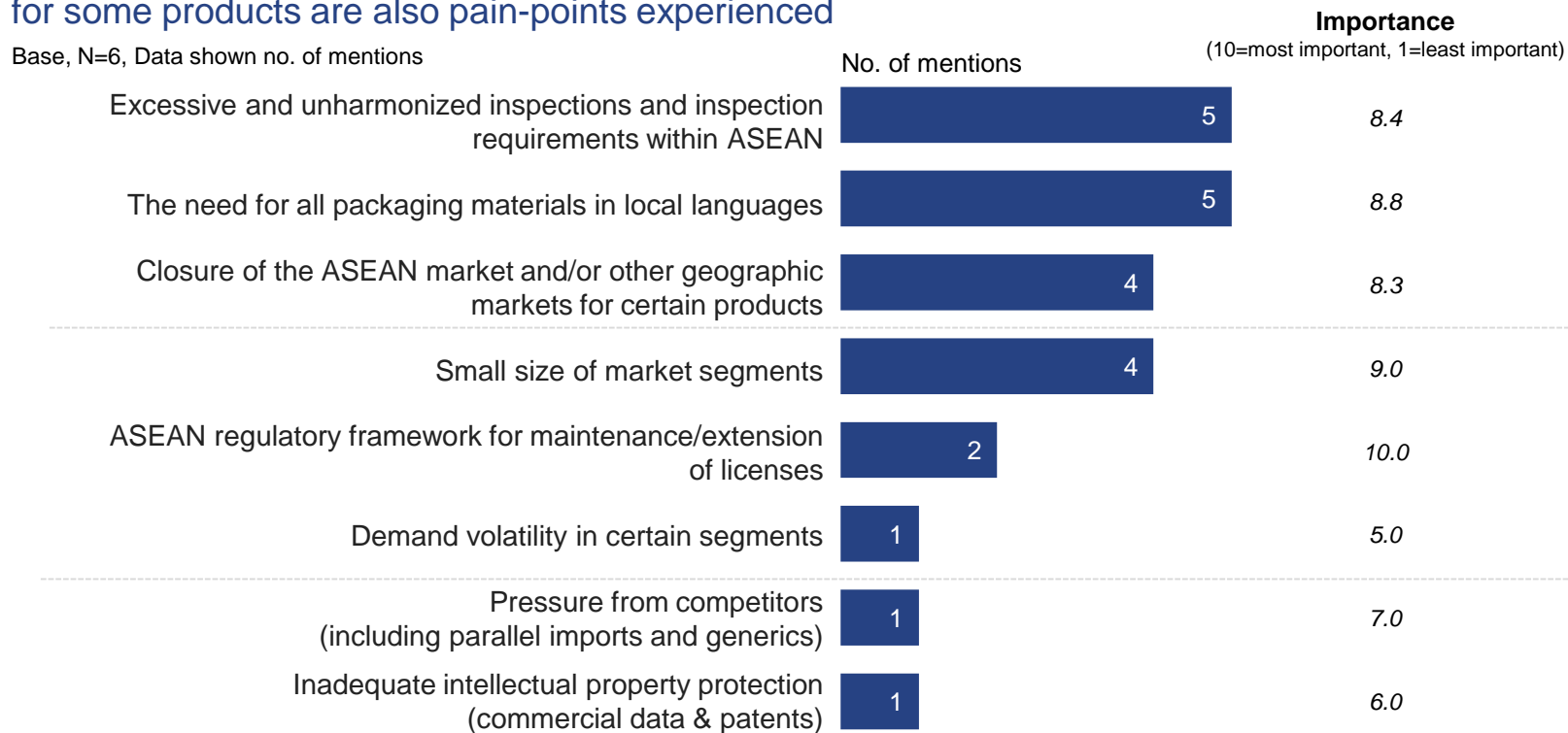




## Maintenance of registration of existing products – challenges faced

REGIONAL: Factors preventing maintenance of registration of existing AH products

Concerns with inspections (excessive, unharmonized and difficult) and the need of having local languages in all packaging are challenges experienced in commercialization of existing products. Small market (size) and inability to sell in some countries/geo for some products are also pain-points experienced



E1. Below is a list of FACTORS RELEVANT TO THE MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS in the animal health industry in your country/ASEAN. Which of these, if any, are significant in preventing efficient commercialization of your existing products?

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

5 in 6 regional regulatory managers concluded that govt. regulation created significant uncertainty to AH business. Additionally, half of the managers said govt. regulation also sidetrack management time from other (more) commercial activities



Base, N=6, Data shown no. of mentions

**Significant**  
(10=most significant, 1=least significant)

No. of mentions



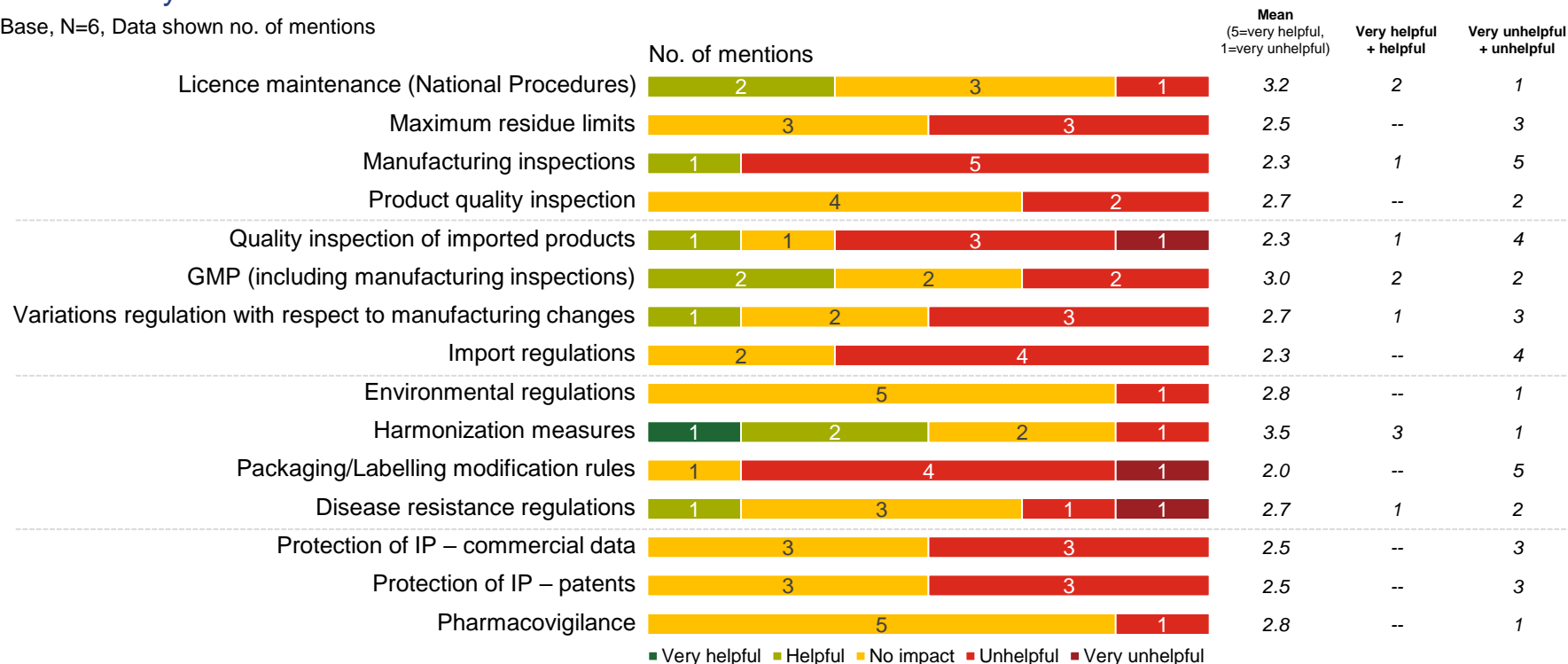
E2. Do government regulations in your country/ASEAN have any of the following effects on your business?

REGIONAL: Impact of different govt. regulations on ability to maintain registration of AH product successfully

Packaging/labelling modification rules, manufacturing inspection and import regulation / inspection are said be least helpful in maintaining registration of AH products. In contrast, harmonization are said to be able to be helpful in maintaining registration of AH product successfully



Base, N=6, Data shown no. of mentions



E3. Thinking about government regulations in your country/ASEAN, how would you assess the impact of each of the areas of regulation listed below on your ABILITY TO PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS successfully?

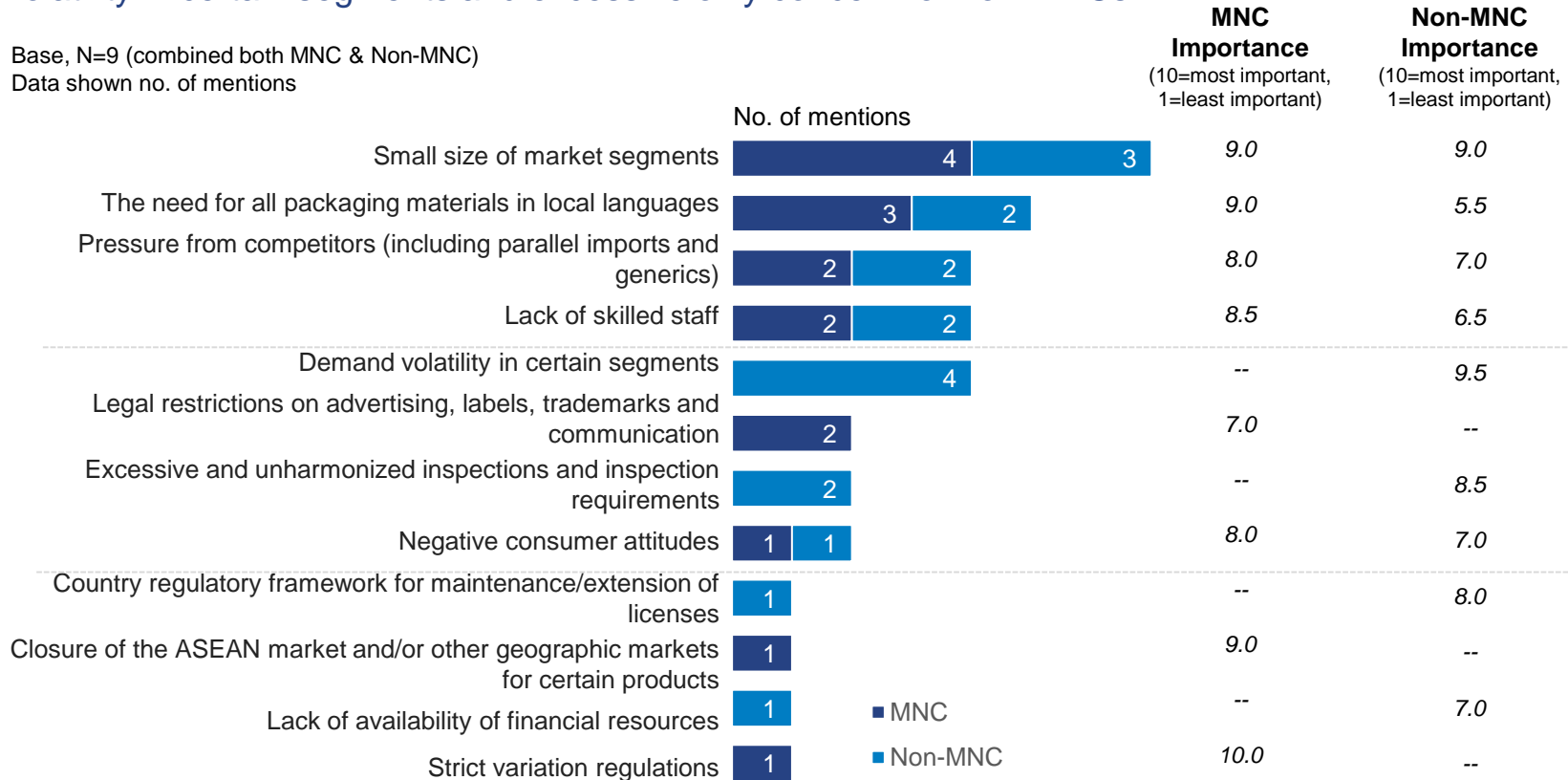
## MALAYSIA: Factors preventing maintenance of registration of existing AH products

Small market size is a concern to both MNC and non-MNC companies. Interestingly, demand volatility in certain segments and excessive only concern for non-MNCs.



Base, N=9 (combined both MNC & Non-MNC)

Data shown no. of mentions



E1. Below is a list of FACTORS RELEVANT TO THE MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS in the animal health industry in your country/ASEAN. Which of these, if any, are significant in preventing efficient commercialization of your existing products?

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

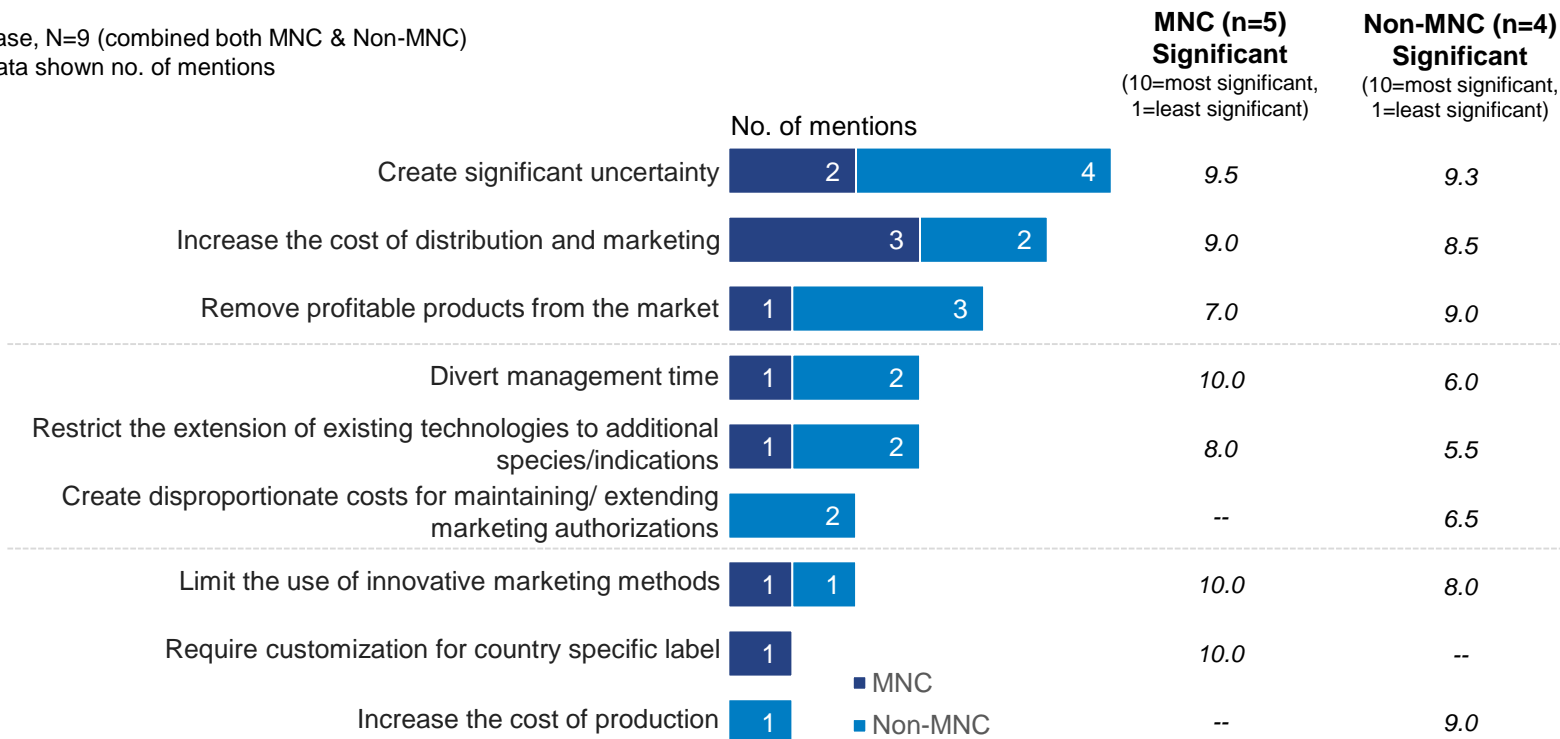
Significant uncertainty in the market is the 'output' due to govt. regulation.

Additionally, 3 in 5 MNC regulatory managers also professed govt. regulation increase cost of distribution and marketing.



Base, N=9 (combined both MNC & Non-MNC)

Data shown no. of mentions



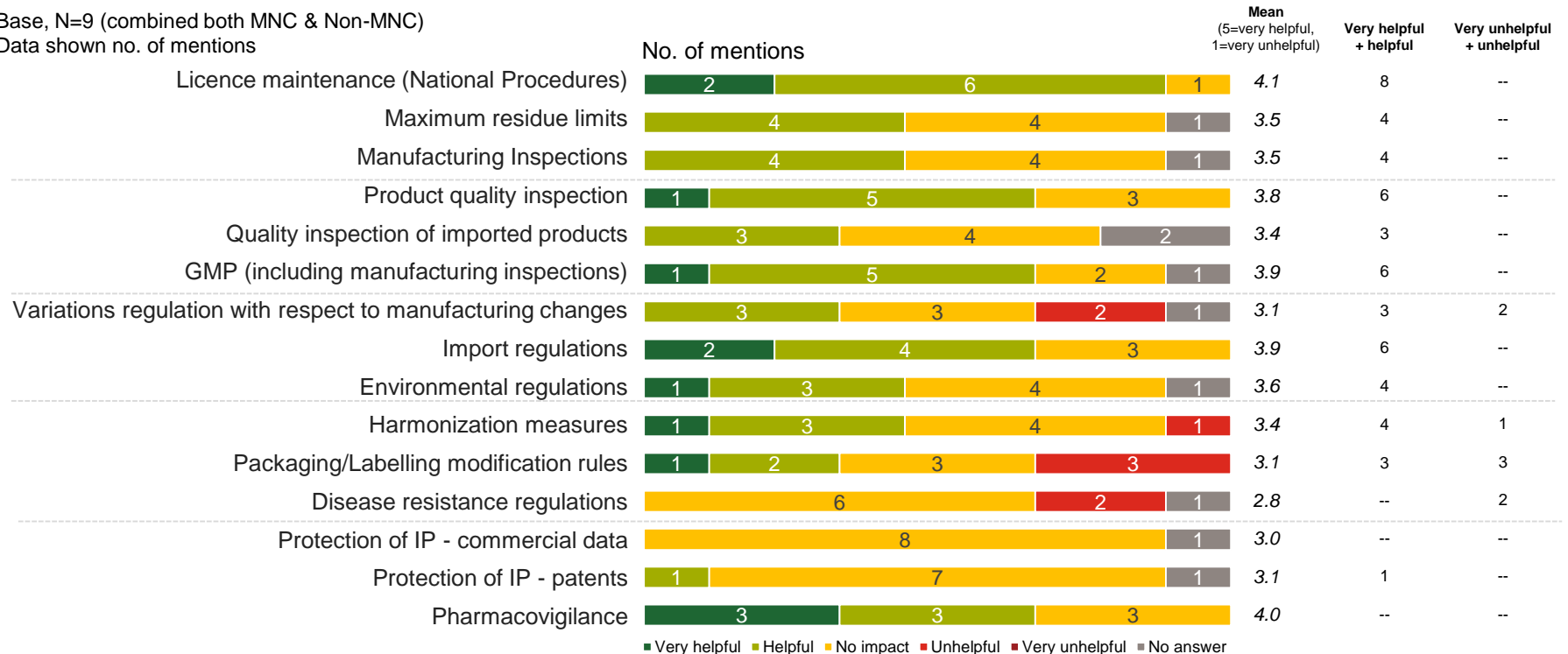
E2. Do government regulations in your country/ASEAN have any of the following effects on your business?

# Packaging/labelling modification rules, disease resistance regulations and variation regulation with respect to manufacturing changes said be least helpful in maintaining registration of AH products.



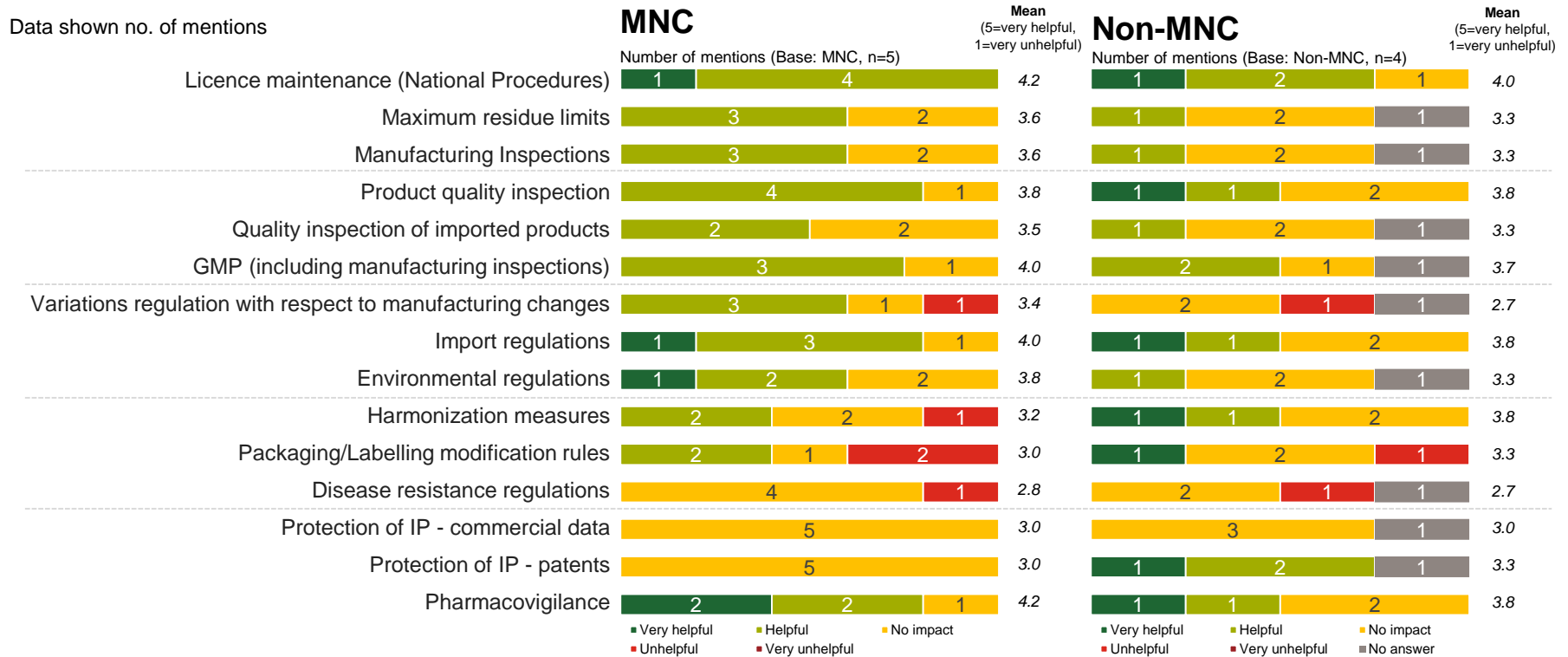
Base, N=9 (combined both MNC & Non-MNC)

Data shown no. of mentions



E3. Thinking about Government Regulations in your country/ASEAN, how would you assess the impact of each of the areas of regulation listed below on your ABILITY TO PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS successfully?

**MALAYSIA: Impact of different govt. regulations on ability to maintain registration of AH product successfully**  
**Packaging/labelling modification rules, disease resistance regulations, variation regulation with respect to manufacturing changes said be least helpful in maintaining registration of AH products.**



E3. Thinking about Government Regulations in your country/ASEAN, how would you assess the impact of each of the areas of regulation listed below on your ABILITY TO PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS successfully?



