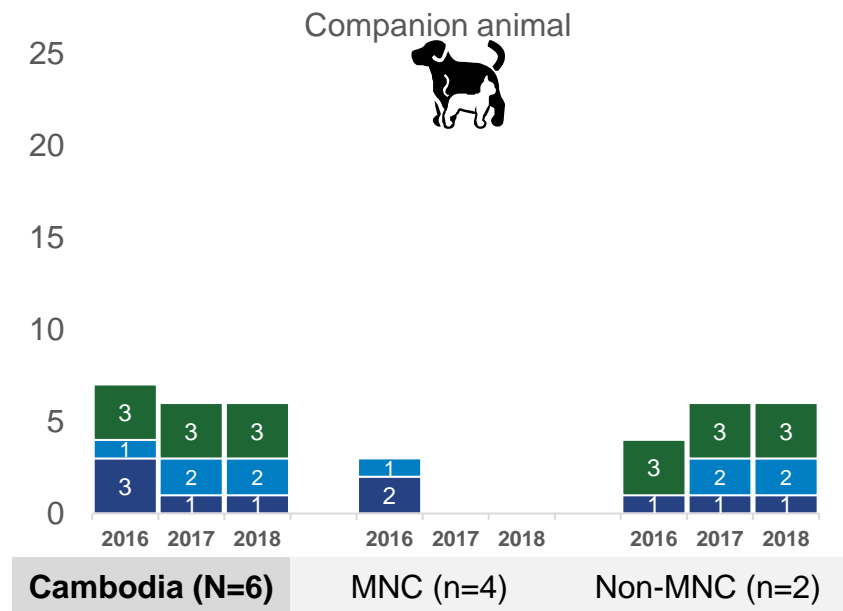
A2b/A3: Thinking about regulatory approval of a minor variation/ re-registration of AH products for your country/ASEAN, can you tell me how many products did your company in 2016, 2017 and 2018?

CAMBODIA: New Animal Health Product Registration for each therapeutic area by species in 2016 – 2018



Cambodia

Data showed no. of products registered in each year by different therapeutic areas and species

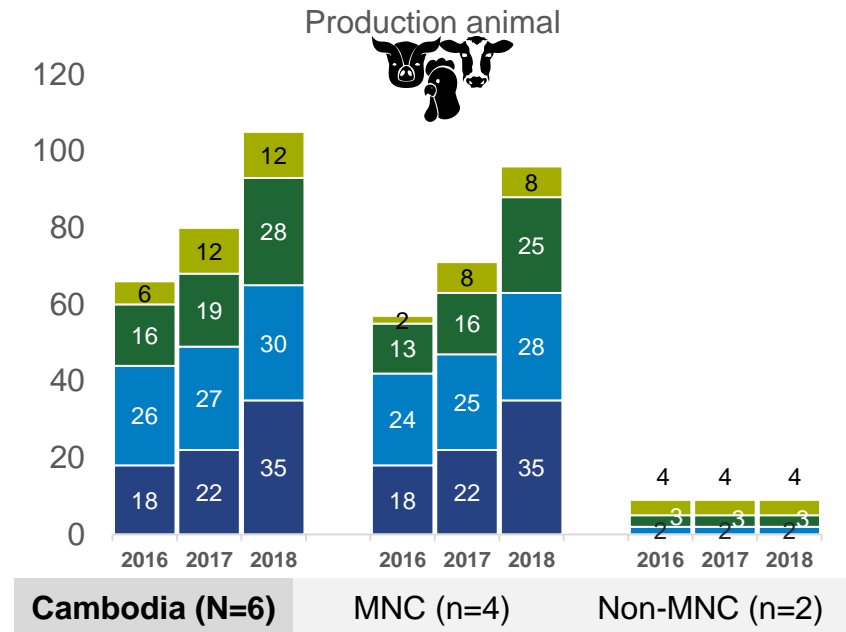
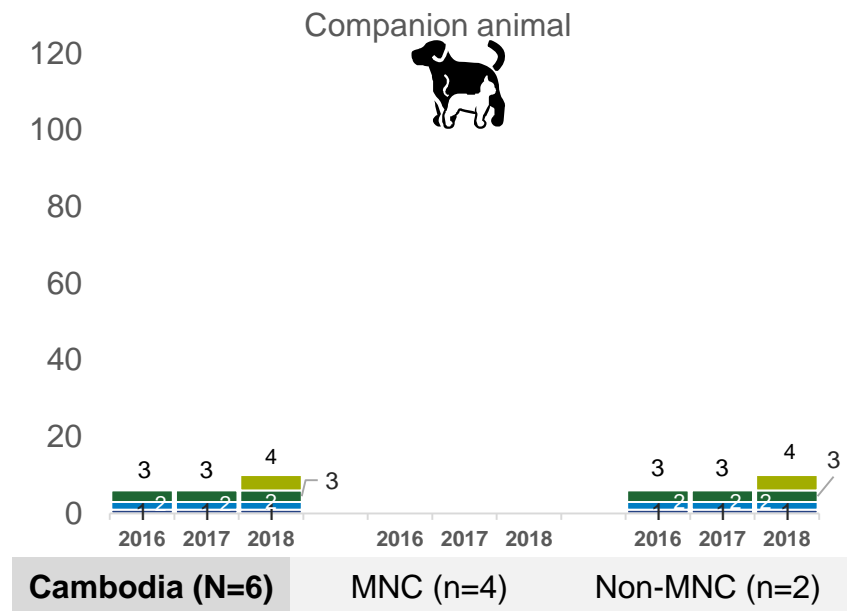