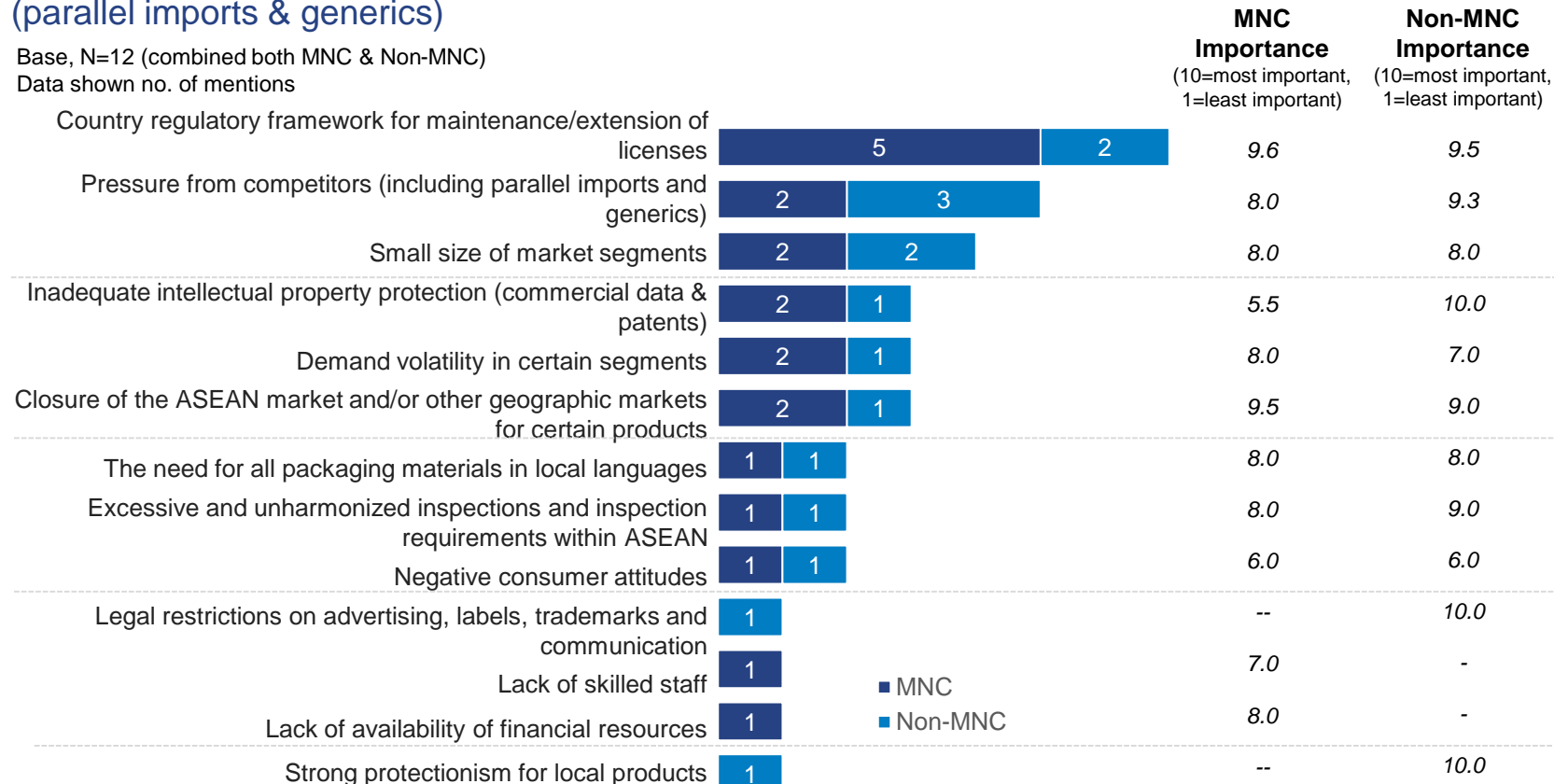
## INDONESIA: Factors preventing maintenance of registration of existing AH products

The main challenge faced seems to be related to current regulatory framework for maintenance / extension of licenses and to lesser extend, pressure from competitors (parallel imports & generics)



Base, N=12 (combined both MNC & Non-MNC)

Data shown no. of mentions



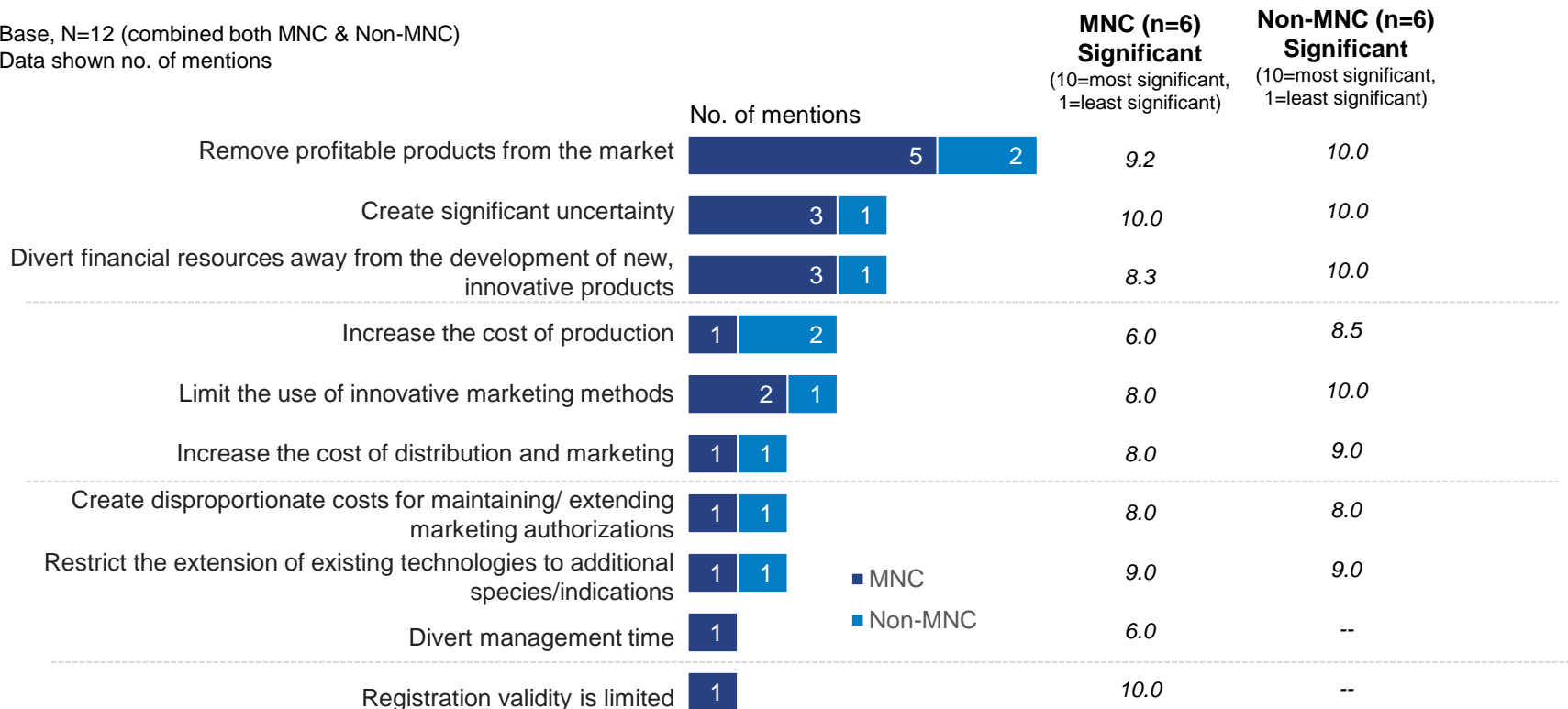
E1. Below is a list of FACTORS RELEVANT TO THE MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS in the animal health industry in your country/ASEAN. Which of these, if any, are significant in preventing efficient commercialization of your existing products?

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

Managers felt that govt. regulation of remove profitable products from market has impacted their AH business. Other aspects include create significant uncertainty and divert financial resources away from development of new, innovative products.



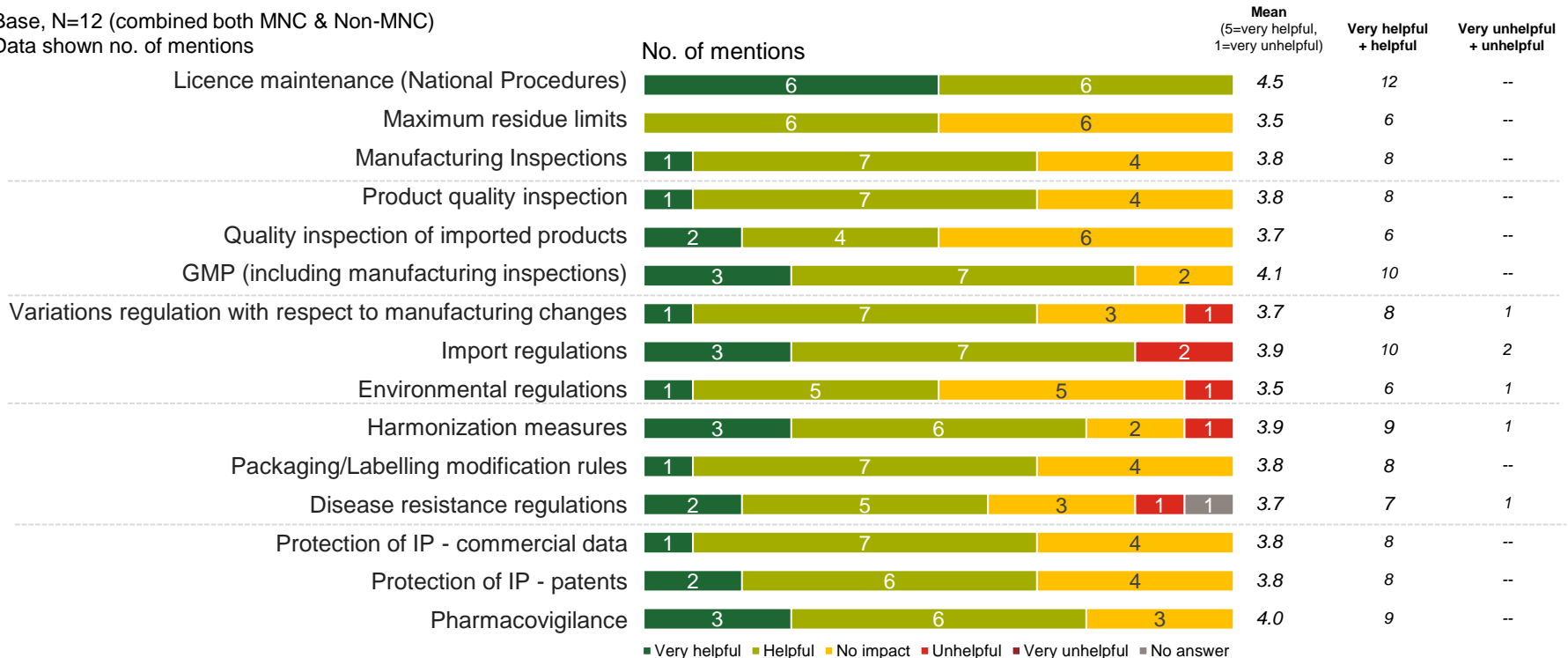
Base, N=12 (combined both MNC & Non-MNC)  
Data shown no. of mentions



E2. Do government regulations in your country/ASEAN have any of the following effects on your business?

By and large, there are very few area of regulation that have adverse impact in maintain registration of AH products successfully. The main complaint is – import regulation.

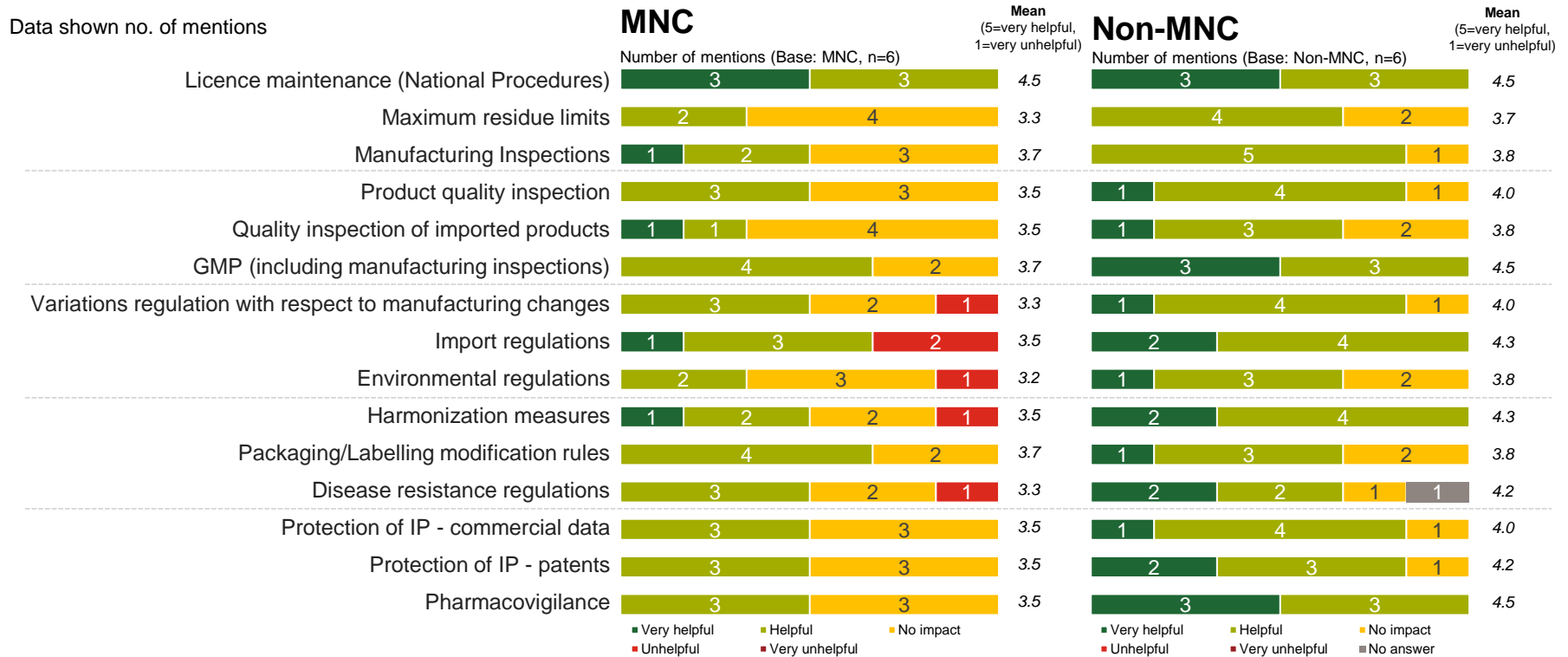
Base, N=12 (combined both MNC & Non-MNC)  
Data shown no. of mentions



E3. Thinking about Government Regulations in your country/ASEAN, how would you assess the impact of each of the areas of regulation listed below on your ABILITY TO PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS successfully?

INDONESIA: Impact of different govt. regulations on ability to maintain registration of AH product successfully

By and large, there are very few area of regulation that have adverse impact in maintain registration of AH products successfully. The main complaint is – import regulation. This area of regulation, expectedly is only a concern to MNC companies.



E3. Thinking about Government Regulations in your country/ASEAN, how would you assess the impact of each of the areas of regulation listed below on your ABILITY TO PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS successfully?

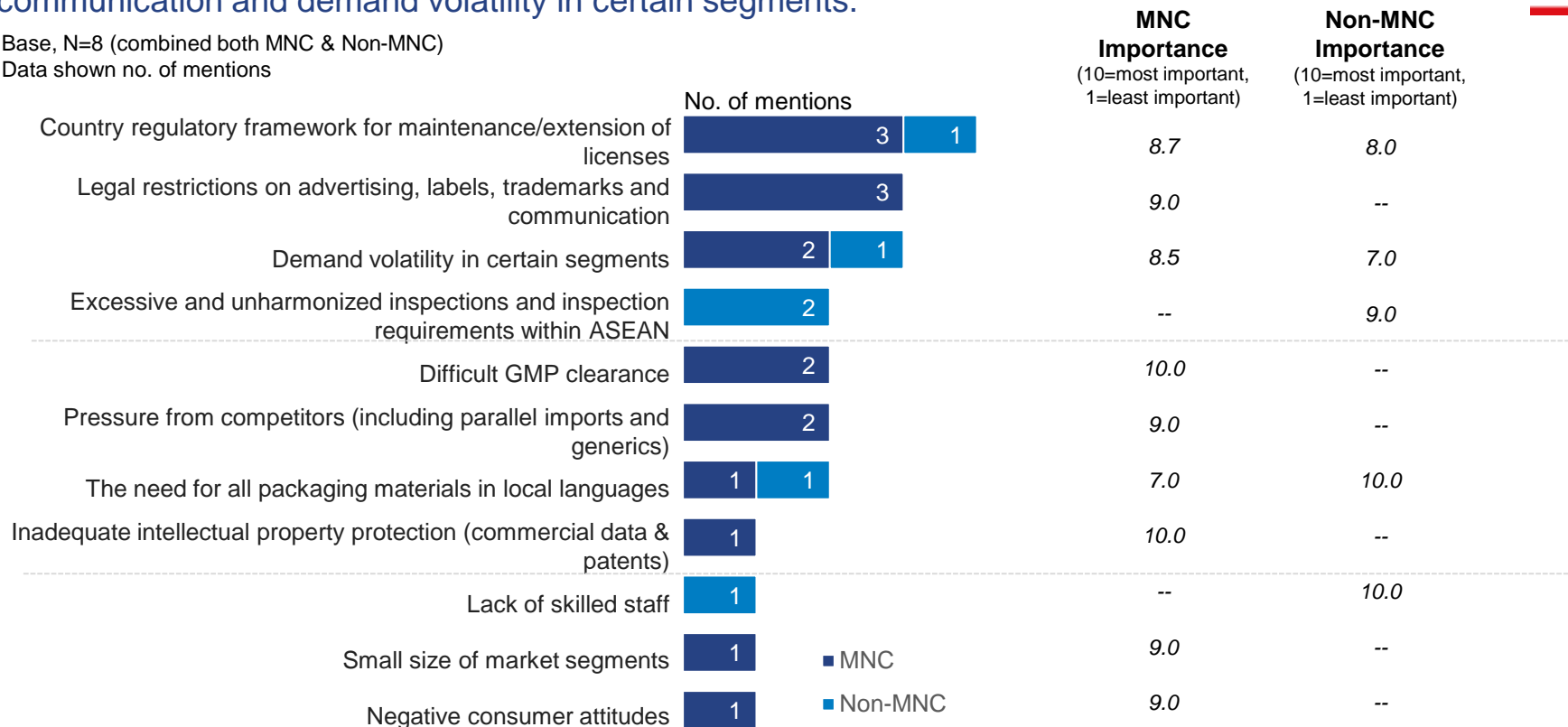
## THAILAND: Factors preventing maintenance of registration of existing AH products

Factors are significant in preventing efficient commercialization of existing products include – country regulation framework, legal restriction on advertising, label, trademark and communication and demand volatility in certain segments.



Base, N=8 (combined both MNC & Non-MNC)

Data shown no. of mentions



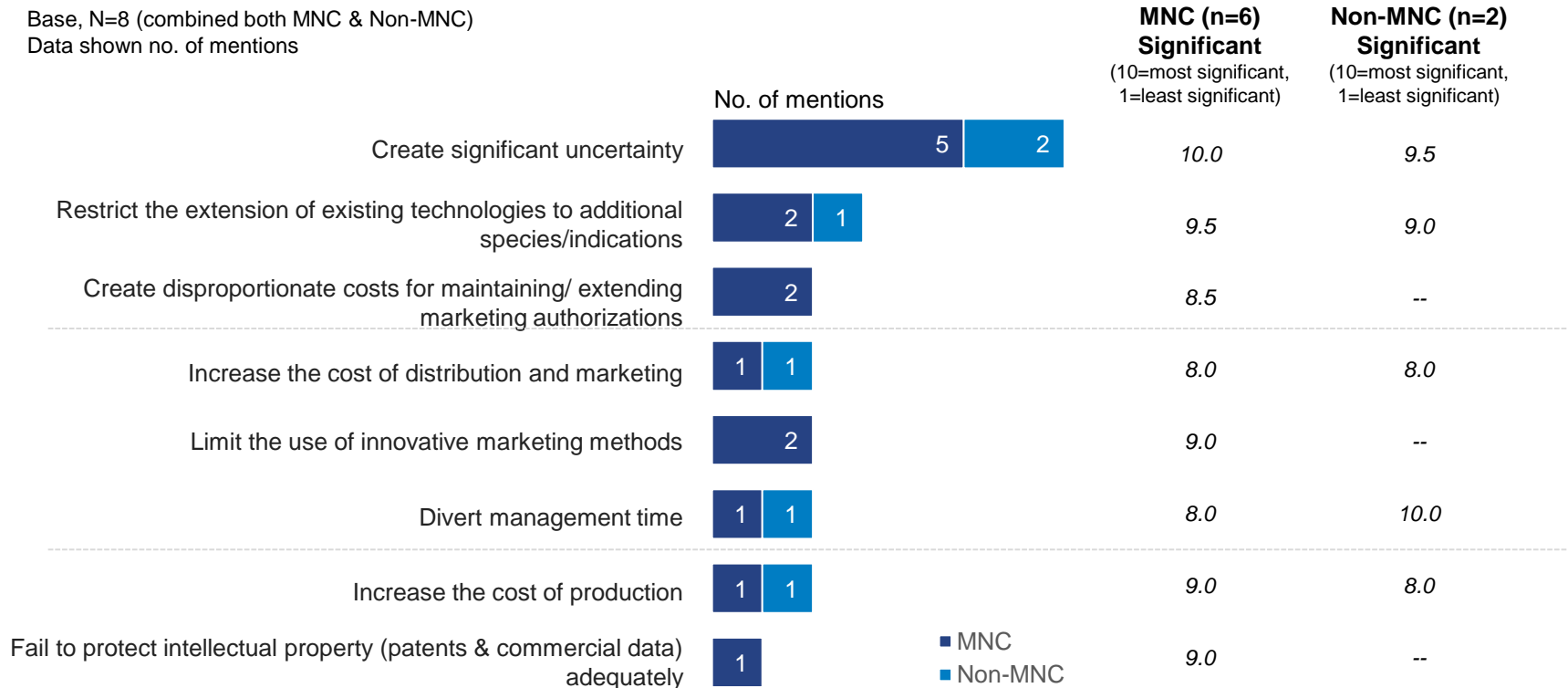
E1. Below is a list of FACTORS RELEVANT TO THE MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS in the animal health industry in your country/ASEAN. Which of these, if any, are significant in preventing efficient commercialization of your existing products?

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

The main drawback of govt. regulations in commercialization of your existing products is creating significant uncertainty to their business.



Base, N=8 (combined both MNC & Non-MNC)  
Data shown no. of mentions



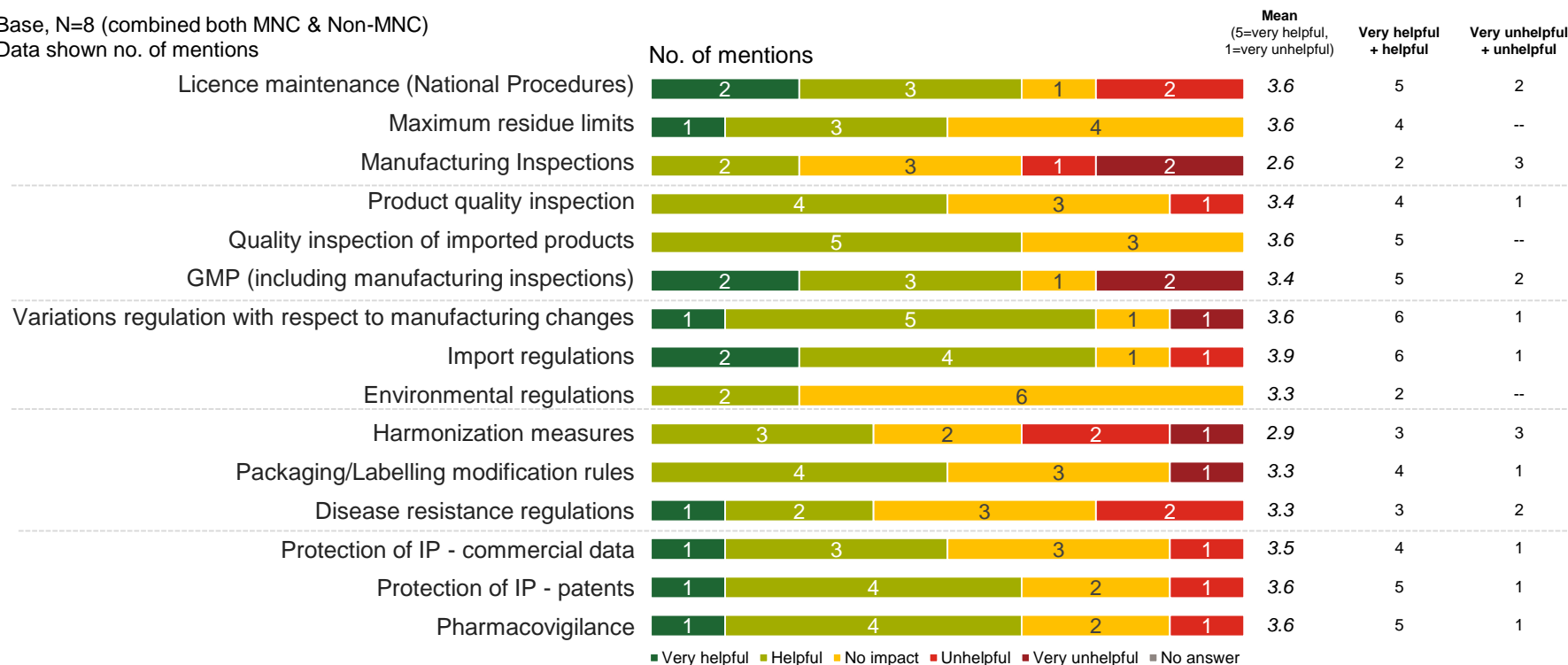
E2. Do government regulations in your country/ASEAN have any of the following effects on your business?