A1a: Thinking about registration of new AH products for your country/ASEAN, can you tell me how many products did your company register in 2016, 2017 and 2018?

CAMBODIA: Generics Product Registration for each therapeutic area by species in 2016 – 2018



Data showed no. of products registered in each year by different therapeutic areas and species



A1b: Thinking about registration of generic AH products for your country/ASEAN, can you tell me how many products did your company register in 2016, 2017 and 2018?

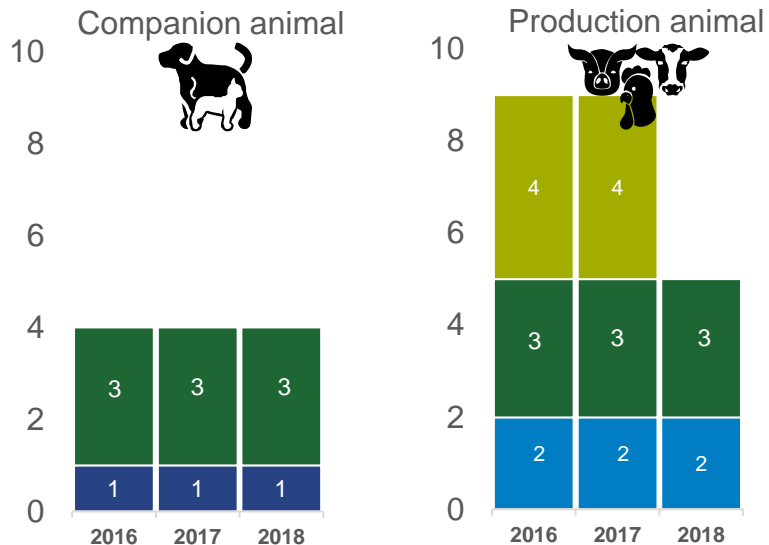
CAMBODIA: Major & Minor Variation Product Registration for each therapeutic area by species in 2016 – 2018



Data showed no. of products registered in each year by different therapeutic areas and species



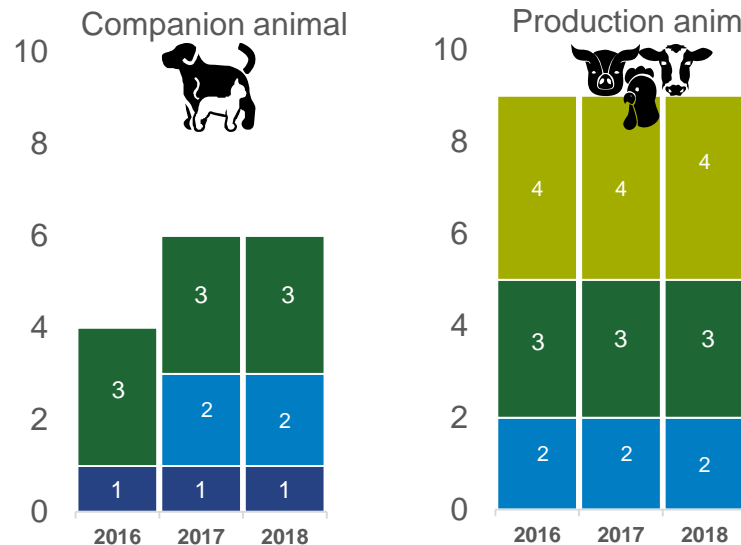
Major Variation Animal Health Product Registration



**Cambodia:
Non-MNC (n=2)**

**Cambodia:
Non-MNC (n=2)**

Minor Variation Animal Health Product Registration



**Cambodia:
Non-MNC (n=2)**

**Cambodia:
Non-MNC (n=2)**

A2a: Thinking about regulatory approval of a major variation of AH products for your country/ASEAN, can you tell me how many products did your company register in 2016, 2017 and 2018?

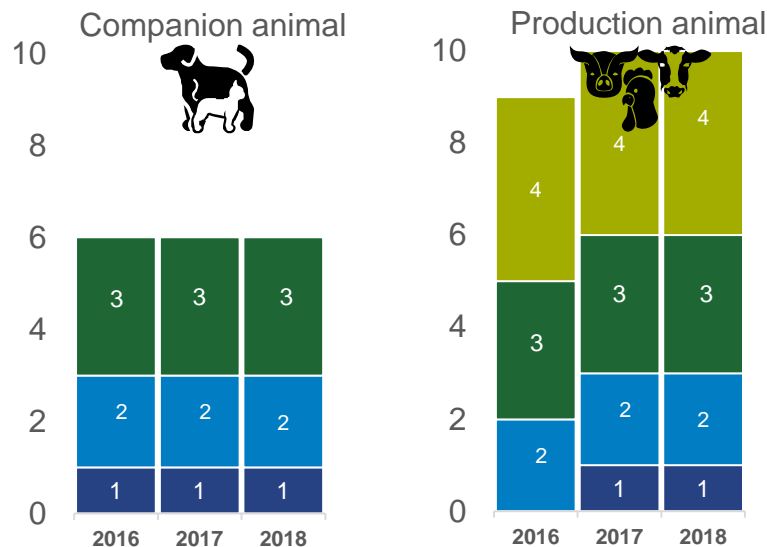
CAMBODIA: Renewal Product Registration for each therapeutic area by species in 2016 – 2018



Data showed no. of products registered in each year by different therapeutic areas and species



Renewal Animal Health Product Registration



**Cambodia:
Non-MNC (n=2)**

**Cambodia:
Non-MNC (n=2)**

A3: Thinking about approval of AH products re-registration for your country/ASEAN, can you tell me how many products did your company register in 2016, 2017 and 2018?

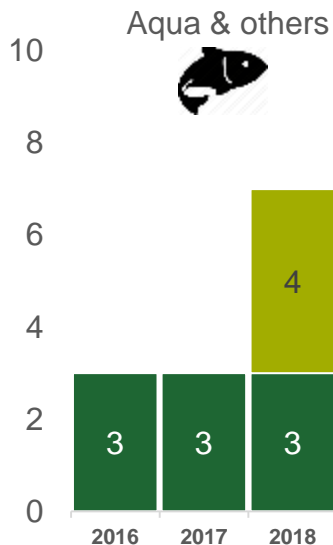
CAMBODIA: New, Generic and Major Variation Product Registration for each therapeutic area by species in 2016 – 2018



Data showed no. of products registered in each year by different therapeutic areas and species

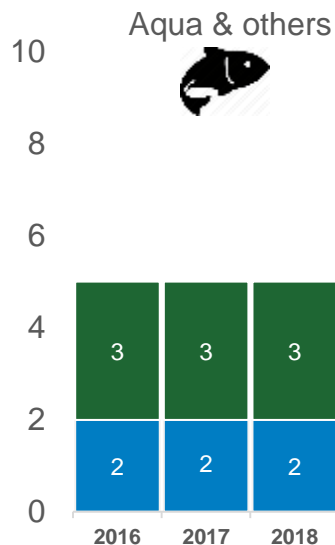


New Animal Health Product Registration



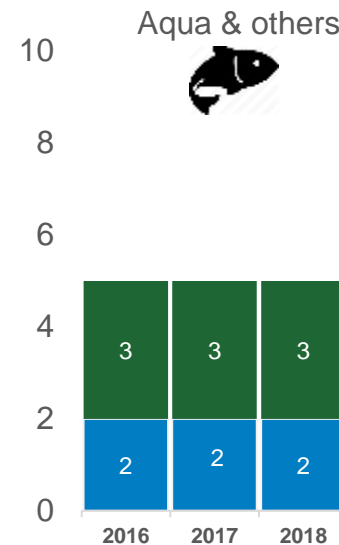
**Cambodia:
Non-MNC (n=2)**

Generic Animal Health Product Registration



**Cambodia:
Non-MNC (n=2)**

Major Variation Animal Health Product Registration



**Cambodia:
Non-MNC (n=2)**

A1a: Thinking about registration of new AH products for your country/ASEAN, can you tell me how many products did your company register in 2016, 2017 and 2018?