# THAILAND: Impact of different govt. regulations on ability to maintain registration of AH product successfully

## Manufacturing inspections and harmonization measures are considered 2 areas of regulation that are not helpful in maintaining registration of existing products



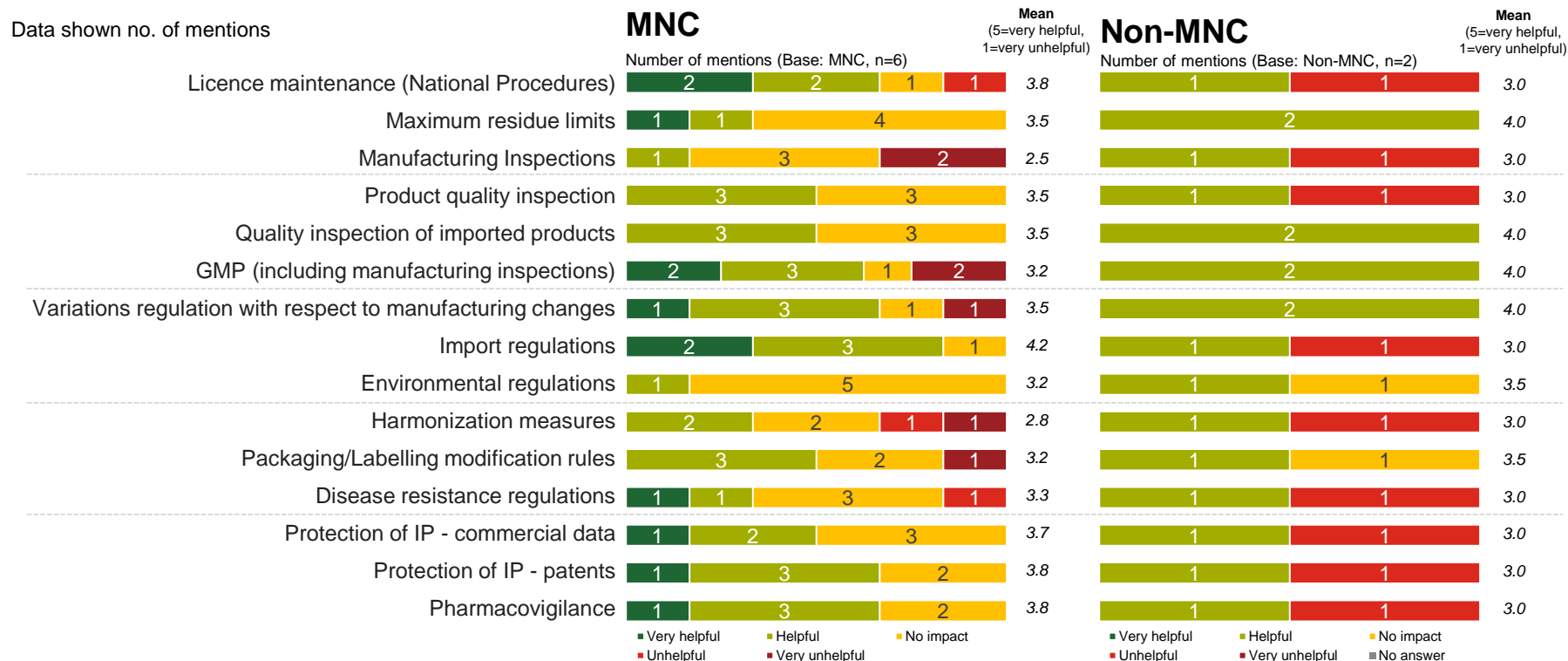
Base, N=8 (combined both MNC & Non-MNC)  
Data shown no. of mentions



E3. Thinking about Government Regulations in your country/ASEAN, how would you assess the impact of each of the areas of regulation listed below on your ABILITY TO PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS successfully?

# THAILAND: Impact of different govt. regulations on ability to maintain registration of AH product successfully

## Manufacturing inspections and harmonization measures are considered 2 areas of regulation that are not helpful in maintaining registration of existing products



E3. Thinking about Government Regulations in your country/ASEAN, how would you assess the impact of each of the areas of regulation listed below on your ABILITY TO PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS successfully?

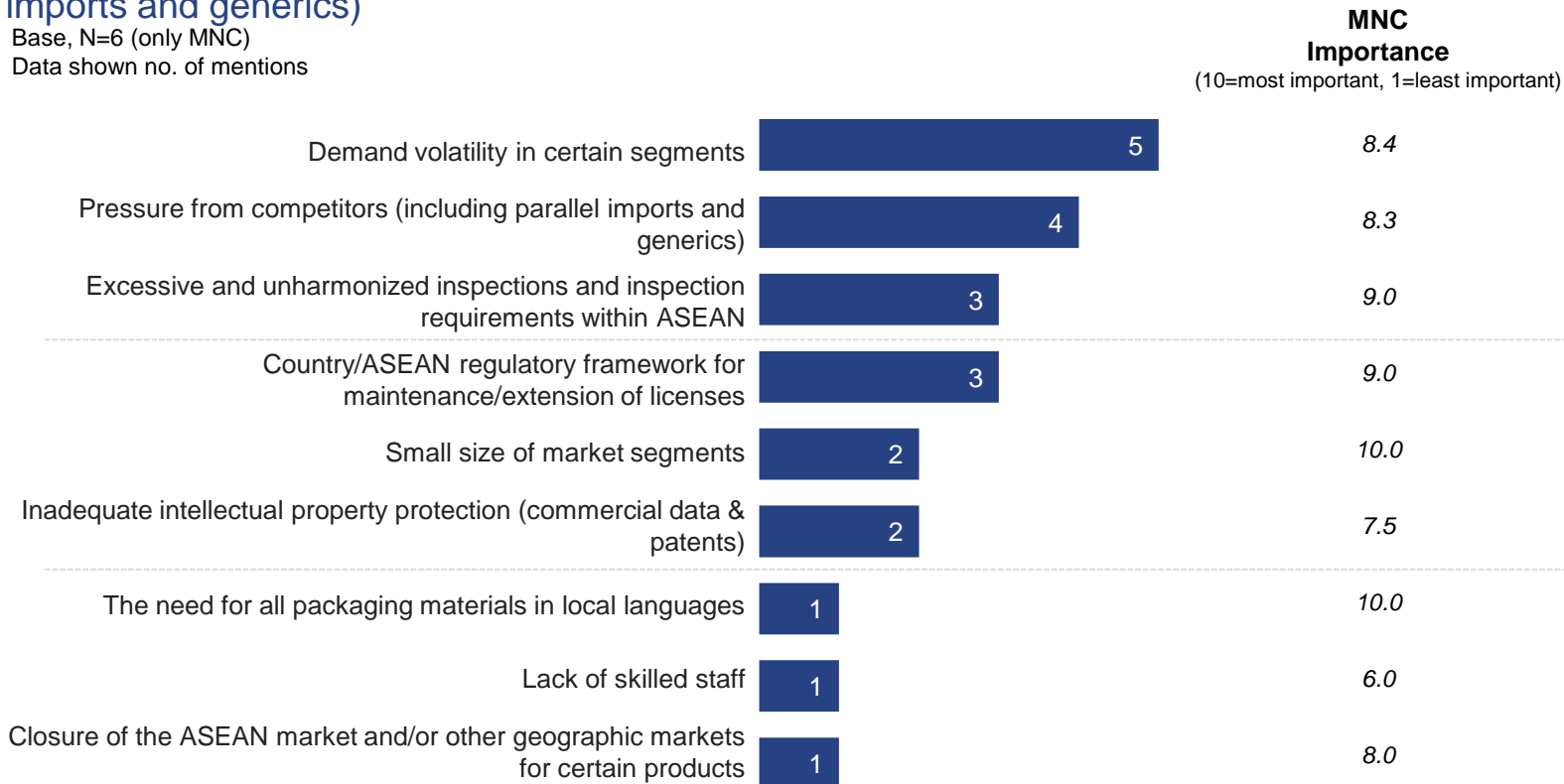


Top 2 factors that considered to prevent efficient commercialization of existing products are demand volatility in certain segments and pressure from competitors (including parallel imports and generics)



Base, N=6 (only MNC)

Data shown no. of mentions

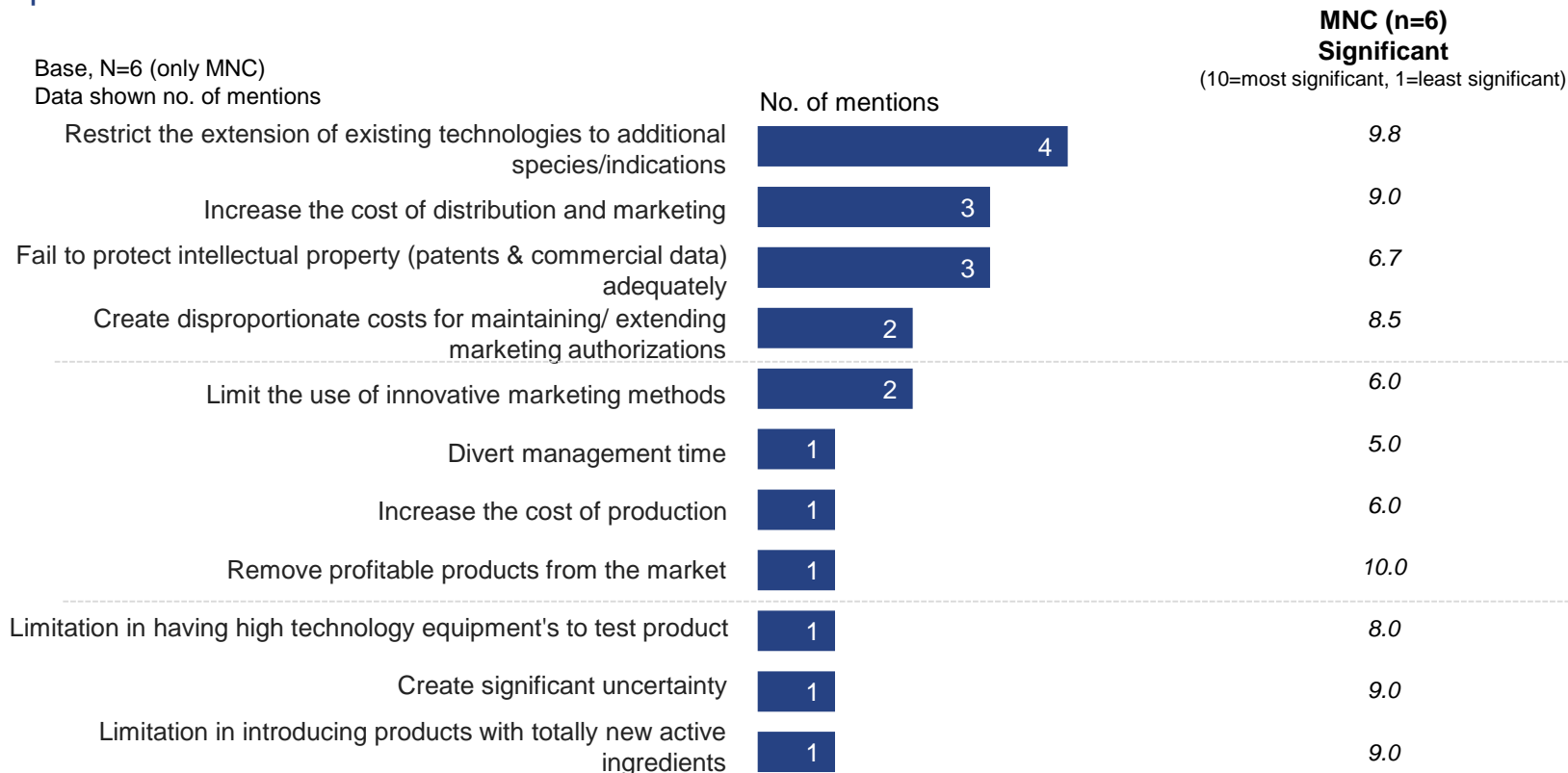


E1. Below is a list of FACTORS RELEVANT TO THE MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS in the animal health industry in your country/ASEAN. Which of these, if any, are significant in preventing efficient commercialization of your existing products?



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

Govt. regulations are said to restrict the extension of existing technologies to additional species/indication, increase cost of distribution of marketing and fail to protect IP.



E2. Do government regulations in your country/ASEAN have any of the following effects on your business?

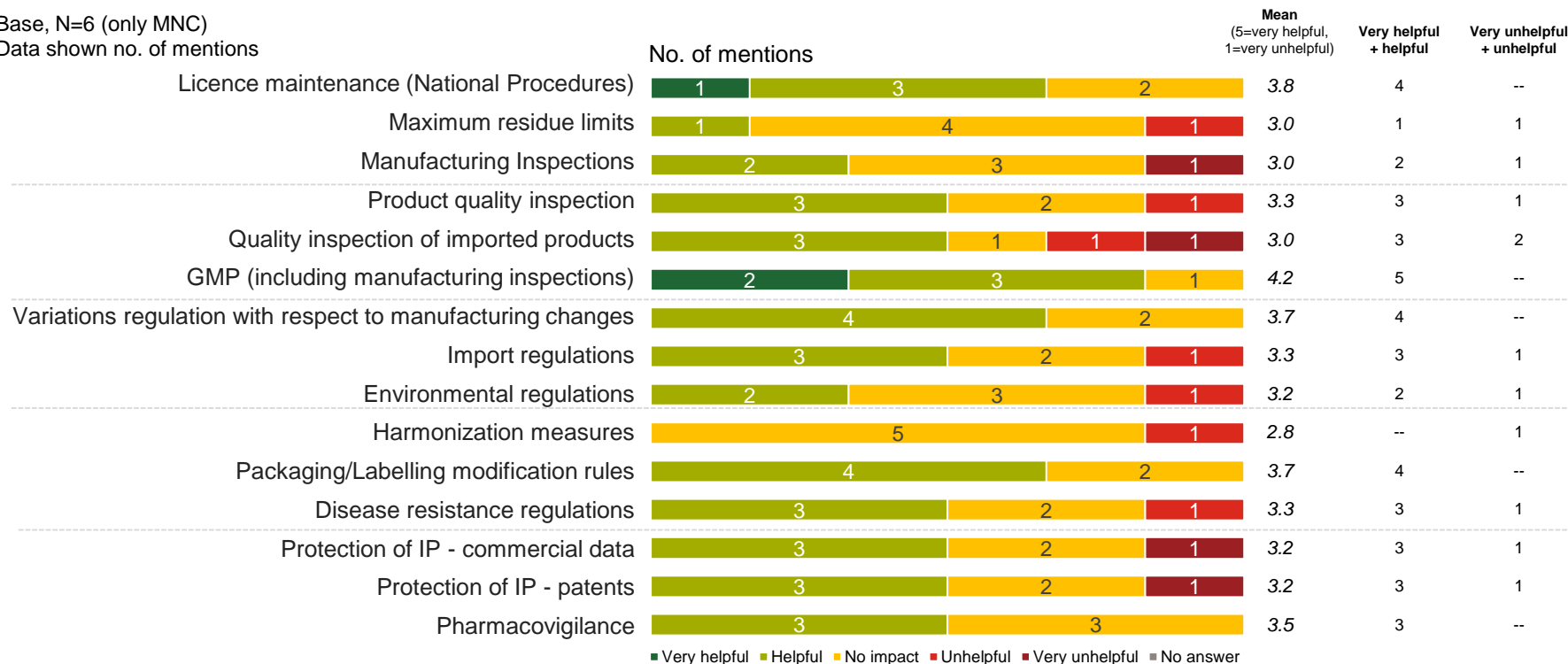
## VIETNAM: Impact of different govt. regulations on ability to maintain registration of AH product successfully

Most managers said harmonization measures have no impact on their ability to maintain registration of AH product successfully. They are concerns with quality inspection of imported products.



Base, N=6 (only MNC)

Data shown no. of mentions



E3. Thinking about Government Regulations in your country/ASEAN, how would you assess the impact of each of the areas of regulation listed below on your ABILITY TO PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS successfully?

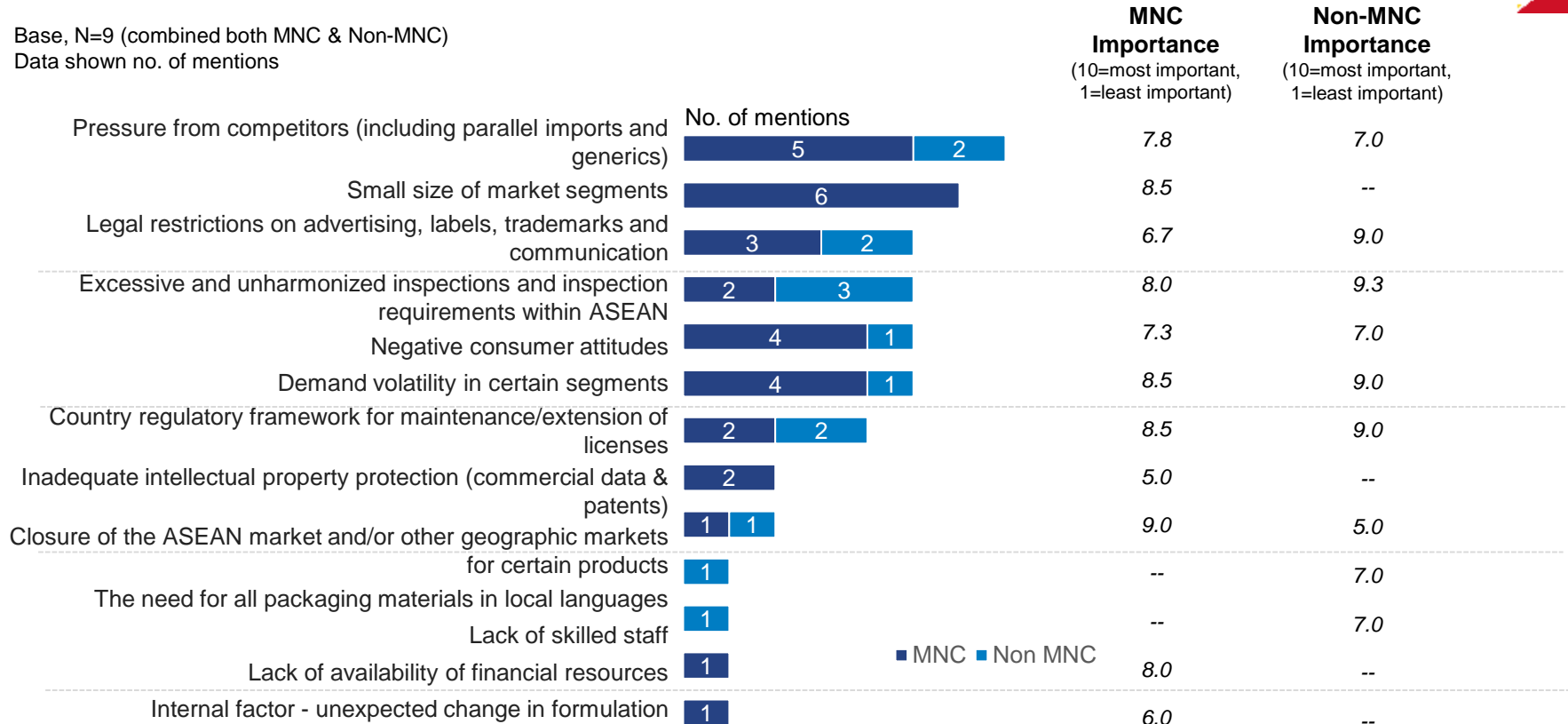
## PHILIPPINES: Factors preventing maintenance of registration of existing AH products

Pressure from competitors and small size of market are the top 2 factors that could prevent efficient commercialization of existing AH products.



Base, N=9 (combined both MNC & Non-MNC)

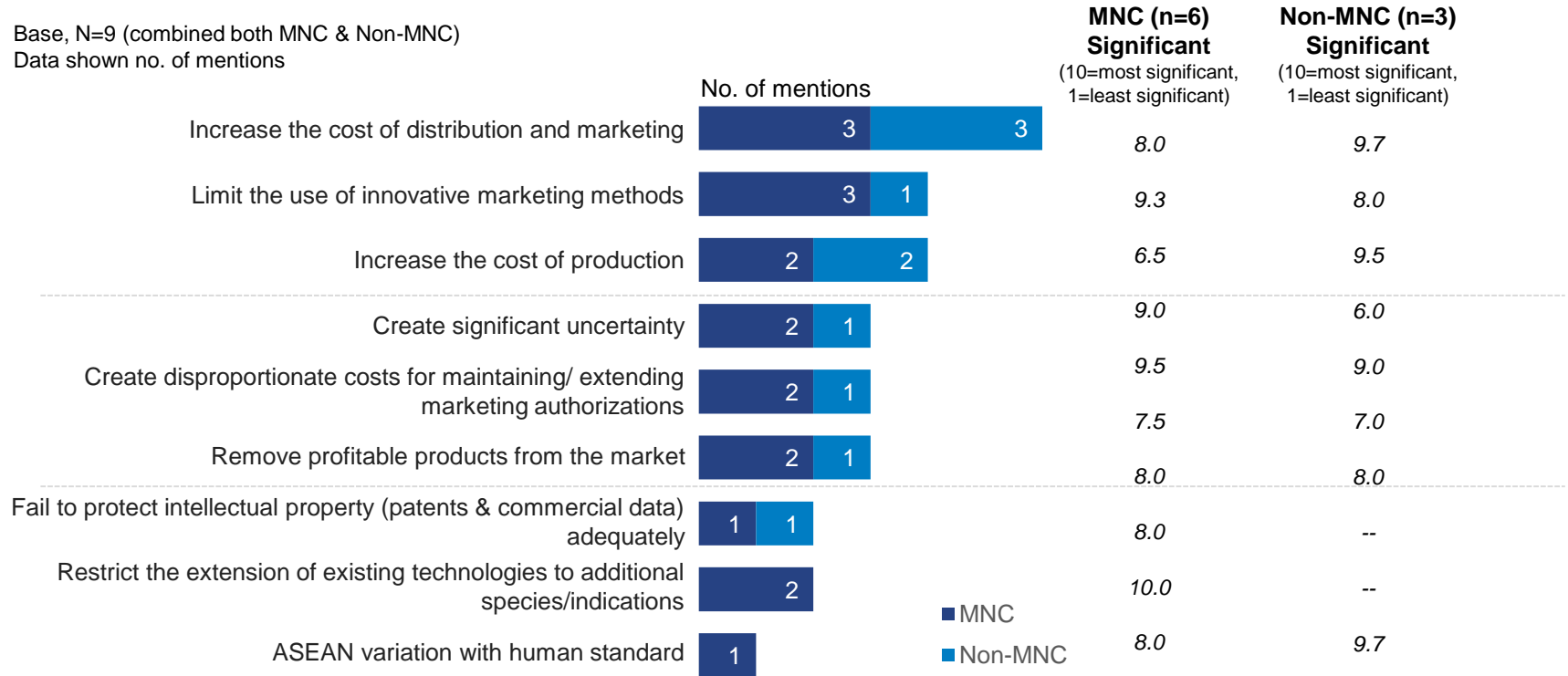
Data shown no. of mentions



E1. Below is a list of FACTORS RELEVANT TO THE MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS in the animal health industry in your country/ASEAN. Which of these, if any, are significant in preventing efficient commercialization of your existing products?

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

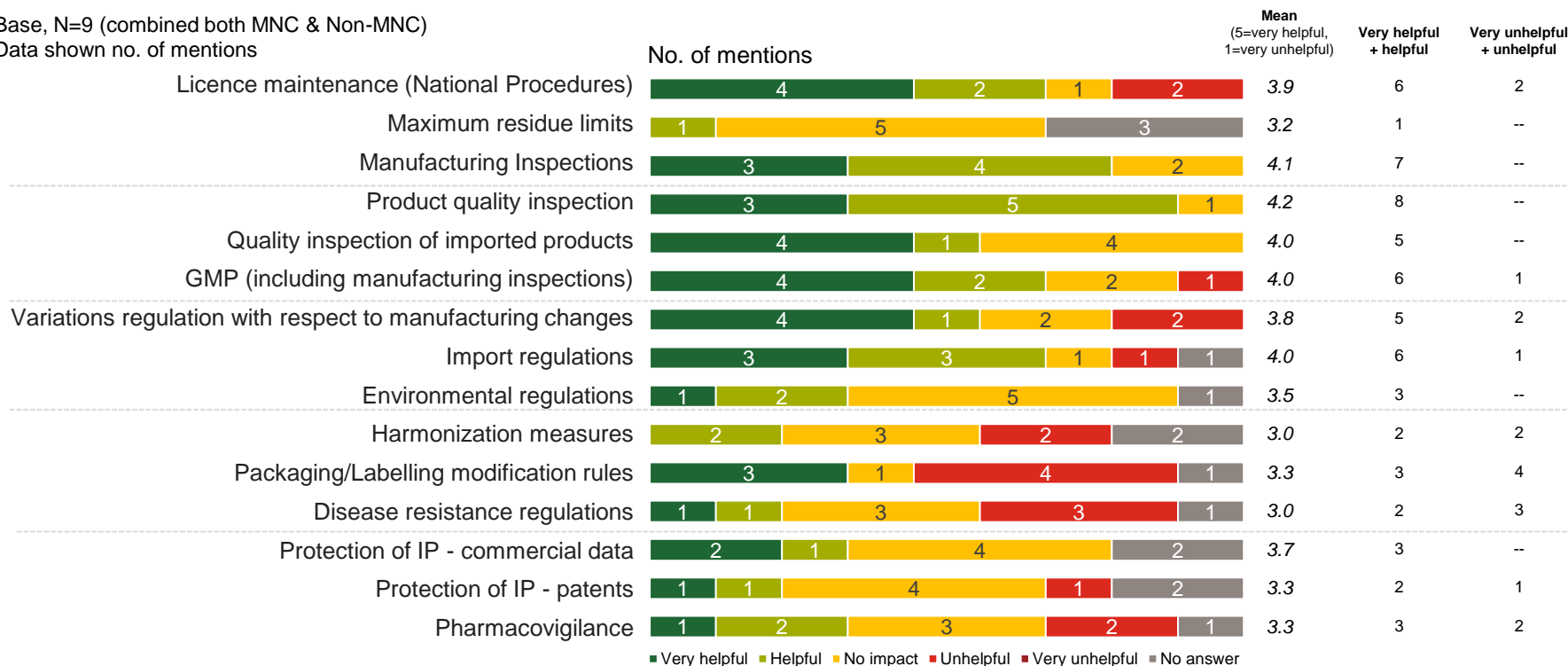
Increase of cost of distribution & marketing, limit use of innovative marketing methods and increase the cost of production are the outcome of govt. regulation on commercialization of existing products.



E2. Do government regulations in your country/ASEAN have any of the following effects on your business?

PHILIPPINES: Impact of different govt. regulations on ability to maintain registration of AH product successfully  
 Harmonization and disease resistance regulations are the 2 areas of regulation that are not helpful in maintaining the registration of existing products.

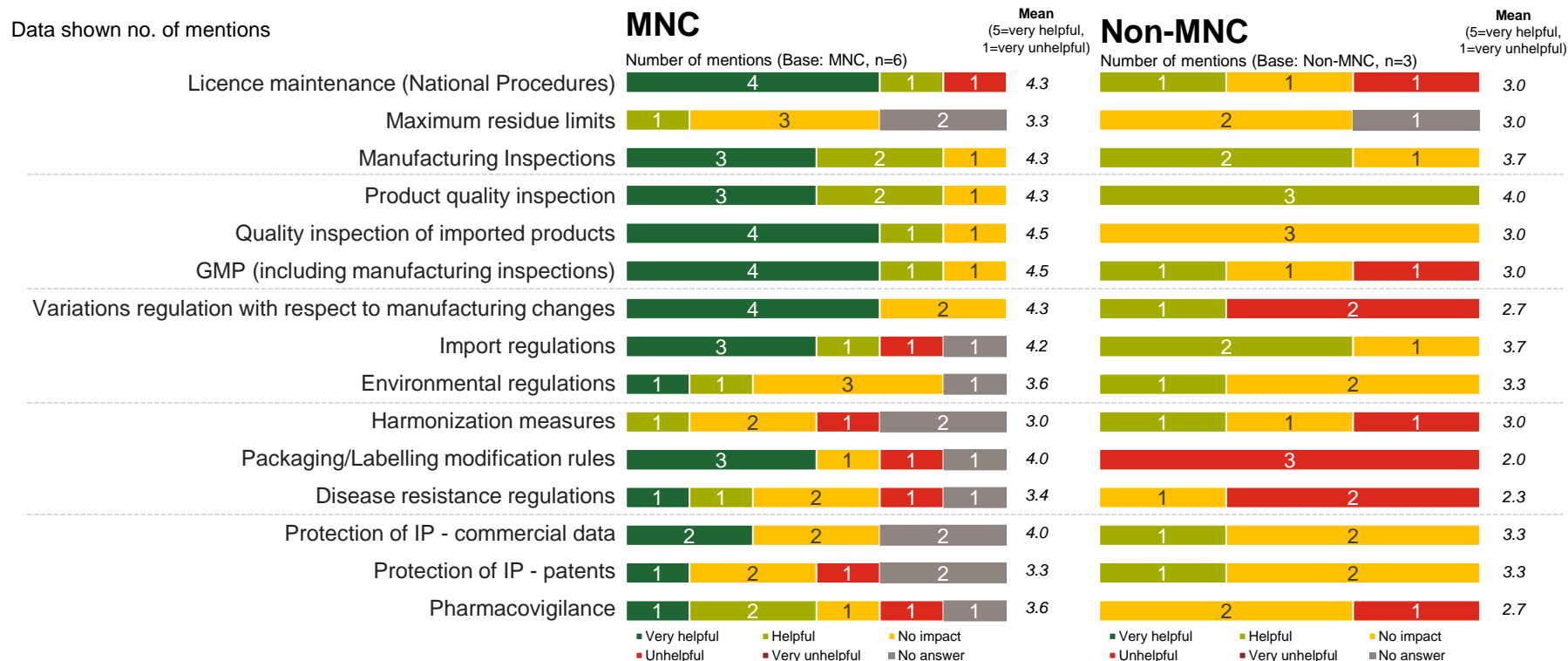
Base, N=9 (combined both MNC & Non-MNC)  
 Data shown no. of mentions



E3. Thinking about Government Regulations in your country/ASEAN, how would you assess the impact of each of the areas of regulation listed below on your ABILITY TO PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS successfully?

# PHILIPPINES: Impact of different govt. regulations on ability to maintain registration of AH product successfully

## Amongst the non-MNC, packaging / labelling modification rules and disease resistance regulations are areas within regulation that could impact their ability to maintain the registration of existing AH products



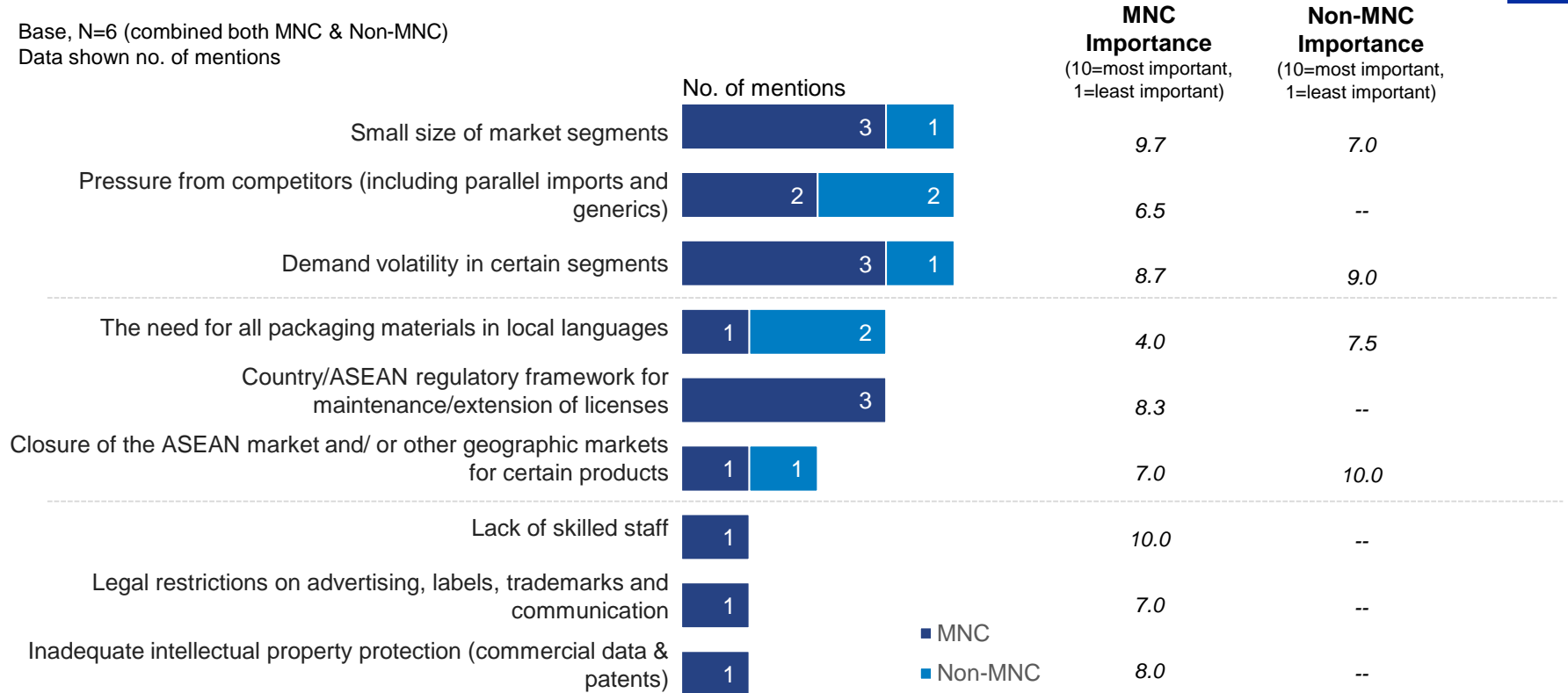
E3. Thinking about Government Regulations in your country/ASEAN, how would you assess the impact of each of the areas of regulation listed below on your ABILITY TO PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS successfully?

## CAMBODIA: Factors preventing maintenance of registration of existing AH products

Small size of market, pressure from competitors and demand volatility in certain segments are the 3 top factors that prevent effective commercialization of existing AH products.



Base, N=6 (combined both MNC & Non-MNC)  
Data shown no. of mentions



E1. Below is a list of FACTORS RELEVANT TO THE MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS in the animal health industry in your country/ASEAN. Which of these, if any, are significant in preventing efficient commercialization of your existing products?

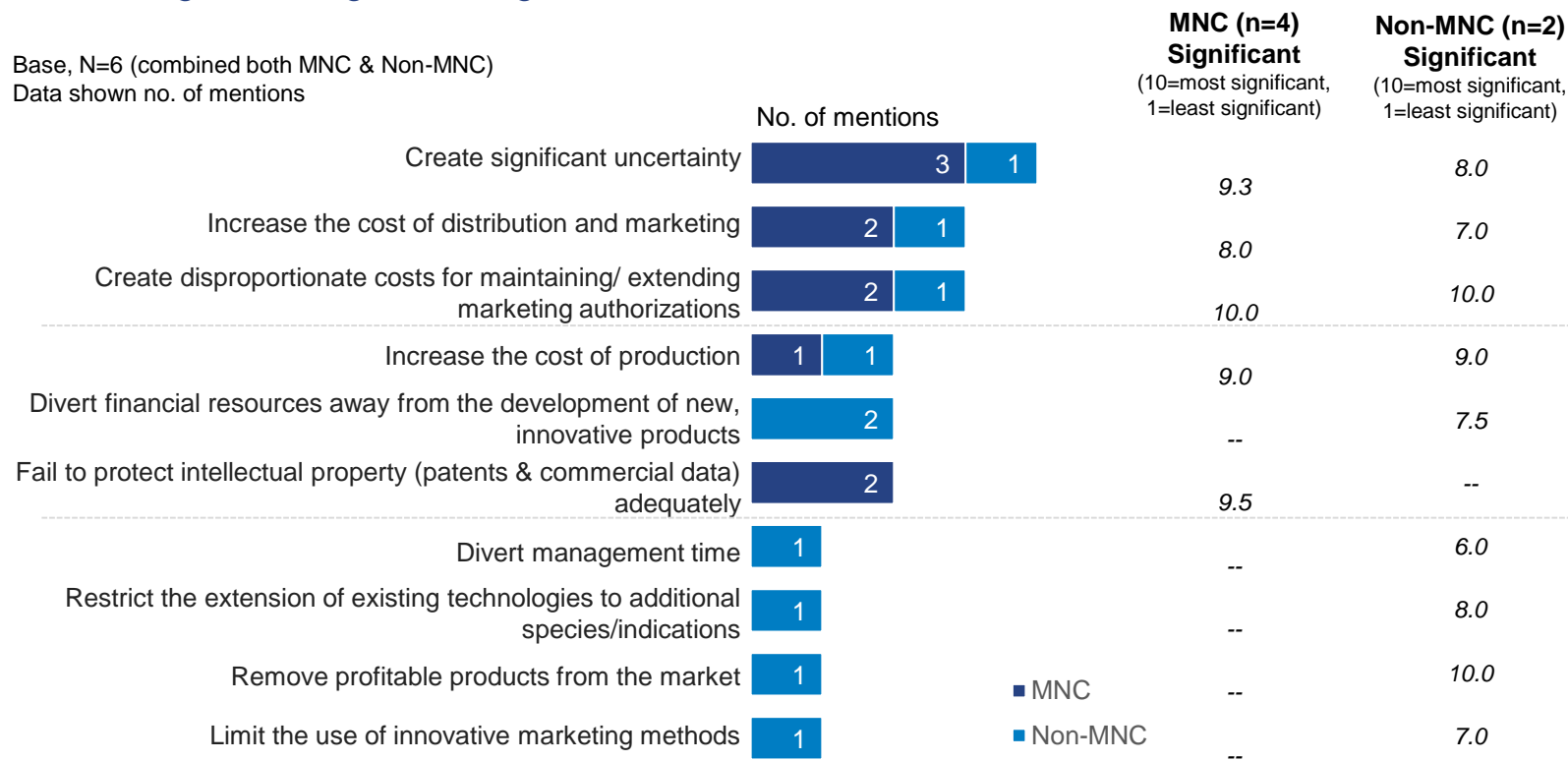


## CAMBODIA: (Negative) effect on the AH business due to govt. regulations

Government regulations are perceived to create significant uncertainty, increase cost of distribution & marketing and create disproportionate cost for maintaining/extending marketing authorizations.

Base, N=6 (combined both MNC & Non-MNC)

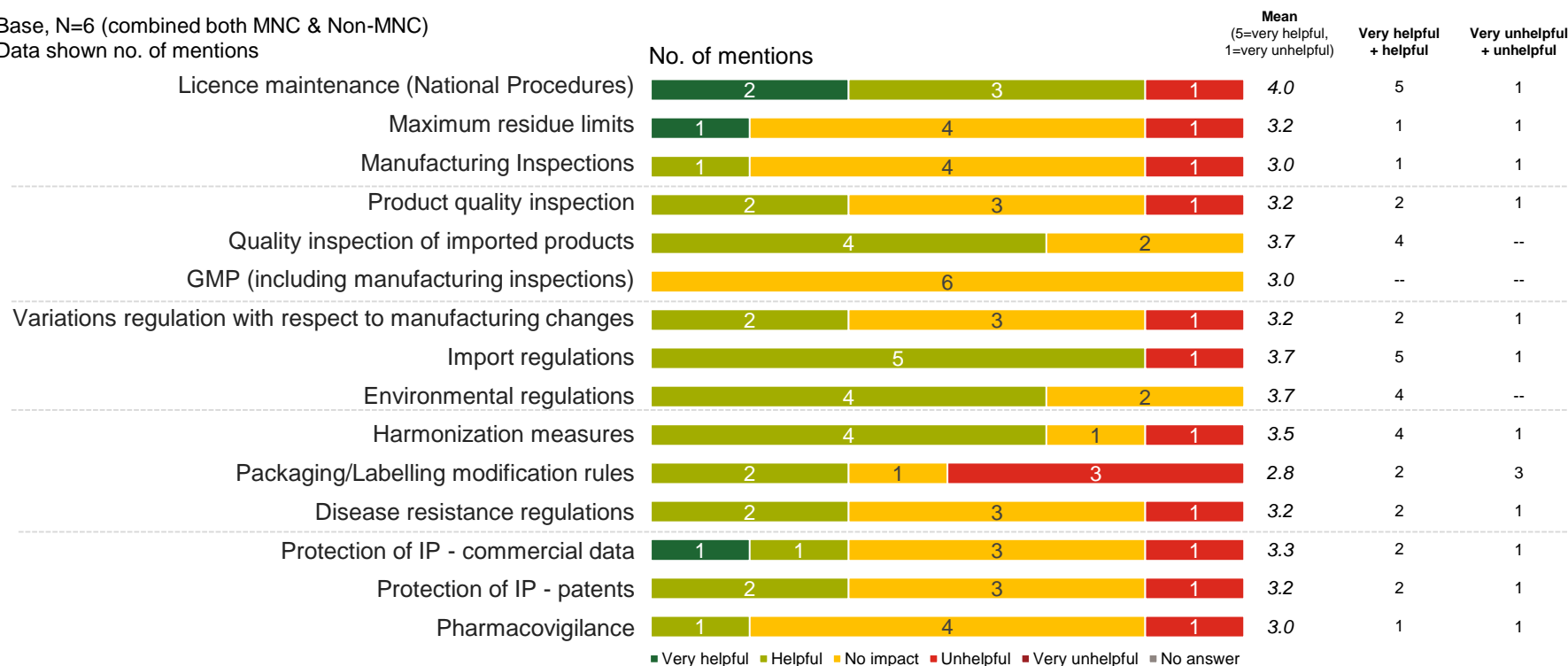
Data shown no. of mentions



E2. Do government regulations in your country/ASEAN have any of the following effects on your business?

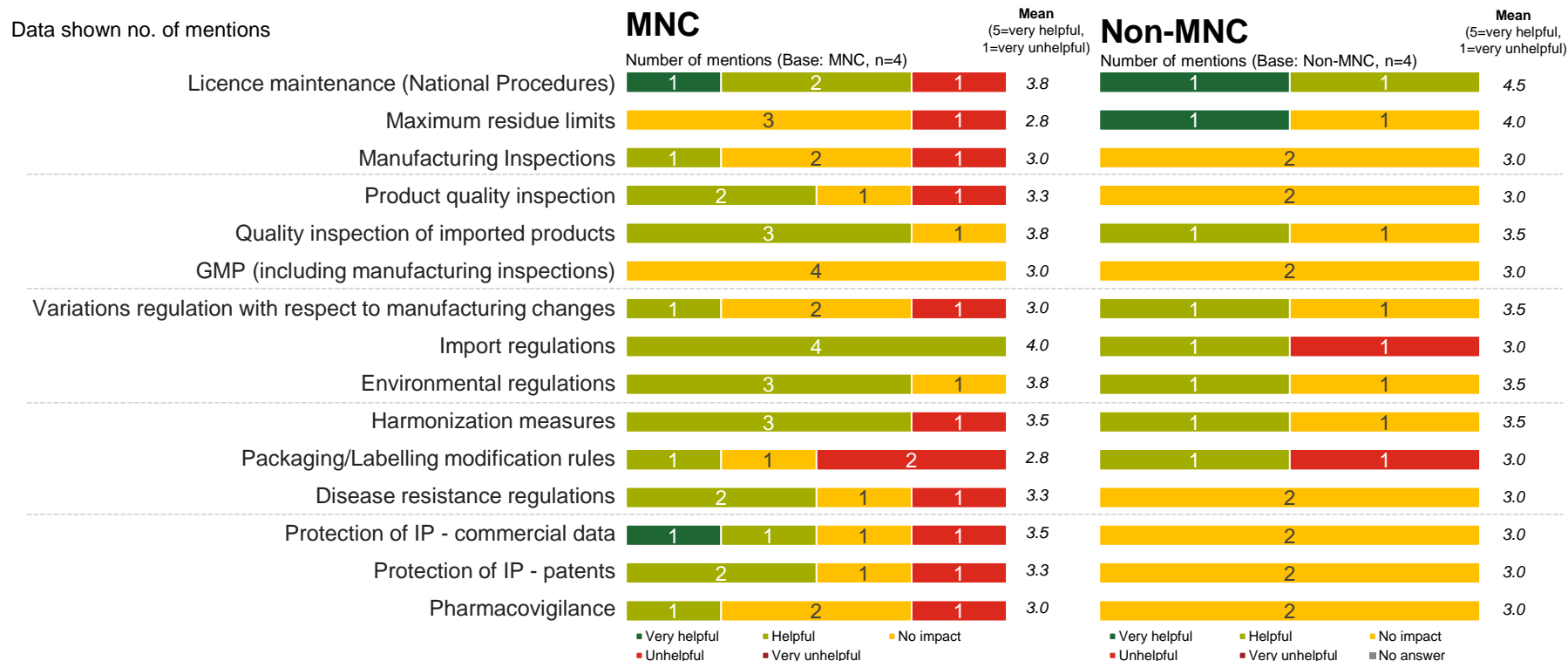
CAMBODIA: Impact of different govt. regulations on ability to maintain registration of AH product successfully  
 Packaging / labelling modification rules is the area of regulation that considered  
 unhelpful to maintenance of registration of existing products successfully.

Base, N=6 (combined both MNC & Non-MNC)  
 Data shown no. of mentions



E3. Thinking about Government Regulations in your country/ASEAN, how would you assess the impact of each of the areas of regulation listed below on your ABILITY TO PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS successfully?

CAMBODIA: Impact of different govt. regulations on ability to maintain registration of AH product successfully  
 Packaging / labelling modification rules is the area of regulation that considered  
 unhelpful to maintenance of registration of existing products successfully.



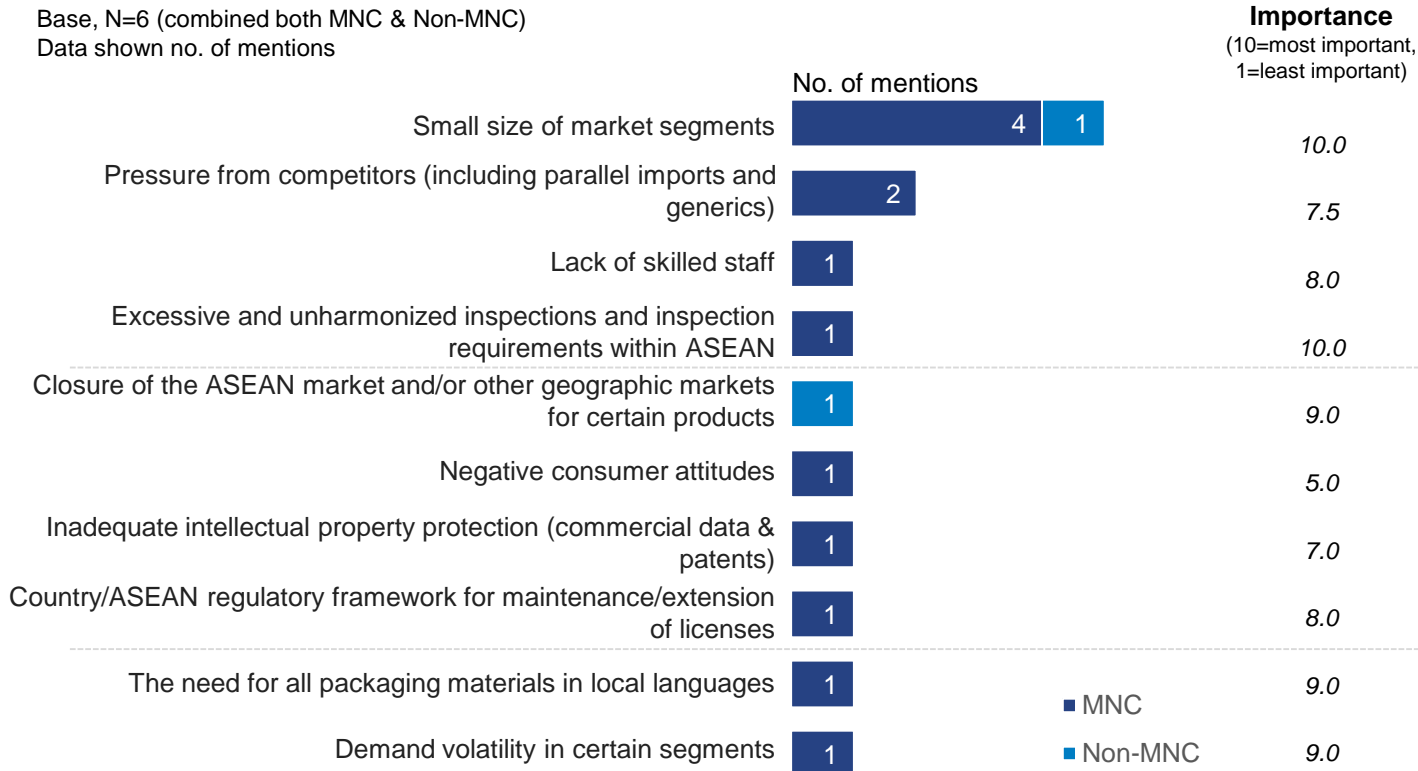
E3. Thinking about Government Regulations in your country/ASEAN, how would you assess the impact of each of the areas of regulation listed below on your ABILITY TO PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS successfully?

## MYANMAR: Factors preventing maintenance of registration of existing AH products

Small size of market and lesser extent, pressure from competitors are considered main factors that prevent effective commercialization of existing AH products.