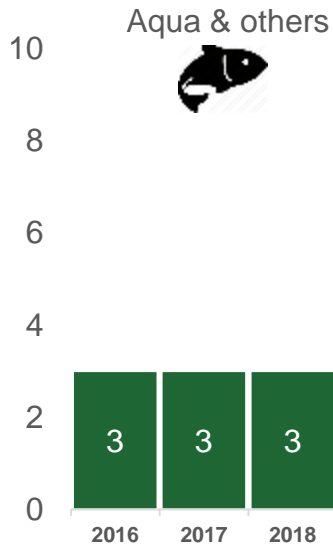
CAMBODIA: Minor Variation & Renewal Product Registration for each therapeutic area by species in 2016 – 2018



Data showed no. of products registered in each year by different therapeutic areas and species

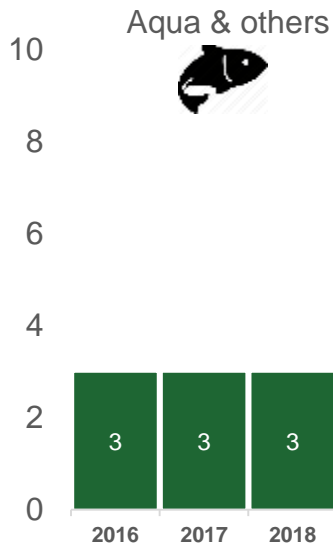


Minor Variation Animal Health Product Registration



**Cambodia:
Non-MNC (n=2)**

Renewal Animal Health Product Registration



**Cambodia:
Non-MNC (n=2)**

A2b: Thinking about regulatory approval of a minor variation of AH products for your country/ASEAN, can you tell me how many products did your company in 2016, 2017 and 2018?

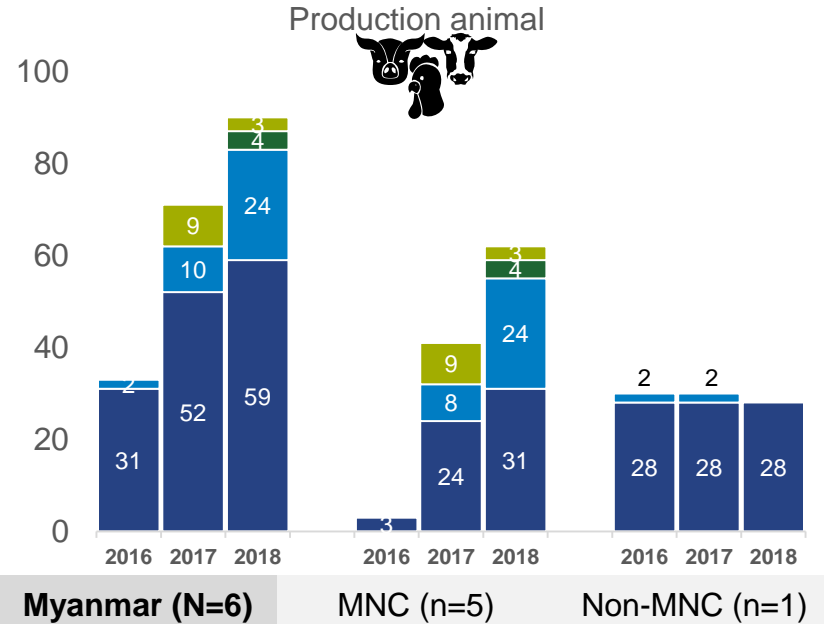
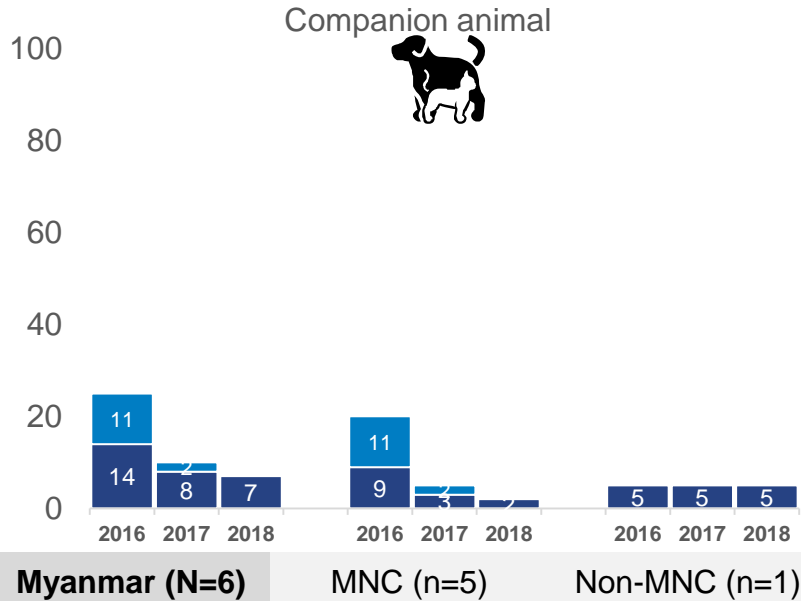
Myanmar does not require product registration