Base, N=6 (combined both MNC & Non-MNC)  
Data shown no. of mentions



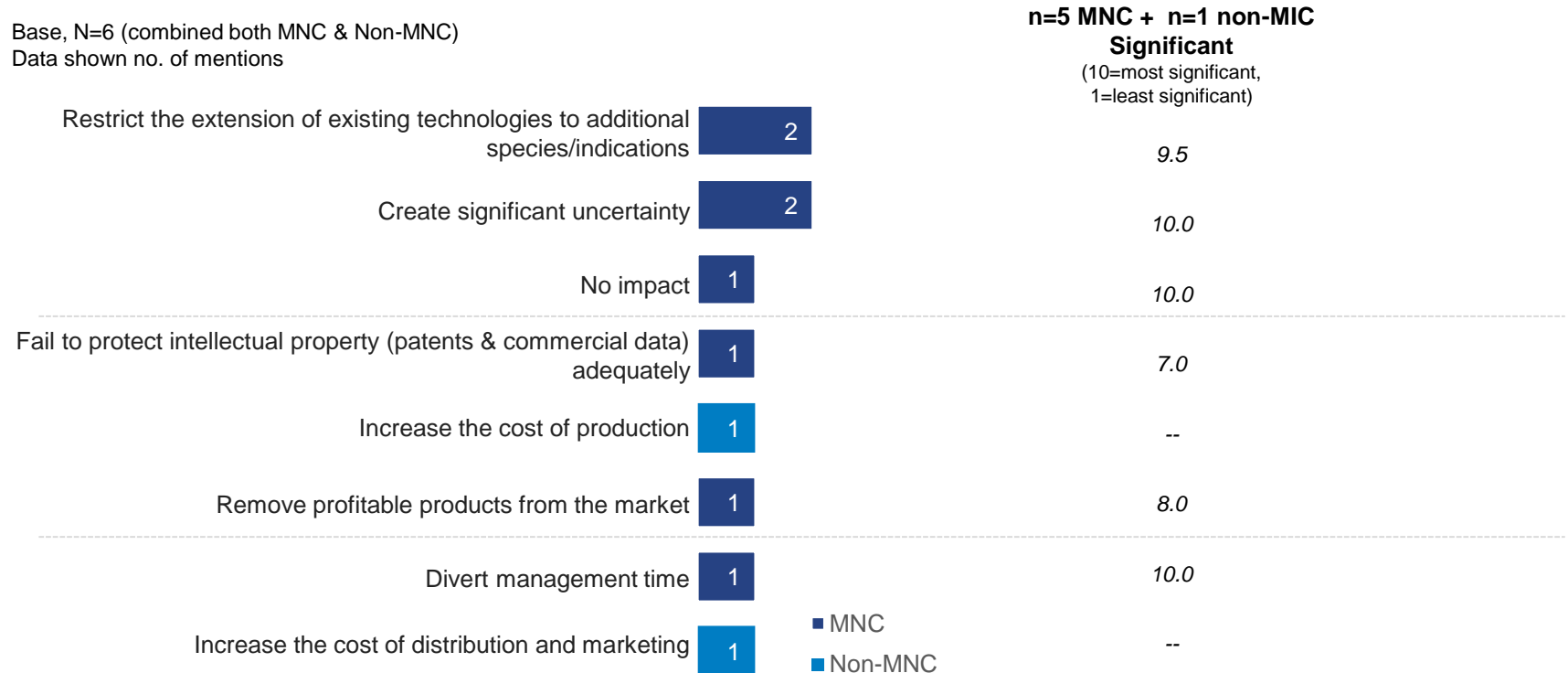
E1. Below is a list of FACTORS RELEVANT TO THE MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS in the animal health industry in your country/ASEAN. Which of these, if any, are significant in preventing efficient commercialization of your existing products?

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

Government regulations is said to restrict the extension of existing technologies to additional species / indication and create significant uncertainty.



Base, N=6 (combined both MNC & Non-MNC)  
Data shown no. of mentions



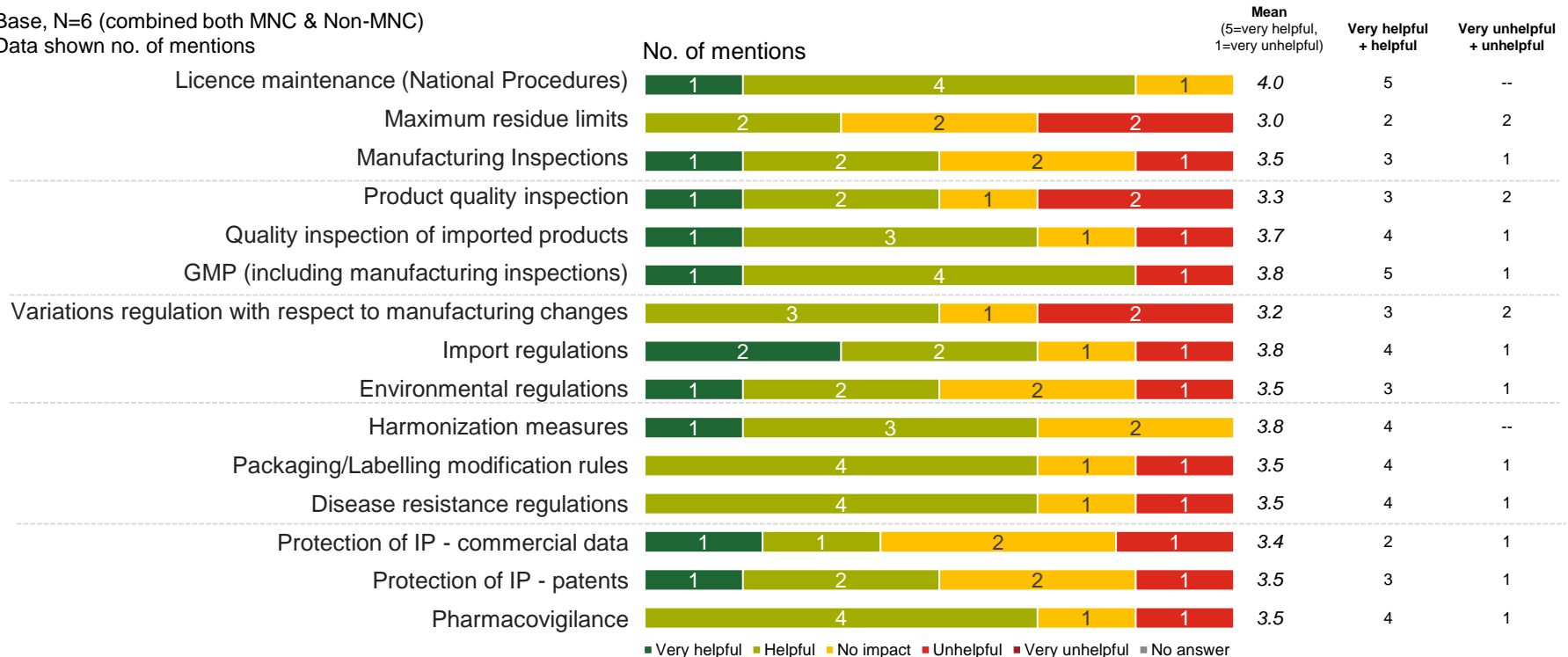
E2. Do government regulations in your country/ASEAN have any of the following effects on your business?

MYANMAR: Impact of different govt. regulations on ability to maintain registration of AH product successfully

Maximum residue limits, variations regulation with respect to manufacturing changes and product quality inspections are key areas of regulation that impact the ability to perform maintenance of registration of existing products successfully.



Base, N=6 (combined both MNC & Non-MNC)  
Data shown no. of mentions



E3. Thinking about Government Regulations in your country/ASEAN, how would you assess the impact of each of the areas of regulation listed below on your ABILITY TO PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS successfully?



## Factors that impact registration achievement and maintaining registration of existing brands



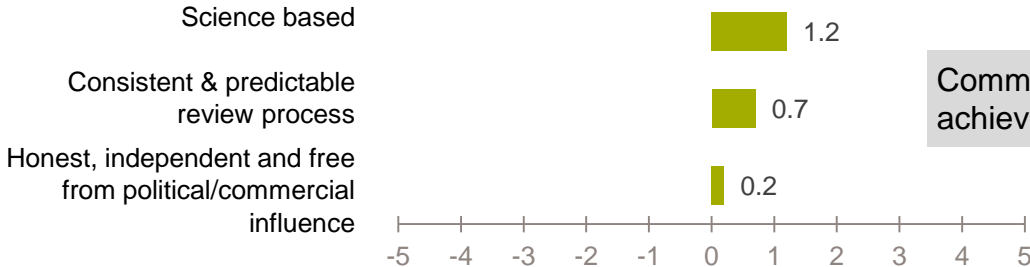
Half of the regional regulatory managers perceived current product registration process is somewhat inconsistent and unpredictable.. However, there is marginal improvement since 2014. Managers agreed that the product registration achievement in 2018 is more science based compared to 2014



Base, N=6

Data shown mean score

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



**Commentary: On all 3 metrics, current product registration achievement are better compared to 5 years ago**

F1. Thinking about CURRENT PRODUCT REGISTRATION ACHIEVEMENT, how well do you consider it is conducted/done based on: science based, consistent & predictable review process, honest, independent & free from political / commercial influence. F1b: COMPARE TO 2014 and NOW on PRODUCT REGISTRATION ACHIEVEMENT, how well do you consider it is conducted/done based on:



# 5 in 6 regional regulatory managers professed that current product registration is very complex, and had been worse compared to 2014

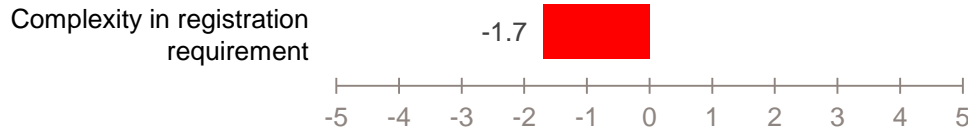


Base, N=6  
Data shown no. of mentions



Base, N=6  
Data shown mean score

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



Commentary: Complexity in registration requirements have increased in the last 5 years

F2. Thinking about CURRENT PRODUCT REGISTRATION COMPLEXITY, how well do you consider it is conducted/done based on: science based, consistent & predictable review process, honest, independent & free from political / commercial influence. F2b: COMPARE TO 2014 and NOW on PRODUCT REGISTRATION COMPLEXITY, how well do you consider it is conducted/done based on:

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

## Improvement of capability / knowledge & manpower of regulators, provision of feedback loop on new regulation before implementation and accept relevant/high quality test result from other sector/species/regions will have positive impact on product registration achievement



Base, N=6 Data shown no. of mentions	Number of mentions	Importance (10=most important, 1=least important)
Improvement of capability / knowledge & manpower of regulators	5	7.8
Provision of feedback loop on new regulation before implementation	4	8.3
Accept relevant/high quality test results from other sectors, species or regions	4	8.5
Less ad-hoc / frequent change of regulation	3	9.0
Less local protectionism (e.g. same standard applies to both local & MNC companies)	3	7.0
Base quality standards solely on animal health industry requirements	3	7.0
Use consultation & impact assessment when developing new guidelines	2	8.5
Change test requirements only with scientific justification	2	4.5
Better border control (to prevent illegal products entering the market)	2	5.0
Remove political involvement in testing and approval	2	6.0
Provision of a comprehensive data protection package covering all major investments in product enhancements other than product extensions	1	3.0
Remove redundant and overlapping guidelines	1	10.0
Provide specific incentives to develop new products for small markets	1	6.0

F3a. The following have been identified as ISSUES that would have impact on PROUDCT REGISTRATION ACHIEVEMENT – which of these have occurred, and which have had or might still have the greatest positive impact on your ability to ACHIEVE PROUDCT REGISTRATION?

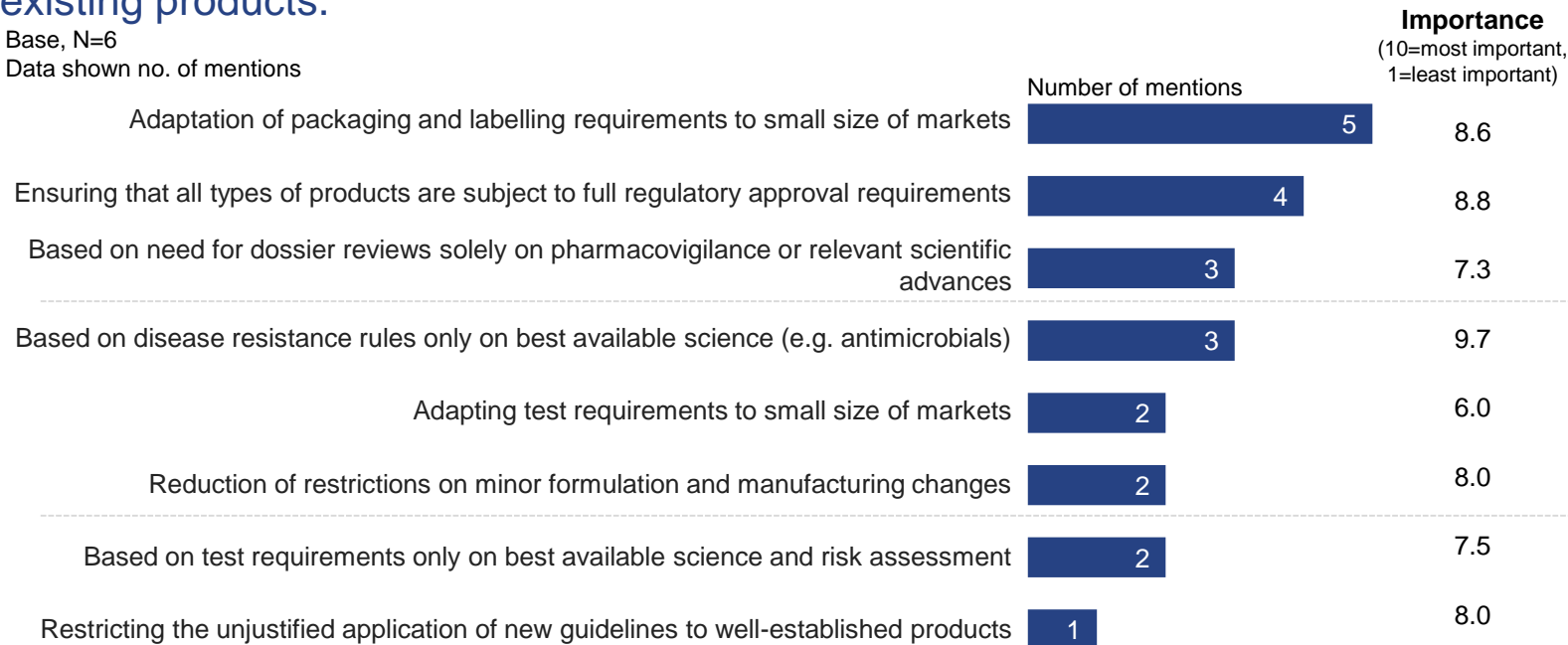
REGIONAL: Issues that have occurred, and would have (positive) impact on performing maintenance of registration of existing products

The adaptation of packaging and labelling requirements to small size of markets and ensuring that all types of products are subject to full regulatory approval requirements are hailed could have positive impact on maintaining registration of existing products.



Base, N=6

Data shown no. of mentions



F3b. The following have been identified as ISSUES that would have impact on the industry's ability to PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS – which of these have occurred, and which have had or might still have the greatest positive impact on your ability to PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS?

REGIONAL: Expected regulatory framework changes that have not occurred since 2014

## Harmonization of requirements across ASEAN countries are expected regulatory framework changes that have not occurred since 2014

kynetec



Base, N=6

Data shown no. of mentions

Expected regulatory framework changes that have not occurred since 2014	No of mentions
Harmonization of requirements across ASEAN countries	3
Transfer of veterinary medicine registration under the Philippines FDA from BAI (mentioned by CEVA)	1
Change of registration flow process to speed up registration time	1
Increase in fee for faster service	1
Consultation with animal health companies before proceeding with major regulatory changes	1

F4. What expected changes have NOT occurred in regulatory frameworks SINCE 2014 despite of expectations of change?

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Difficult GMP clearance is considered the changes in regulatory since 2014 that caused most problem.



Base, N=6

Data shown no. of mentions

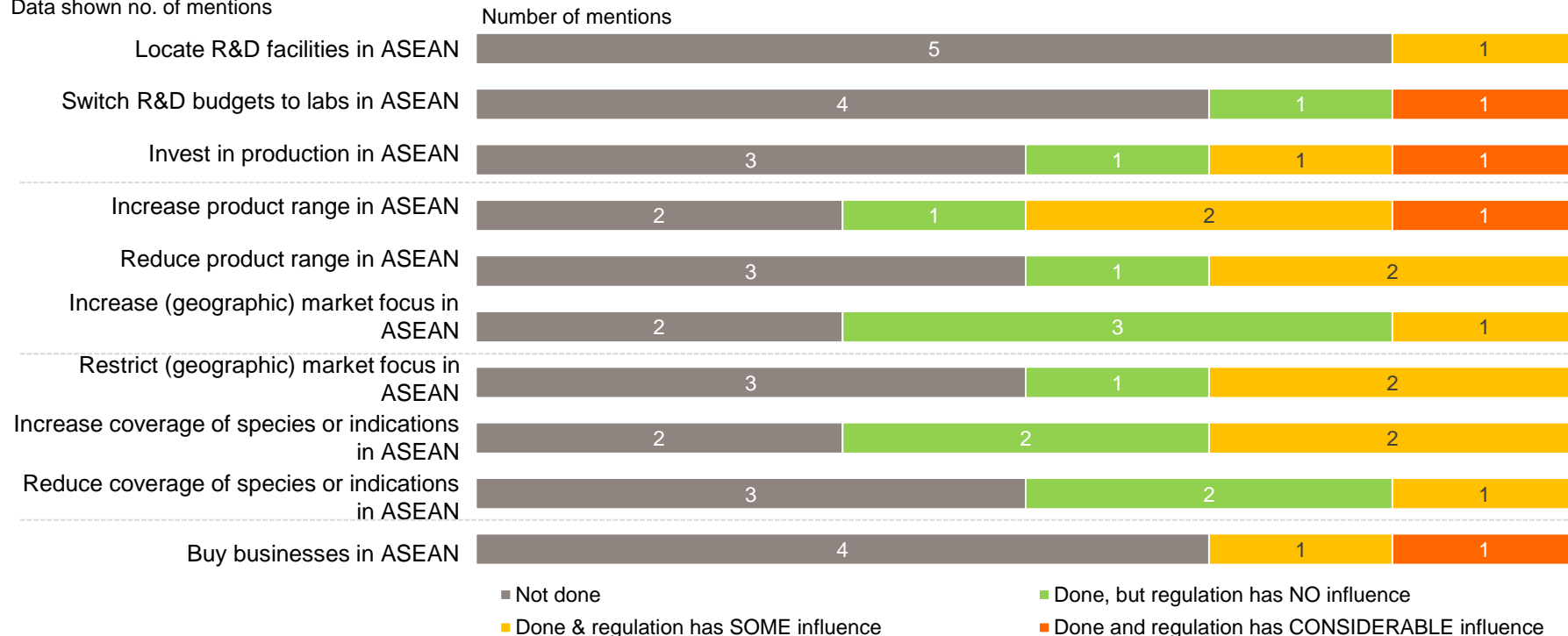
Regulatory change since 2014 that has given most problems	No of mentions
Difficult GMP clearance	4
Implementation of AMR related restrictions on the use of anticroccidials without appropriate consultation and systems in place for better oversight	1
Local protectionism (e.g., evidence of vaccine strains existence in Indonesia)	1
Lack of skilled dossier readers which affects consistency and speed of dossier evaluation	1
Laboratories are incapable of conducting some testing methods	1
Country specific label for even small volume products	1
Requirement for FSC - ASEAN will not be the first globally to register a product but has to wait until others have already registered the product	1
New requirements i.e. manufacturer ISO certification, Halal certification, new compound entity registration for compound not been registered in country	1

# Increase product range in ASEAN, introduce more 'breakthrough' products and focus on new technologies in ASEAN are major decisions taken over the past 5 years due to regulation in place



Base, N=6

Data shown no. of mentions



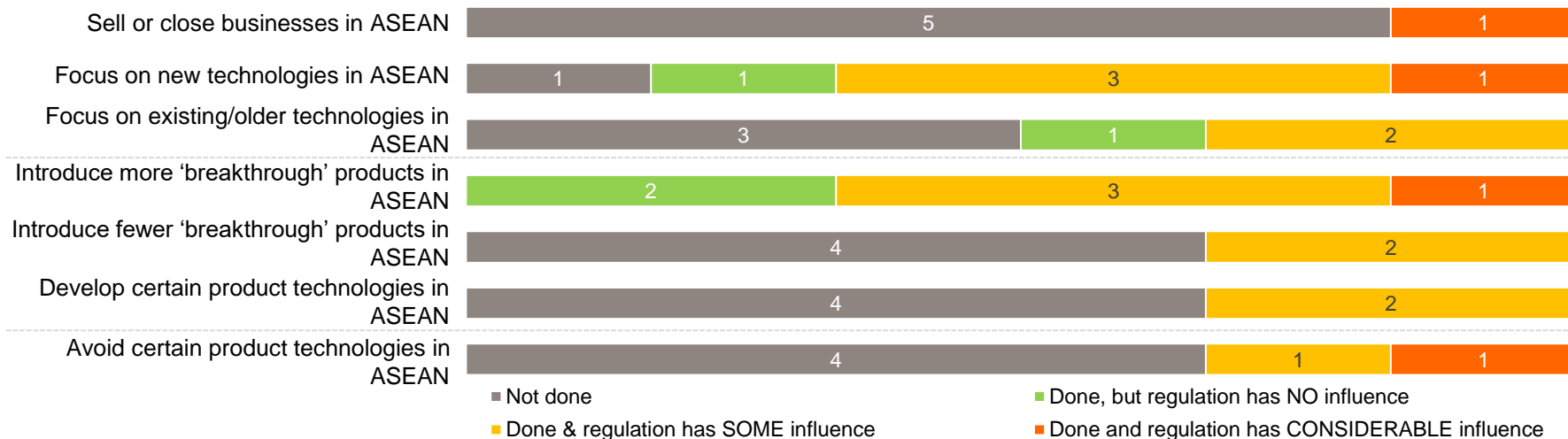
## Increase product range in ASEAN, introduce more 'breakthrough' products and focus on new technologies in ASEAN are major decisions taken over the past 5 years due to regulation in place



Base, N=6

Data shown no. of mentions

Number of mentions



More than two thirds of managers do not considered current product registration achievement is conducted with honest, independent and free from political/commercial influence. It is also said the review process is not consistent and predictable. Interestingly, this feedbacks are more prominent amongst non-MNC companies

Base, N=9 (combined both MNC & Non-MNC)

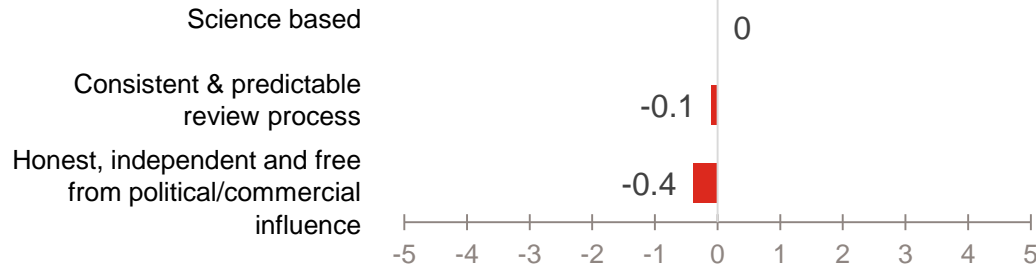
Data shown no. of mentions



Base, N=9

Data shown mean score

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



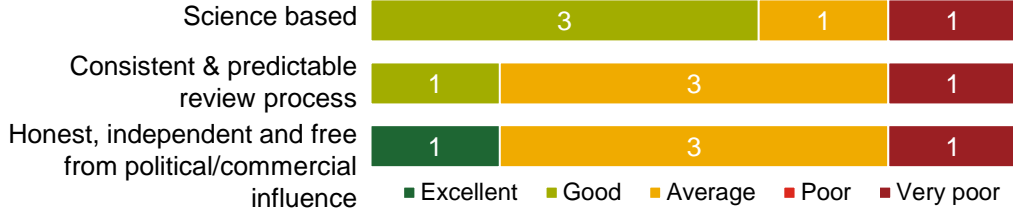
F1. Thinking about CURRENT PRODUCT REGISTRATION ACHIEVEMENT, how well do you consider it is conducted/done based on: science based, consistent & predictable review process, honest, independent & free from political / commercial influence. F1b: COMPARE TO 2014 and NOW on PRODUCT REGISTRATION ACHIEVEMENT, how well do you consider it is conducted/done based on:



More than two thirds of managers do not considered current product registration achievement is conducted with honest, independent and free from political/commercial influence. It is also said that the review process is not consistent and predictable. Interestingly, this feedbacks are more prominent amongst non-MNC companies

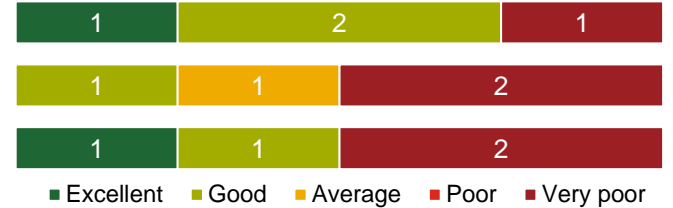
**MNC** Current product registration achievement

Number of mentions (Base: MNC, n=5)



**Non-MNC** Current product registration achievement

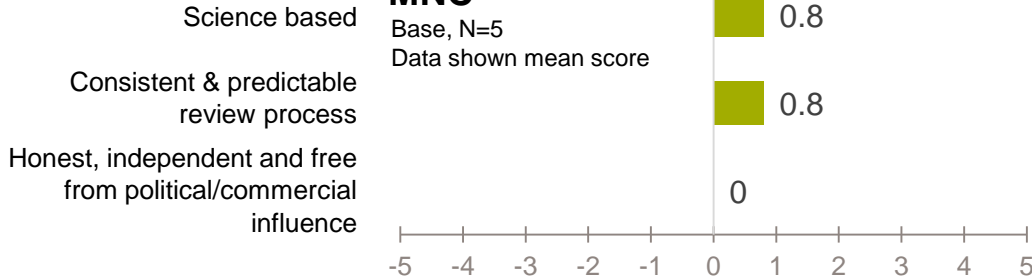
Number of mentions (Base: Non-MNC, n=4)



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

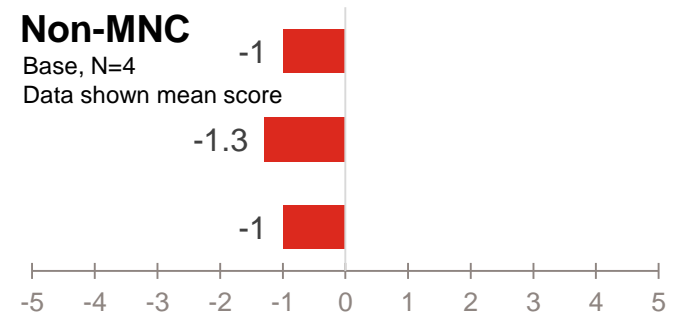
**MNC**

Base, N=5  
Data shown mean score



**Non-MNC**

Base, N=4  
Data shown mean score

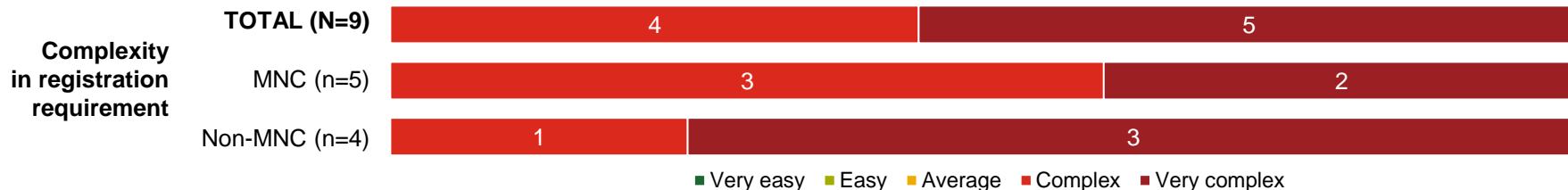


F1. Thinking about CURRENT PRODUCT REGISTRATION ACHIEVEMENT, how well do you consider it is conducted/done based on: science based, consistent & predictable review process, honest, independent & free from political / commercial influence. F1b: COMPARE TO 2014 and NOW on PRODUCT REGISTRATION ACHIEVEMENT, how well do you consider it is conducted/done based on:

All regulatory managers claimed current product registration is very complex. However, some MNCs have noticed some slight improvement compared to 5 years before

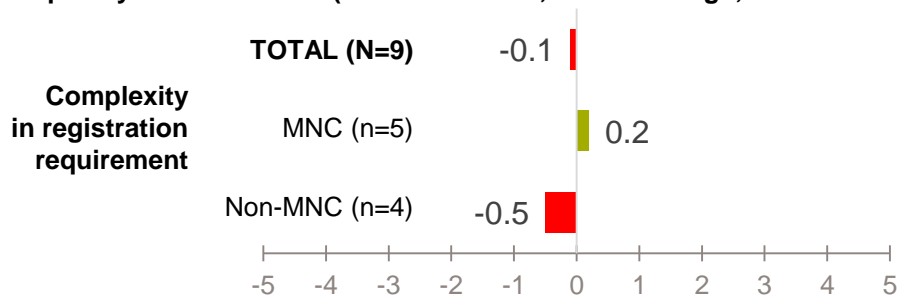
Base, N=9  
Data shown no. of mentions

Current product registration complexity



Base, N=9  
Data shown mean score

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



F2. Thinking about CURRENT PRODUCT REGISTRATION COMPLEXITY, how well do you consider it is conducted/done based on: science based, consistent & predictable review process, honest, independent & free from political / commercial influence

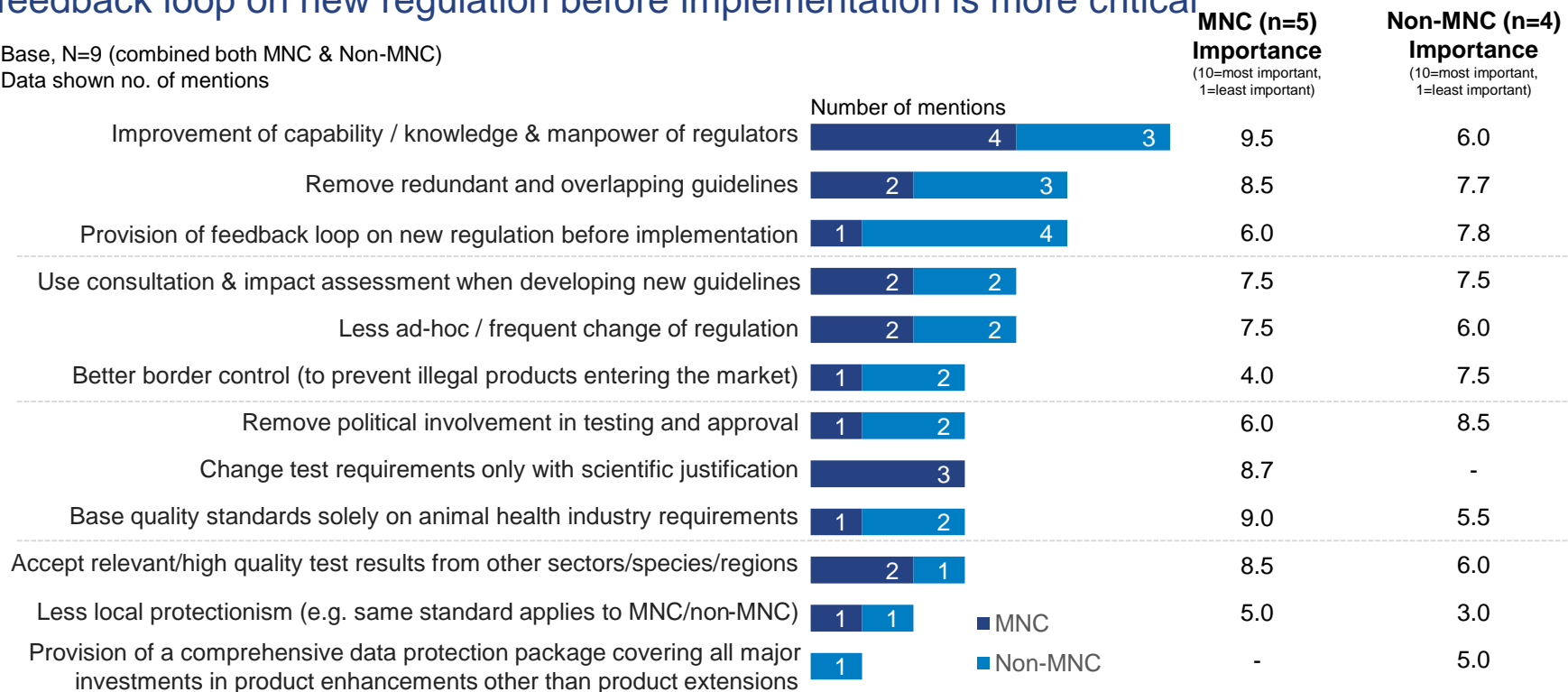
F2b: COMPARE TO 2014 and NOW on PRODUCT REGISTRATION COMPLEXITY, how well do you consider it is conducted/done based on:

# Improvement of capability / knowledge & manpower of regulators has positive impact on product registration achievement for MNC companies, whilst non-MNC felt provision of feedback loop on new regulation before implementation is more critical



Base, N=9 (combined both MNC & Non-MNC)

Data shown no. of mentions

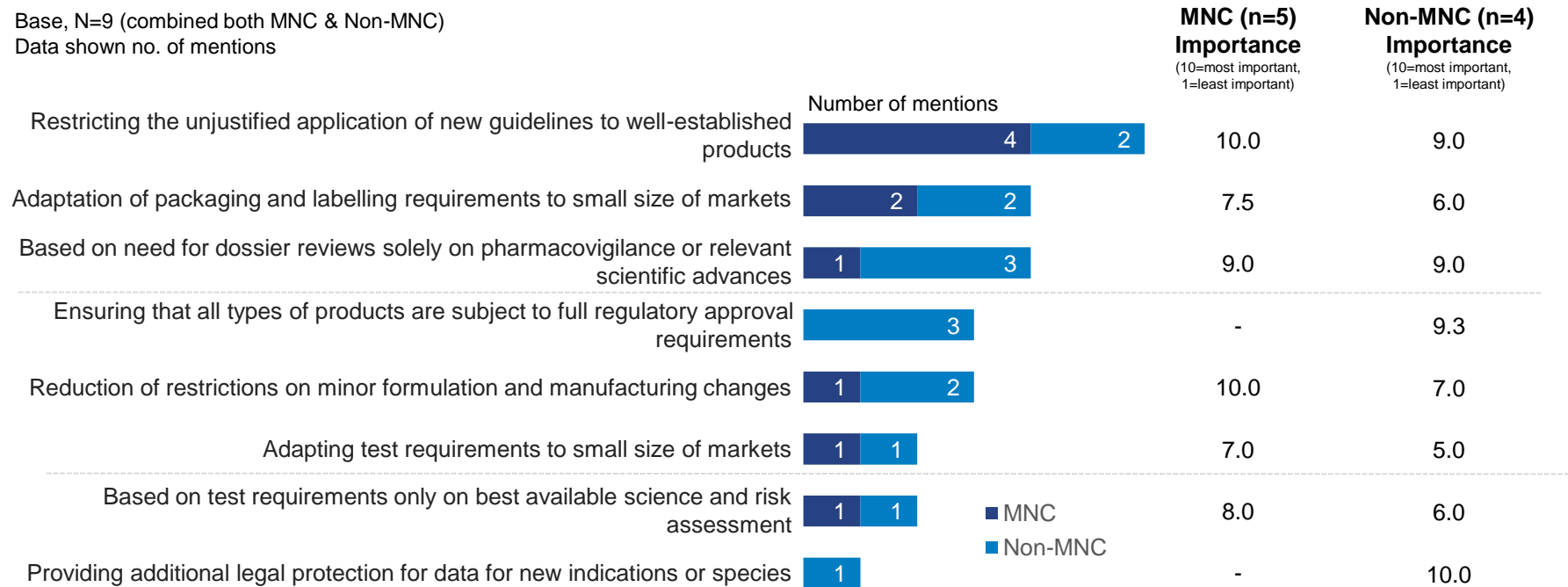


F3a. The following have been identified as ISSUES that would have impact on PROUDCT REGISTRATION ACHIEVEMENT – which of these have occurred, and which have had or might still have the greatest positive impact on your ability to ACHIEVE PROUDCT REGISTRATION?

# Restricting the unjustified application of new guidelines to well-established products have huge positive impact in maintenance of registration of existing products



Base, N=9 (combined both MNC & Non-MNC)  
Data shown no. of mentions



F3b. The following have been identified as ISSUES that would have impact on the industry's ability to PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS – which of these have occurred, and which have had or might still have the greatest positive impact on your ability to PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS?

## Across the board, regulatory managers claimed improvement of quality of evaluation of products from govt. agencies has not happened

Data shown no. of mentions

Expected regulatory framework changes that have not occurred since 2014	No. of mentions		
	TOTAL (N=9)	MNC (n=5)	Non – MNC (n=4)
Improvement of quality of evaluation of products from the government agency	3	2	1
Product sample is required for analysis as part of product (pharmaceutical & in-feed medications) registration requirements	1	-	1
Consolidate veterinary product registration under one authority	1	-	1
Resolving the issue of uncertainties of rules and regulations in veterinary sector	1	1	-
Resolving the issue of using pesticides requirement to regulate veterinary products like disinfectant who has never been regulated before	1	1	-

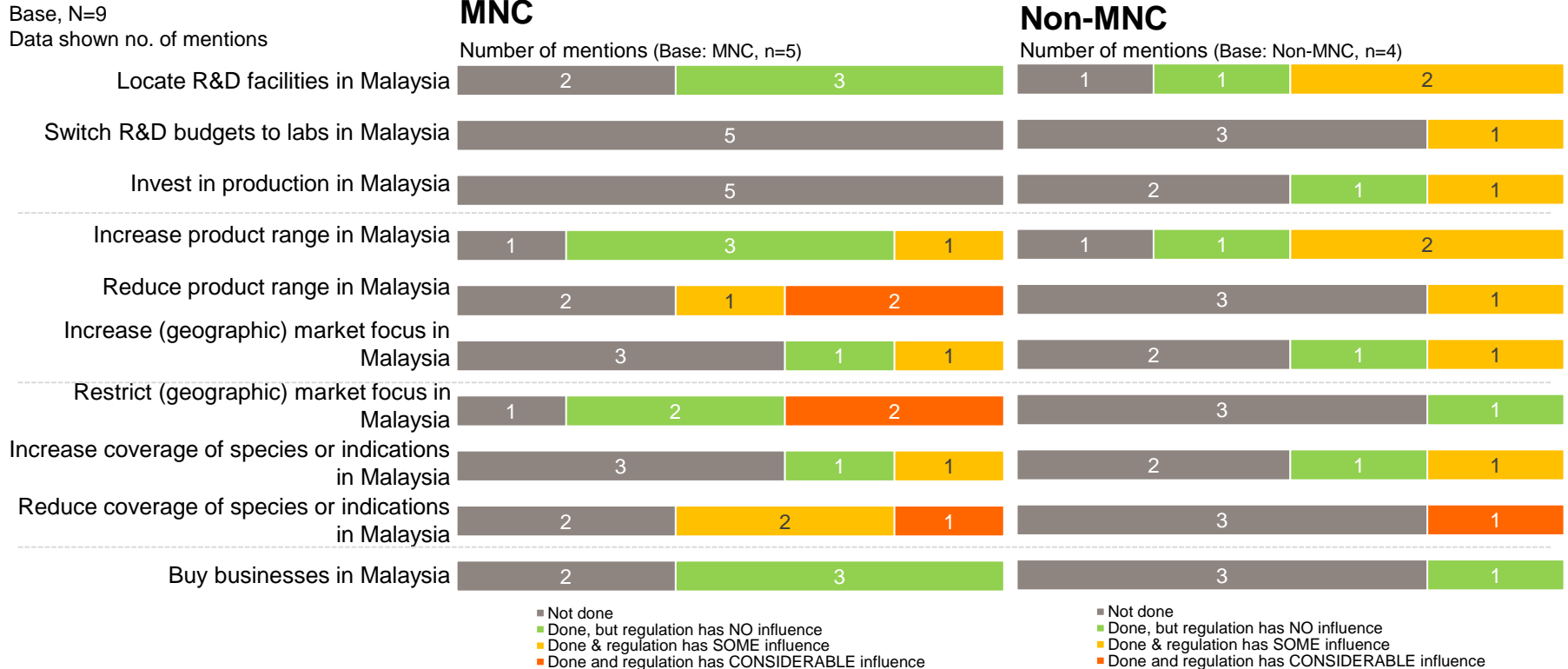
## Lack of skilled dossier readers and very strict new product registration (new chemical entity) are changes in regulatory since 2014 that caused biggest problem



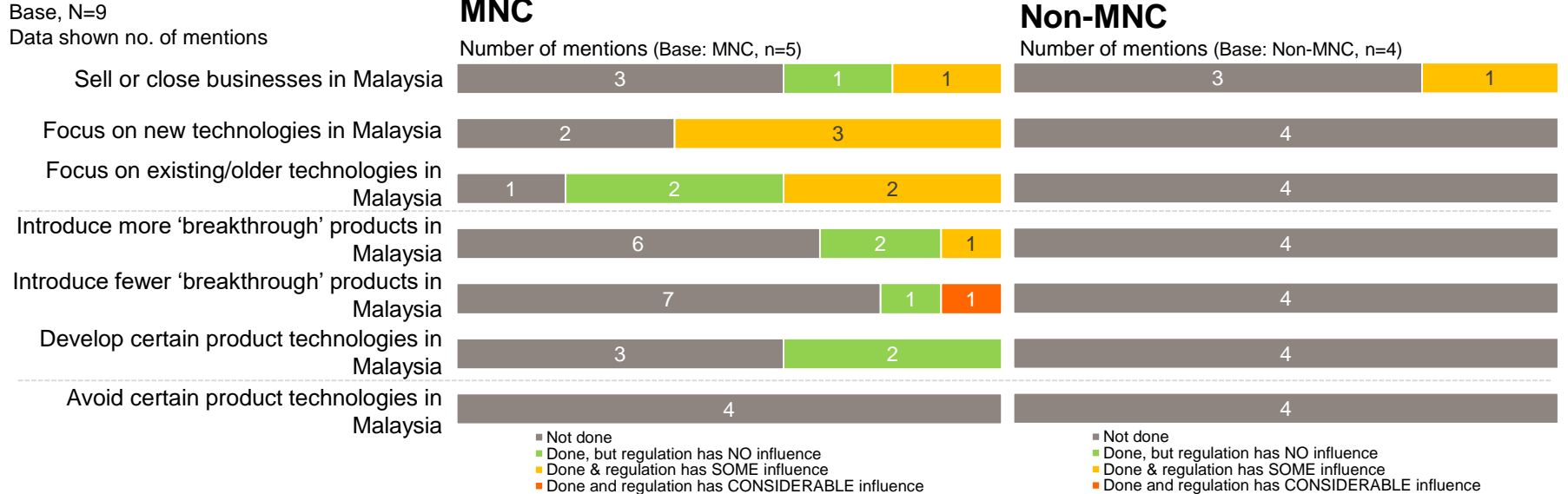
Data shown no. of mentions

Regulatory change since 2014 that has given most problems	No. of mentions		
	TOTAL (N=9)	MNC (n=5)	Non – MNC (n=4)
Lack of skilled dossier readers which affects consistency and speed of dossier evaluation	4	3	1
New product registration (new chemical entity) evaluation is very strict even though the product has been approved by EMA	3	2	1
New regulation on the use of medicated feed and hormones in feed	2	-	2
Pesticide Board requirement very strict and not applicable to vet products	2	2	-
Complicated system to get approval for the changing of existing label	1	-	1
Internal policies changes	1	-	1
More details on active pharmaceutical ingredient (API) information and quality control which affects the delay of finished product approval	1	-	1

For MNC, reduced product range, restricted market focus and focus on new technologies had taken place due to regulations in place. For non-MNC some had located their R&D facilities in Malaysia and increased product range since 5 years ago



For MNC, reduced product range, restricted market focus and focus on new technologies had taken place due to regulations in place. For non-MNC some had located their R&D facilities in Malaysia and increased product range since 5 years ago





Managers are concerned about current product registration achievement is related primarily to inconsistency and unpredictable review process. It is said compared to 2014, the current product registration achievement is better on: science based, consistency, predictability and independent & free from political/commercial influence

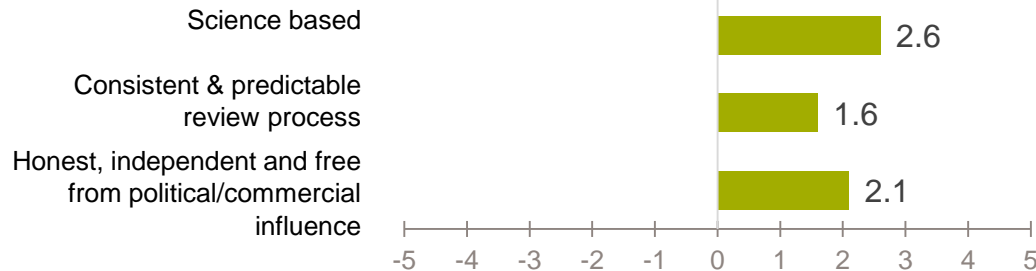
Base, N=12 (combined both MNC & Non-MNC)  
Data shown no. of mentions



Base, N=12

Data shown mean score

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



F1. Thinking about CURRENT PRODUCT REGISTRATION ACHIEVEMENT, how well do you consider it is conducted/done based on: science based, consistent & predictable review process, honest, independent & free from political / commercial influence. F1b: COMPARE TO 2014 and NOW on PRODUCT REGISTRATION ACHIEVEMENT, how well do you consider it is conducted/done based on:

# Expectedly, non-MNC companies felt current climate on product registration achievement is more positive compared to MNC companies



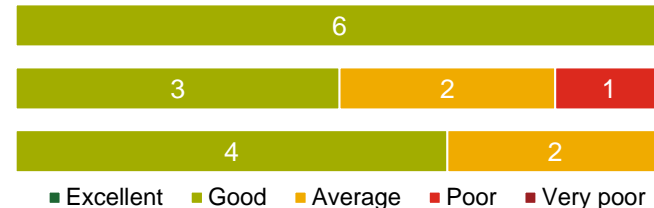
## MNC Current product registration achievement

Number of mentions (Base: MNC, n=6)



## Non-MNC Current product registration achievement

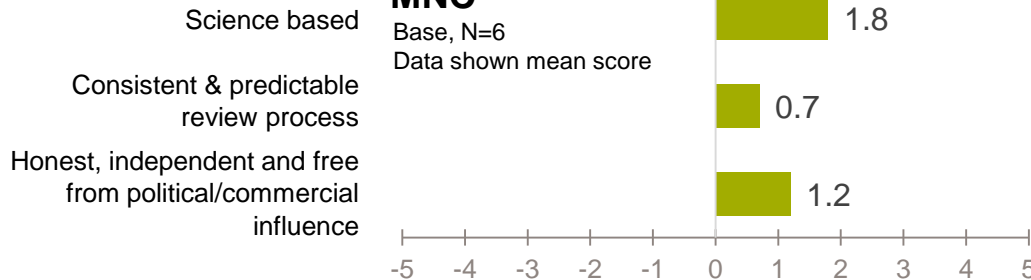
Number of mentions (Base: Non-MNC, n=6)



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

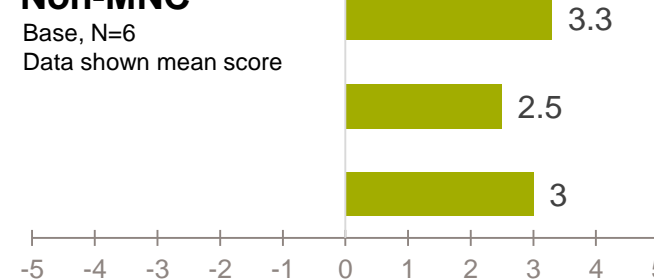
## MNC

Base, N=6  
Data shown mean score



## Non-MNC

Base, N=6  
Data shown mean score



F1. Thinking about CURRENT PRODUCT REGISTRATION ACHIEVEMENT, how well do you consider it is conducted/done based on: science based, consistent & predictable review process, honest, independent & free from political / commercial influence. F1b: COMPARE TO 2014 and NOW on PRODUCT REGISTRATION ACHIEVEMENT, how well do you consider it is conducted/done based on:



# Half of the regulatory managers claimed current product registration in Indonesia is complex. Only some MNC manages felt current product registration is not complex (easy), but it is more complex compared to 2014