MYANMAR: New Animal Health Import License for each therapeutic area by species in 2016 – 2018

Data showed no. of products registered in each year by different therapeutic areas and species



Myanmar



For **species – Aqua and others**, only 1 MNC company registered 1 product in 2018. No product was registered in previous years

We have excluded major and minor variation as we understood all variations will be treated as a new registration

A1a: Thinking about registration of new AH products for your country/ASEAN, can you tell me how many products did your company register in 2016, 2017 and 2018?

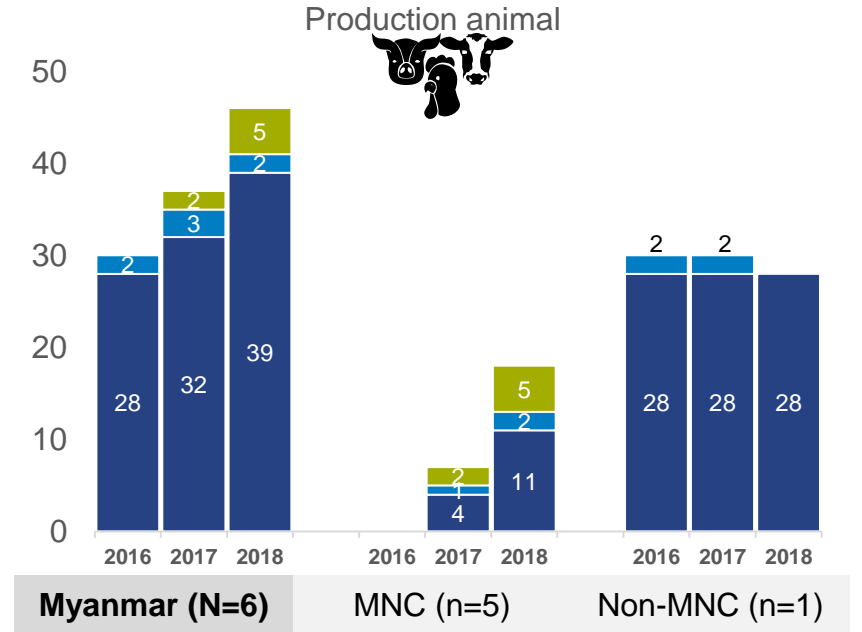
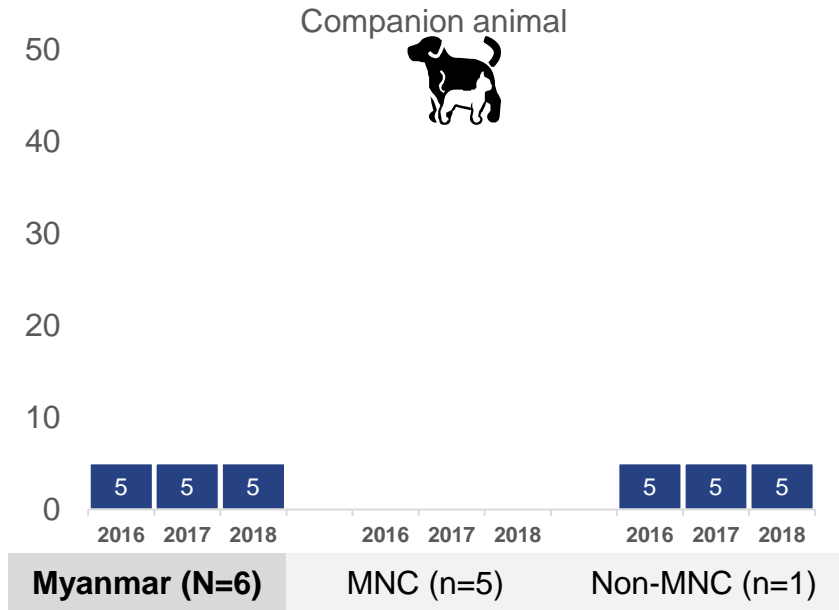
Myanmar does not require product registration