Base, N=12

Data shown no. of mentions

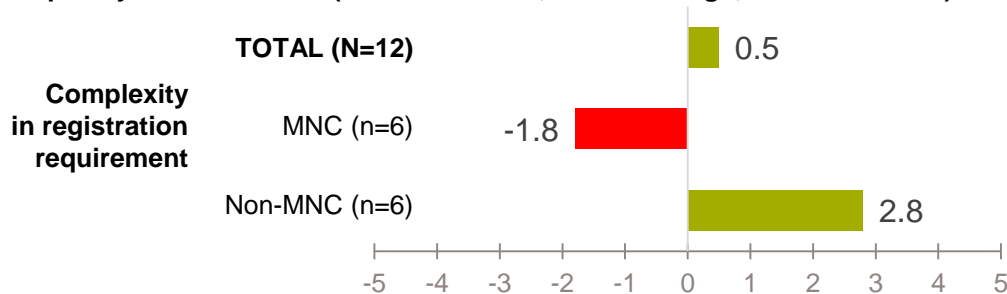
Current product registration complexity



Base, N=12

Data shown mean score

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



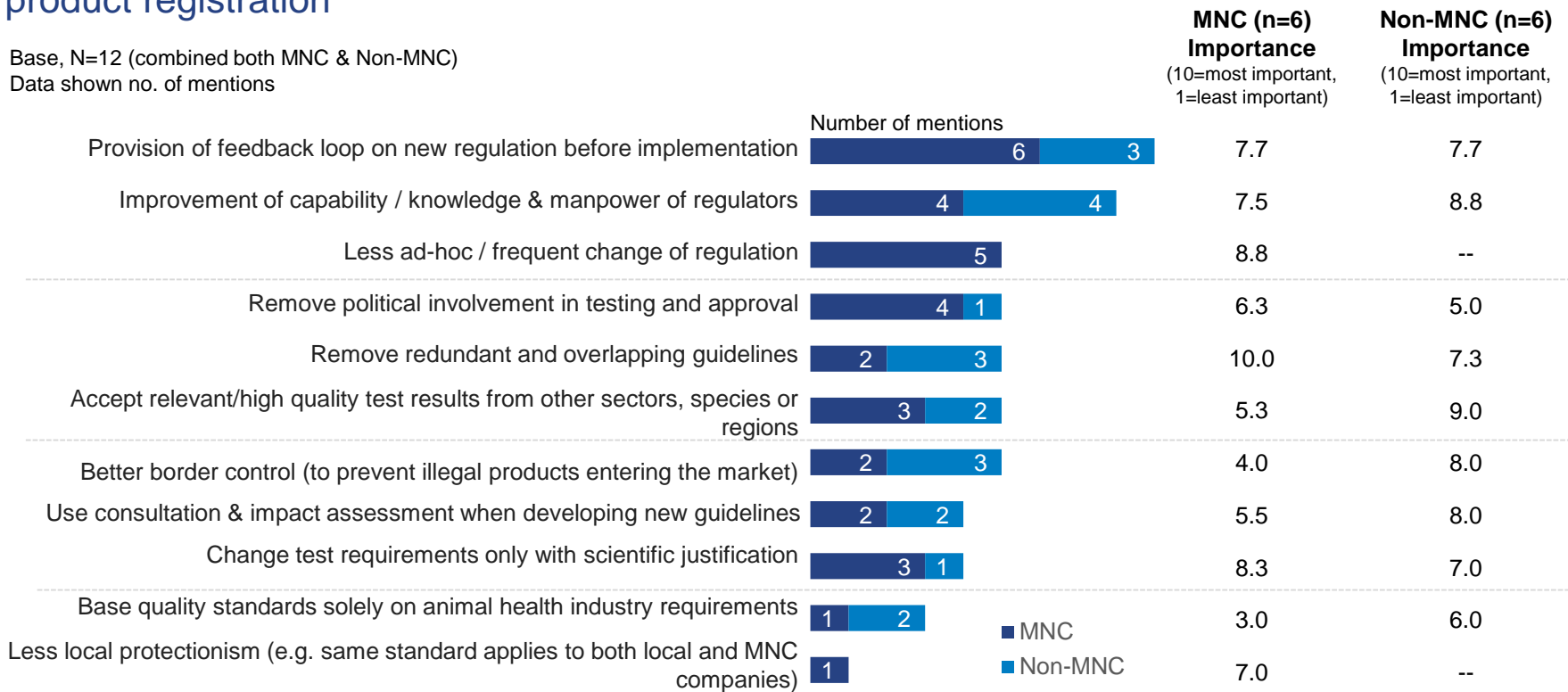
F2. Thinking about CURRENT PRODUCT REGISTRATION COMPLEXITY, how well do you consider it is conducted/done based on: science based, consistent & predictable review process, honest, independent & free from political / commercial influence

F2b: COMPARE TO 2014 and NOW on PRODUCT REGISTRATION COMPLEXITY, how well do you consider it is conducted/done based on:



# Provision of feedback loops on new regulation before implementation and improvement on capability / knowledge & manpower of regulators are likely to have positive impact in achieving product registration

Base, N=12 (combined both MNC & Non-MNC)  
Data shown no. of mentions

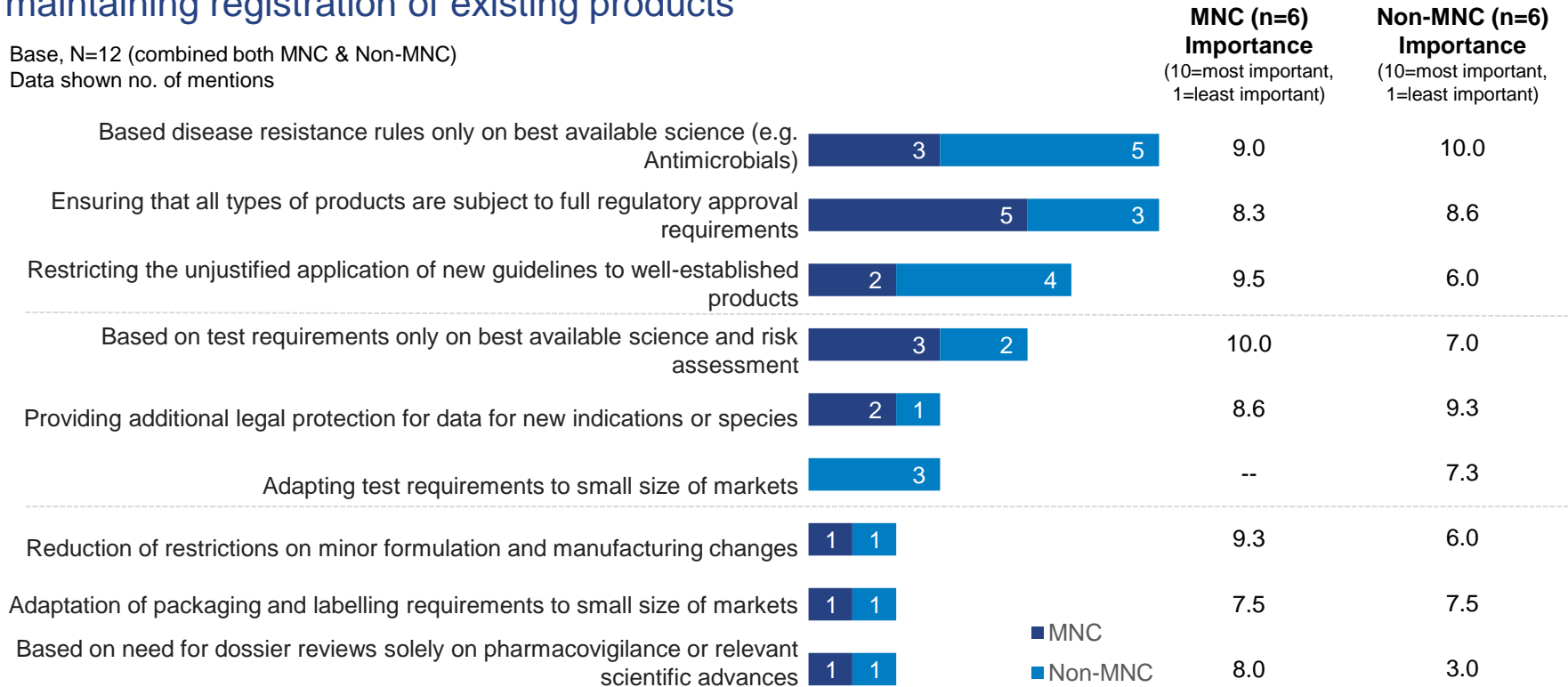


F3a. The following have been identified as ISSUES that would have impact on PROUDCT REGISTRATION ACHIEVEMENT – which of these have occurred, and which have had or might still have the greatest positive impact on your ability to ACHIEVE PROUDCT REGISTRATION?



## Following best available science for disease resistance rules and ensuring all types of products are subject to full regulatory approval requirements are expected to have positive impact in maintaining registration of existing products

Base, N=12 (combined both MNC & Non-MNC)  
Data shown no. of mentions



F3b. The following have been identified as ISSUES that would have impact on the industry's ability to PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS – which of these have occurred, and which have had or might still have the greatest positive impact on your ability to PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS?

There are multiple regulatory framework changes that not occurred since 2014 – resolve the issue of uncertainties in the regulation, simplified the registration checklist, not making transfer of technology compulsory and improve the quality of product evaluation



Data shown no. of mentions

Expected regulatory framework changes that have not occurred since 2014	No. of mentions		
	TOTAL (N=12)	MNC (n=6)	Non – MNC (n=6)
Resolving the issue of uncertainties of rules and regulations in the AH sector	3	1	2
Simplify the registration checklist	2	--	2
Not making transfer of technology compulsory for manufacturers	2	2	--
Improvement in quality of product evaluation from the government agency	2	2	--
Incentivize local companies for exporting products by easing the regulations and lowering recommendation fees	1	--	1
Change of registration flow process to speed up registration time	1	1	--
Not limit the number or types of products for re-registration	1	1	--
Regulation on supply and distribution of veterinary drug	1	1	--



## New regulation on usage of medicated feed and hormones in feeds and lack of skilled dossier reader have caused problem since the change in regulation from 2014

Data shown no. of mentions

Regulatory change since 2014 that has given most problems	No. of mentions		
	TOTAL (N=12)	MNC (n=6)	Non – MNC (n=6)
New regulation on the use of medicated feed and hormones in feed	3	3	--
Lack of skilled dossier readers which affects consistency and speed of dossier evaluation	2	2	--
Animal drug classification 14/PERMENTAN/ PK.350/5/2017 - Ban of AGP products caused some products to be unable to be sold	1	--	1
Business license procedures for the agricultural sector - Business license should follow OSS (Online Single Submission) system	1	--	1
Constant change of regulations itself without considering the public opinions and their own capabilities	1	--	1
Variation registration requirements are the same as new registration requirements	1	1	--
Complicated system to get an approval for the changing of existing label	1	1	--
Skepticism in efficacy and safety tests done by manufacturers	1	--	1

In the past 5 years, non-MNC had taken more major decision due to regulation in place compared to MNC companies. This non-MNC widened their coverage (with more products or cover more species) and introduced newer products / technologies



Base, N=12

Data shown no. of mentions

**MNC**

Number of mentions (Base: MNC, n=6)

**Non-MNC**

Number of mentions (Base: Non-MNC, n=6)





In the past 5 years, non-MNC had taken more major decision due to regulation in place compared to MNC companies. Non-MNC widened their coverage (with more products or cover more species) and introduced newer products / technologies



Base, N=12

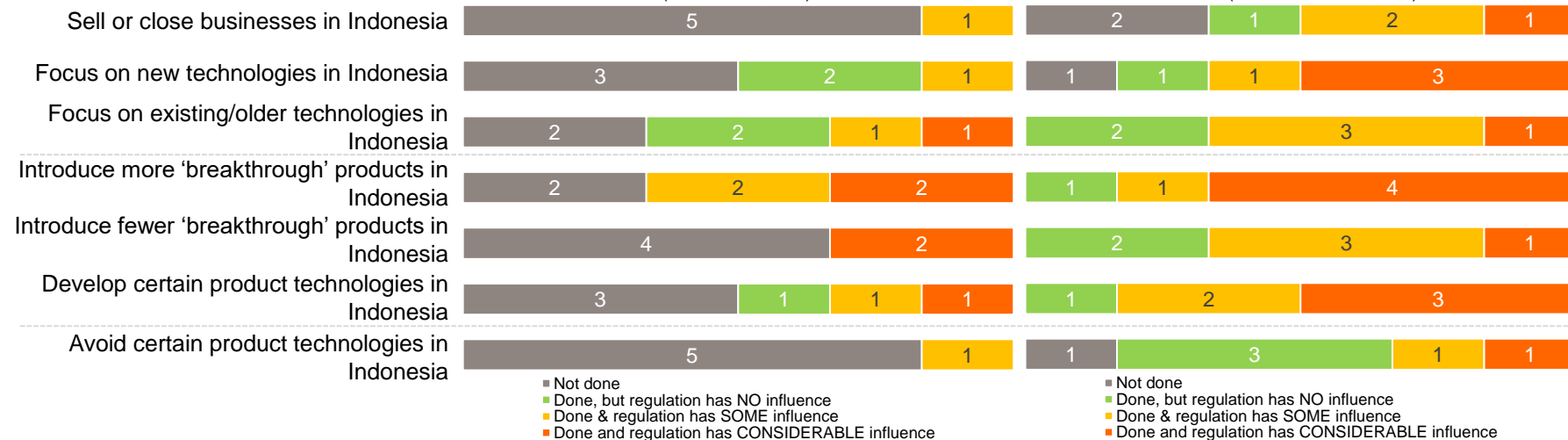
Data shown no. of mentions

### MNC

Number of mentions (Base: MNC, n=6)

### Non-MNC

Number of mentions (Base: Non-MNC, n=6)



Thailand is performing relatively well in all areas in creating a positive environment for AH companies to achieve product registration. This has brought a more positive change compared to 2014



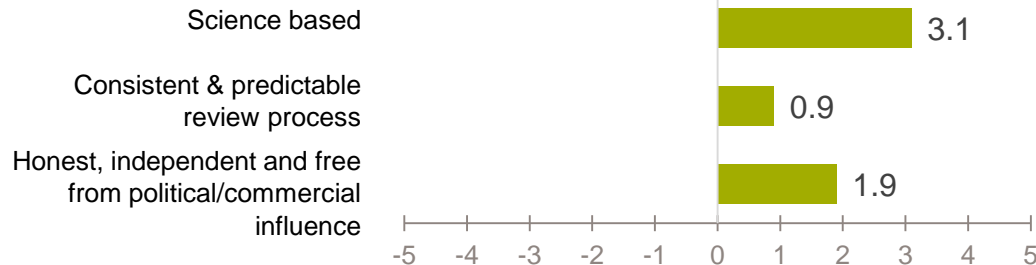
Base, N=8 (combined both MNC & Non-MNC)  
Data shown no. of mentions



Base, N=8

Data shown mean score

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



F1. Thinking about CURRENT PRODUCT REGISTRATION ACHIEVEMENT, how well do you consider it is conducted/done based on: science based, consistent & predictable review process, honest, independent & free from political / commercial influence. F1b: COMPARE TO 2014 and NOW on PRODUCT REGISTRATION ACHIEVEMENT, how well do you consider it is conducted/done based on:

Both MNC and non-MNC managers note better product registration compared to year 2014. However, MNC companies do believe there are rooms to improve on honest, independent and free from political / commercial influence



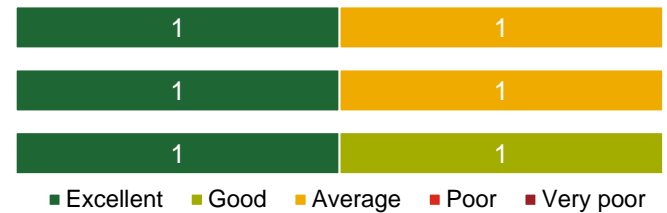
**MNC Current product registration achievement**

Number of mentions (Base: MNC, n=6)



**Non-MNC Current product registration achievement**

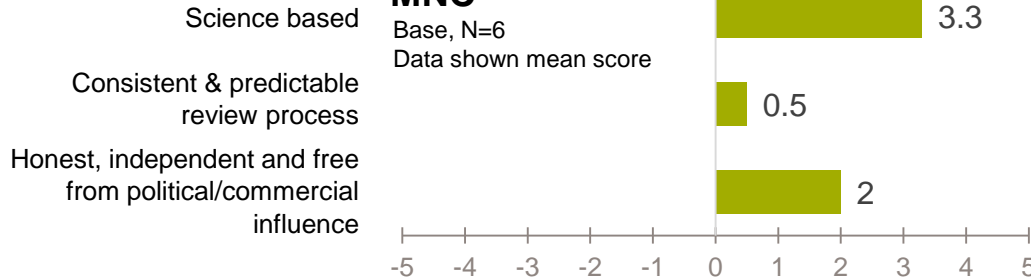
Number of mentions (Base: Non-MNC, n=2)



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

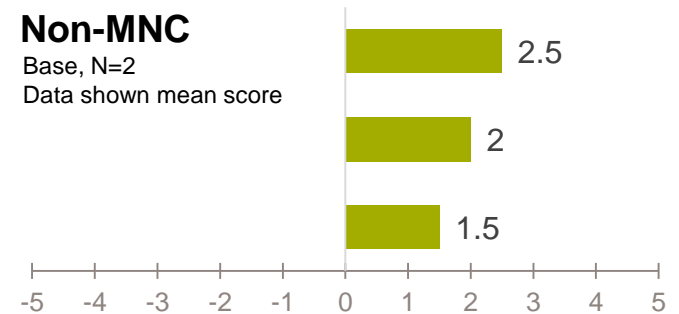
**MNC**

Base, N=6  
Data shown mean score



**Non-MNC**

Base, N=2  
Data shown mean score



F1. Thinking about CURRENT PRODUCT REGISTRATION ACHIEVEMENT, how well do you consider it is conducted/done based on: science based, consistent & predictable review process, honest, independent & free from political / commercial influence. F1b: COMPARE TO 2014 and NOW on PRODUCT REGISTRATION ACHIEVEMENT, how well do you consider it is conducted/done based on:

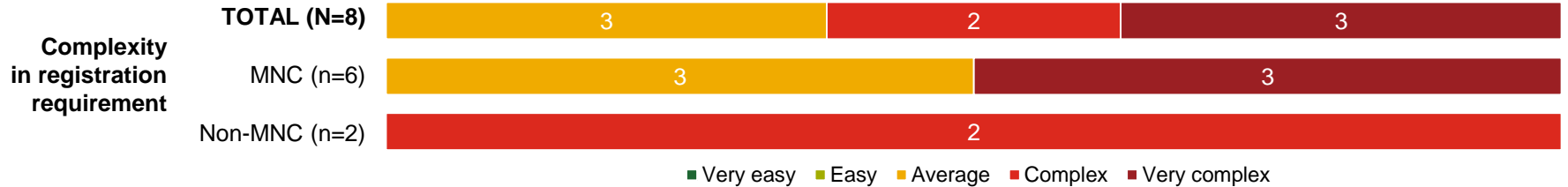
The more scientific approach in product evaluation has led to higher complexity in registration requirement that is mentioned by all non-MNCs managers. They said this has gotten a lot worse compared to last year



Base, N=8

Data shown no. of mentions

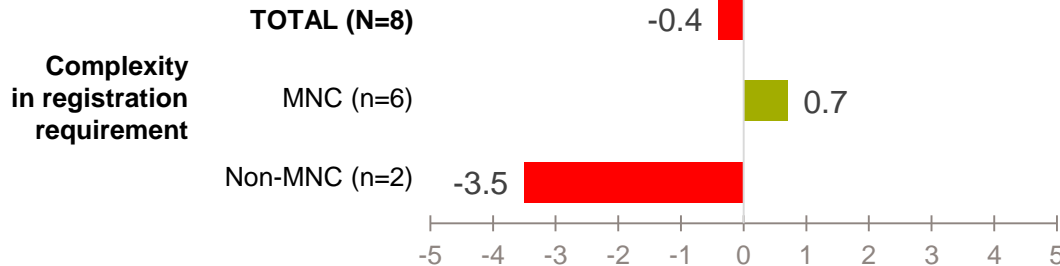
Current product registration complexity



Base, N=8

Data shown mean score

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

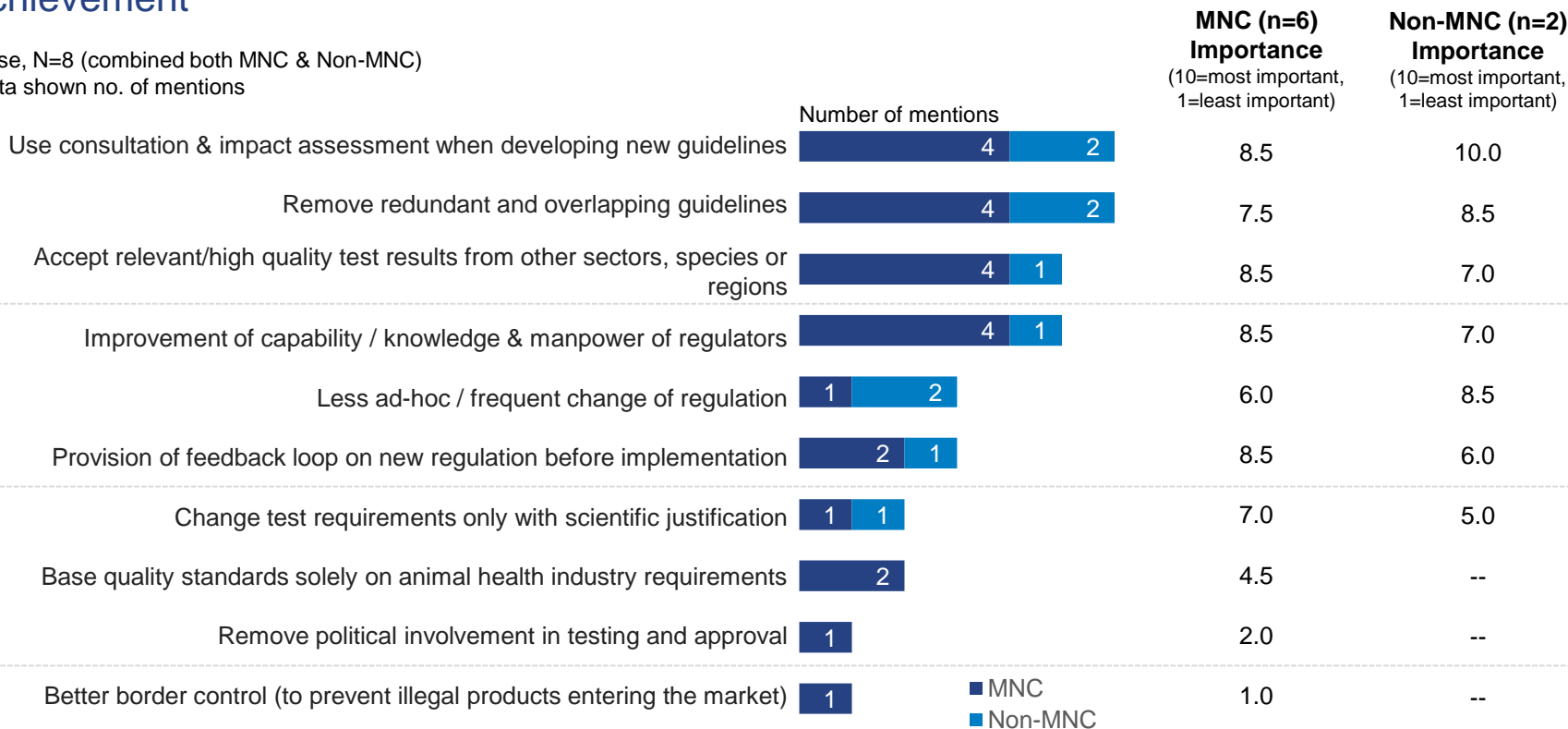


F2. Thinking about CURRENT PRODUCT REGISTRATION COMPLEXITY, how well do you consider it is conducted/done based on: science based, consistent & predictable review process, honest, independent & free from political / commercial influence. F2b: COMPARE TO 2014 and NOW on PRODUCT REGISTRATION COMPLEXITY, how well do you consider it is conducted/done based on:

# Using consultation & impact assessment when developing new guidelines is considered the most important factor to bring positive impact to product registration achievement



Base, N=8 (combined both MNC & Non-MNC)  
Data shown no. of mentions



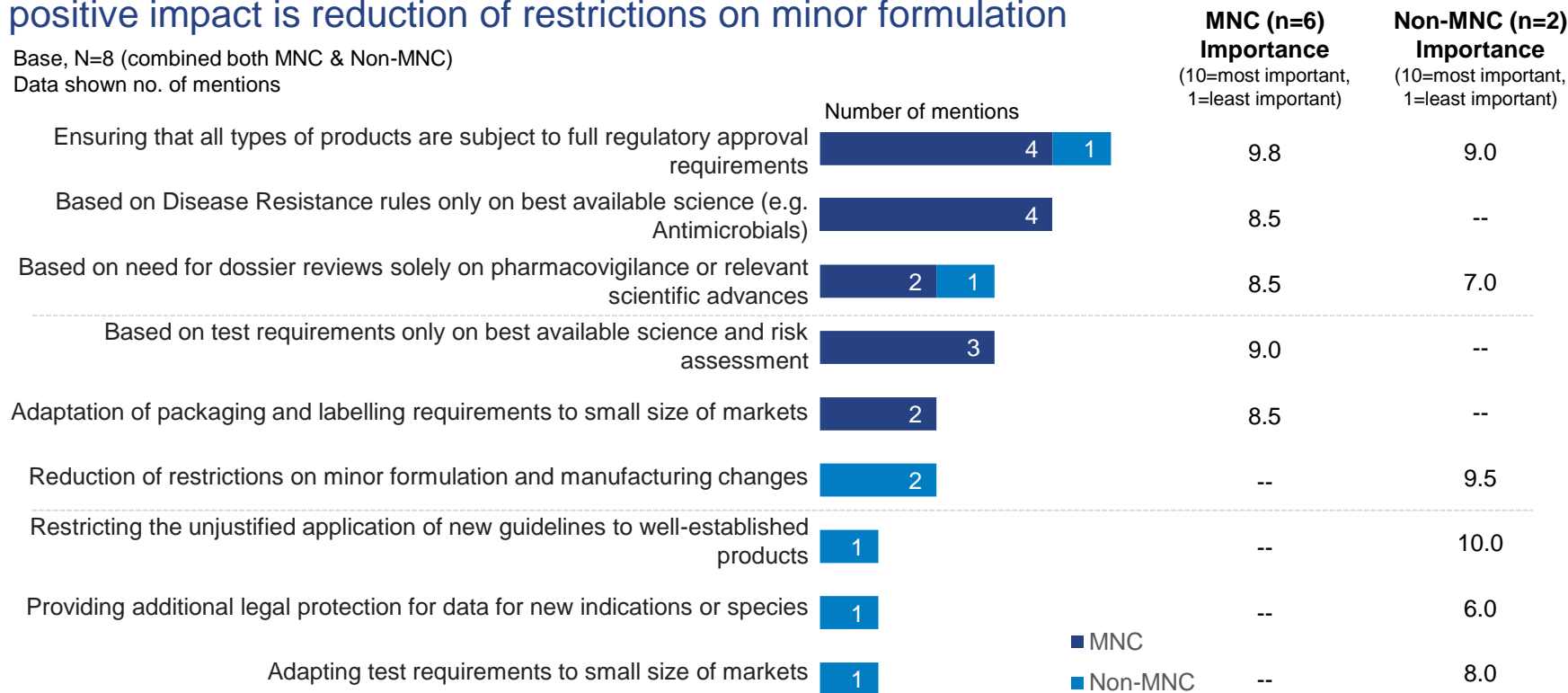
F3a. The following have been identified as ISSUES that would have impact on PROUDCT REGISTRATION ACHIEVEMENT – which of these have occurred, and which have had or might still have the greatest positive impact on your ability to ACHIEVE PROUDCT REGISTRATION?