MYANMAR: Generics Import License for each therapeutic area by species in 2016 – 2018



Myanmar

Data showed no. of products registered in each year by different therapeutic areas and species



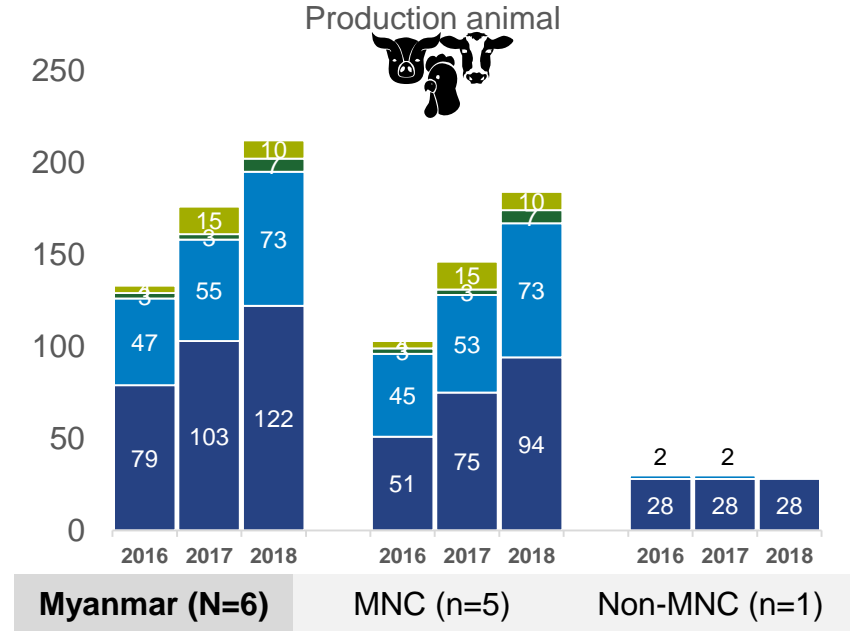
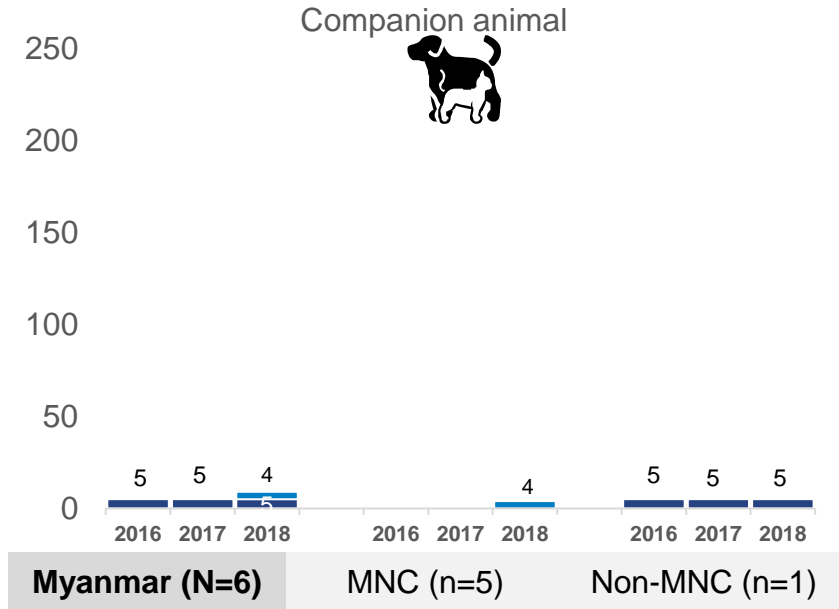
For species – Aqua and others, only 1 MNC company registered 1 product in 2018. No product was registered in previous years

A1b: Thinking about registration of generic AH products for your country/ASEAN, can you tell me how many products did your company register in 2016, 2017 and 2018?

Myanmar does not require product registration

MYANMAR: **Renewal of Import License** for each therapeutic area by species in 2016 – 2018

Data showed no. of products registered in each year by different therapeutic areas and species



A3: Thinking about approval of [AH products re-registration](#) for your country/ASEAN, can you tell me how many products did your company register in 2016, 2017 and 2018?