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

# Ensuring all types of products are subject to full regulatory approval requirement is deemed to be the most positive impact by MNCs while the non-MNCs think the most positive impact is reduction of restrictions on minor formulation



Base, N=8 (combined both MNC & Non-MNC)  
Data shown no. of mentions



F3b. The following have been identified as ISSUES that would have impact on the industry's ability to PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS – which of these have occurred, and which have had or might still have the greatest positive impact on your ability to PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS?

THAILAND: Expected regulatory framework changes that have not occurred since 2014

## Most MNCs expected the update of registration guidelines specific for animal industry but this has not occurred since 2014



Data shown no. of mentions

Expected regulatory framework changes that have not occurred since 2014	No. of mentions		
	TOTAL (N=8)	MNC (n=6)	Non – MNC (n=2)
Updating of registration guidelines specific for animal industry	3	3	--
To implement bioequivalence	1	1	--
To have data exclusivity	1	1	--
Change of registration flow process to speed up registration time	1	--	1
Strong control to post marketing more than premarketing	1	1	--
Resolving the issue of uncertainties of rules and regulations in veterinary sector	1	1	--
None	1	--	1

F4. What expected changes have NOT occurred in regulatory frameworks SINCE 2014 despite of expectations of change?

© Kynetec June 11, 2019 | ASEAN Animal Health Regulatory Benchmarking Survey – Stage 3 (Online Quantitative)

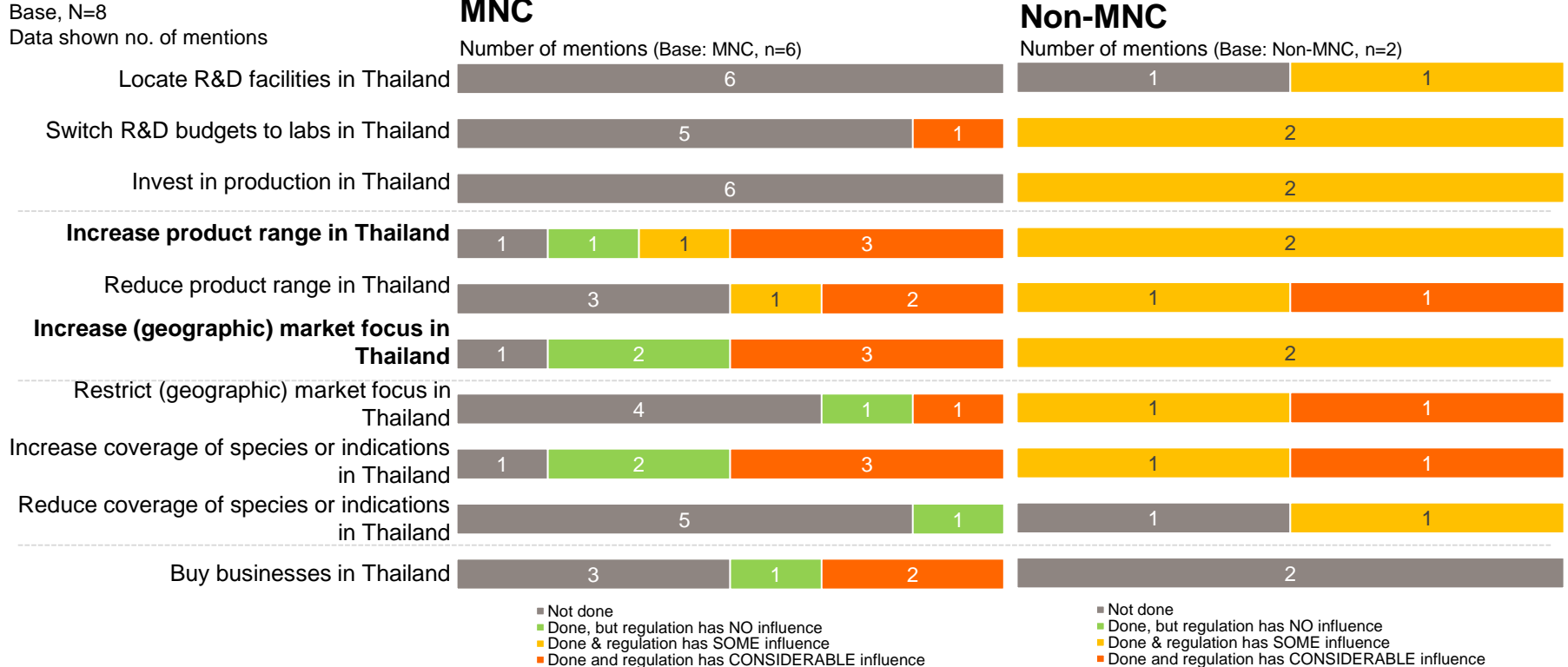
75% of MNCs agree that difficult GMP clearance have given them the most problem while all non-MNC feel that the constant change of regulations have given them a lot problem because the authorities did not seek for public opinion prior to implementation

Regulatory change since 2014 that has given most problems	No. of mentions		
	TOTAL (N=8)	MNC (n=6)	Non – MNC (n=2)
Difficult GMP clearance	6	6	--
Constant change of regulations itself, cannot cope up with the gush of new regulations that need to be adopted and implements regulations without considering the public opinions and their own capabilities	2	--	2
Registration fees increasing	1	--	1
Timeline is not practical based on the resource limitation of both authority officers and RA personnel	1	1	--
Unclear registration processes	1	1	--

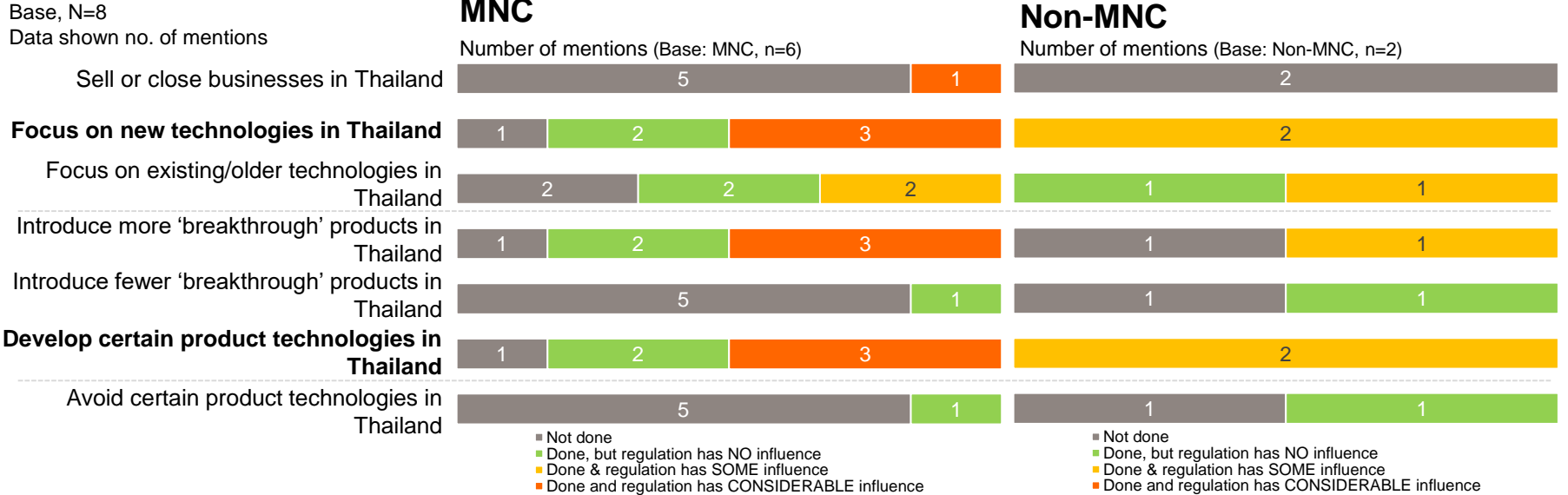
Data shown no. of mentions



# Most MNCs all non-MNC have increased their product range, market focus, develop new technologies in Thailand in the past 5 years due to regulations in place

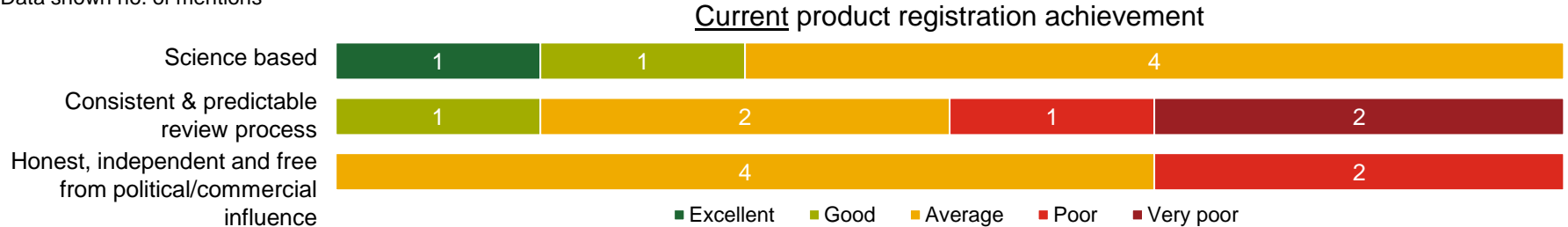


Most MNCs all non-MNC have increased their product range, market focus, develop new technologies in Thailand in the past 5 years due to regulations in place



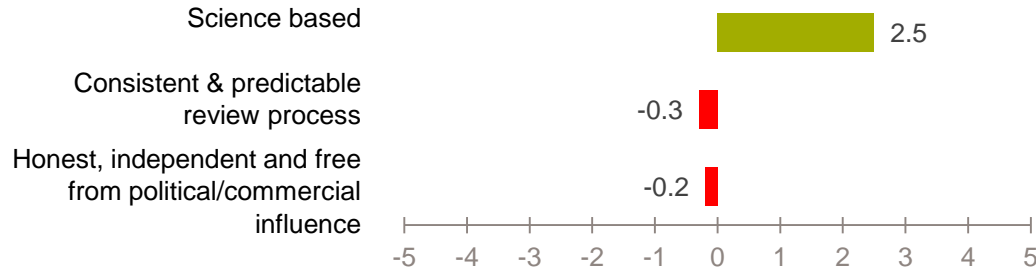
# The current climate on product registration achievement has approved a lot better due to product evaluation that is more scientifically based

Base, N=6  
Data shown no. of mentions



Base, N=6  
Data shown mean score

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



F1. Thinking about CURRENT PRODUCT REGISTRATION ACHIEVEMENT, how well do you consider it is conducted/done based on: science based, consistent & predictable review process, honest, independent & free from political / commercial influence. F1b: COMPARE TO 2014 and NOW on PRODUCT REGISTRATION ACHIEVEMENT, how well do you consider it is conducted/done based on:

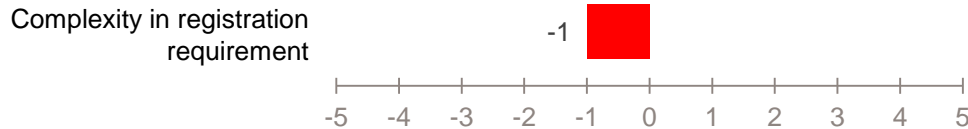
# Overall speaking, product registration in considered complex and has become slightly worse compared to 2014

Base, N=6  
Data shown no. of mentions



Base, N=6  
Data shown mean score

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



F2. Thinking about CURRENT PRODUCT REGISTRATION COMPLEXITY, how well do you consider it is conducted/done based on: science based, consistent & predictable review process, honest, independent & free from political / commercial influence. F2b: COMPARE TO 2014 and NOW on PRODUCT REGISTRATION COMPLEXITY, how well do you consider it is conducted/done based on:

# Most believe that capacity building of regulators, removing redundant guidelines and accept relevant test results from other sectors will bring significantly positive impact to product registration achievement

Base, N=6

Data shown no. of mentions



F3a. The following have been identified as ISSUES that would have impact on PROUDCT REGISTRATION ACHIEVEMENT – which of these have occurred, and which have had or might still have the greatest positive impact on your ability to ACHIEVE PROUDCT REGISTRATION?

# Most companies believe that ensuring all types of products are subject to full regulatory approval requirements is the most important factor in bringing positive impact in product registration maintenance



Base, N=6

Data shown no. of mentions



F3b. The following have been identified as ISSUES that would have impact on the industry's ability to PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS – which of these have occurred, and which have had or might still have the greatest positive impact on your ability to PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS?

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

## Resolving the issues of uncertainties of the rules and regulation and having clear guidelines that stick to pre-set timeline is still an expectation that has not been achieved by the Vietnamese regulatory authorities

Base, N=6

Data shown no. of mentions

Expected regulatory framework changes that have not occurred since 2014	No of mentions
Resolving the issue of uncertainties of rules and regulations in veterinary sector	1
Registration time adhering to pre-set rule	1
Separation of anticoccidial products from general Antimicrobial agents (AMR)	1
Harmonization of requirements among the ASEAN countries	1
None	2

VIETNAM: Regulatory change since 2014 that has given most problems

## Echoing the failed expectation in having clear registration process, this issue has also posed a significant problem since 2014



Base, N=6

Data shown no. of mentions

Regulatory change since 2014 that has given most problems	No of mentions
Unclear registration processes	2
Circular 13 on inspection of imported goods and Circular 18 on conformity of regulations, regulations on studying update stability and update in production process	2
Laboratories are incapable of conducting some testing methods	1
Requirement for regulatory trials for new products although Active Pharmaceutical (API) is not new because this is costly and time consuming	1

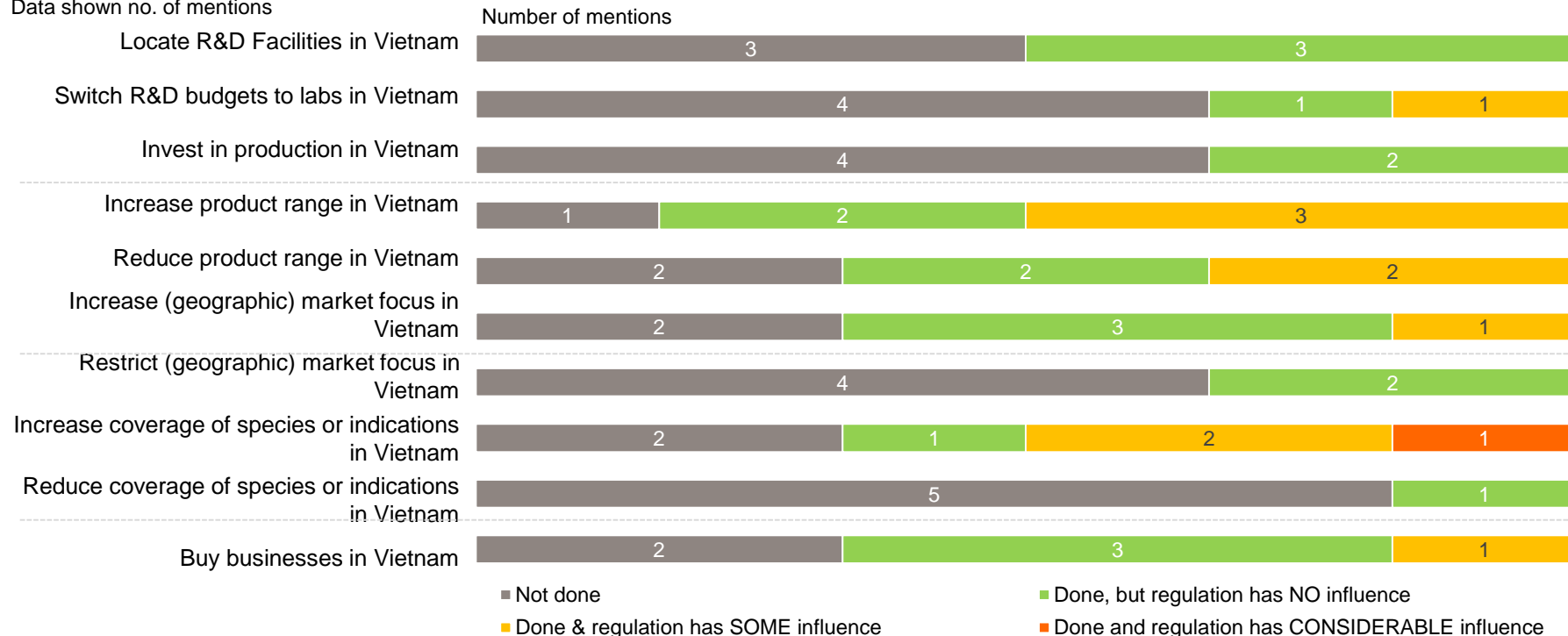


# Some companies think regulations have placed considerable influence them focusing on existing/older technologies in Vietnam while others influenced the coverage of species or indications in Vietnam



Base, N=6

Data shown no. of mentions



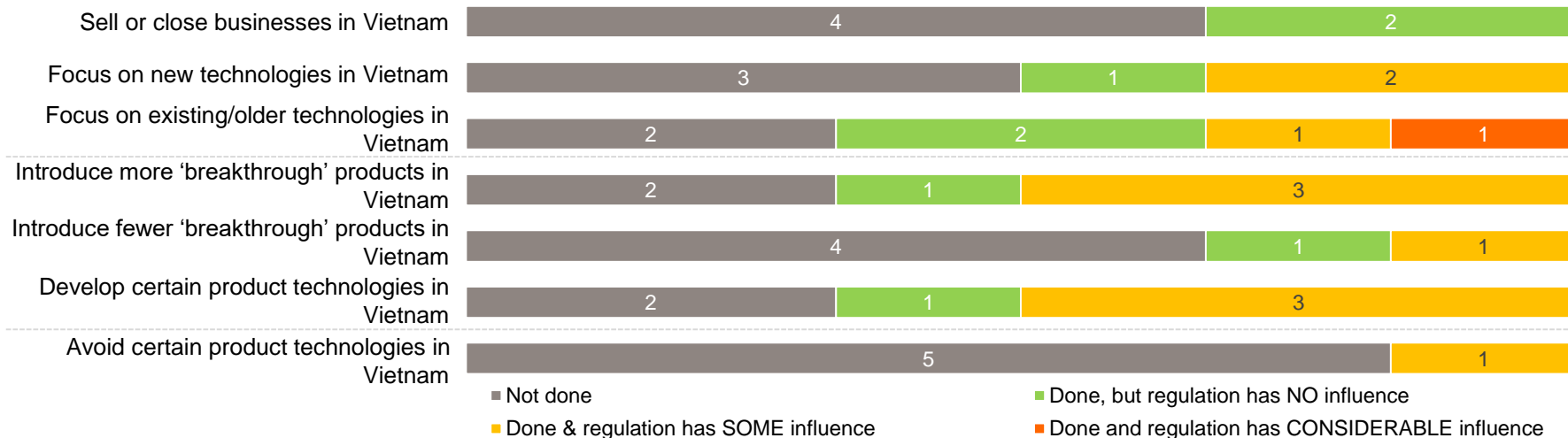
# Some companies think regulations have placed considerable influence them focusing on existing/older technologies in Vietnam while others influenced the coverage of species or indications in Vietnam



Base, N=6

Data shown no. of mentions

Number of mentions



Although most companies think the current product registration achievement is quite **kynetec** good, it is still seen as performing slightly worse compared to 2014



Base, N=9 (combined both MNC & Non-MNC)

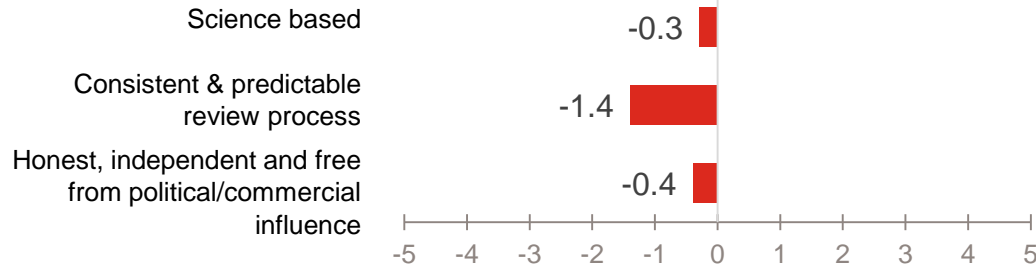
Data shown no. of mentions



Base, N=9

Data shown mean score

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



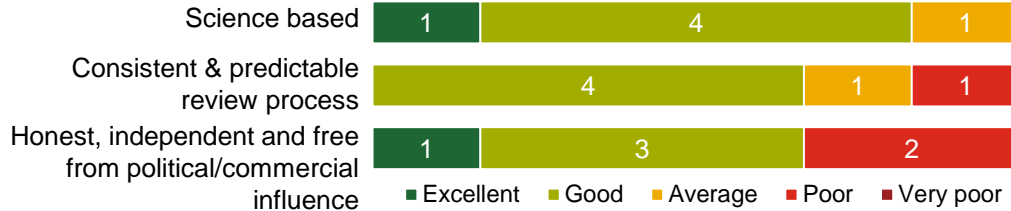
F1. Thinking about CURRENT PRODUCT REGISTRATION ACHIEVEMENT, how well do you consider it is conducted/done based on: science based, consistent & predictable review process, honest, independent & free from political / commercial influence. F1b: COMPARE TO 2014 and NOW on PRODUCT REGISTRATION ACHIEVEMENT, how well do you consider it is conducted/done based on:

Non-MNCs consider their current product registration achievement to be poorer than the MNCs. However they still think that the regulatory is performing slightly better in honesty and independence from other influences



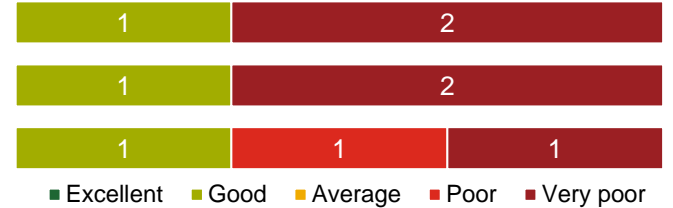
**MNC Current product registration achievement**

Number of mentions (Base: MNC, n=6)



**Non-MNC Current product registration achievement**

Number of mentions (Base: Non-MNC, n=3)

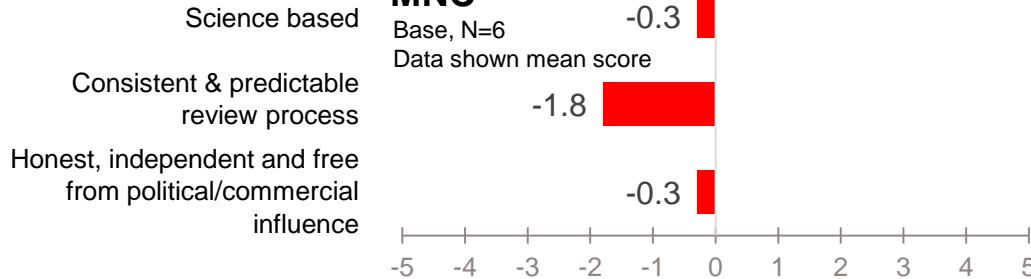


In comparison with 2014 (benchmark), is current product registration achievement better or worst (-5 = A lot worse, 0 = No change; +5=A lot better)

**MNC**

Base, N=6

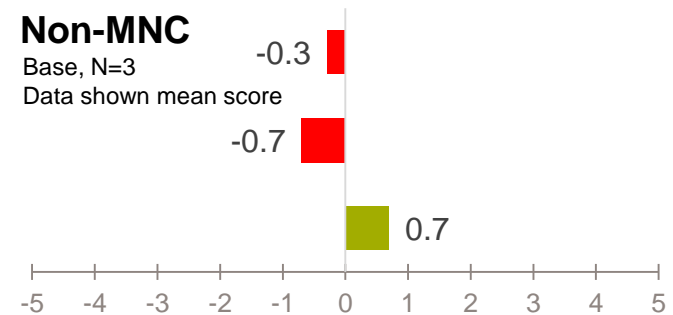
Data shown mean score



**Non-MNC**

Base, N=3

Data shown mean score



F1. Thinking about CURRENT PRODUCT REGISTRATION ACHIEVEMENT, how well do you consider it is conducted/done based on: science based, consistent & predictable review process, honest, independent & free from political / commercial influence. F1b: COMPARE TO 2014 and NOW on PRODUCT REGISTRATION ACHIEVEMENT, how well do you consider it is conducted/done based on:

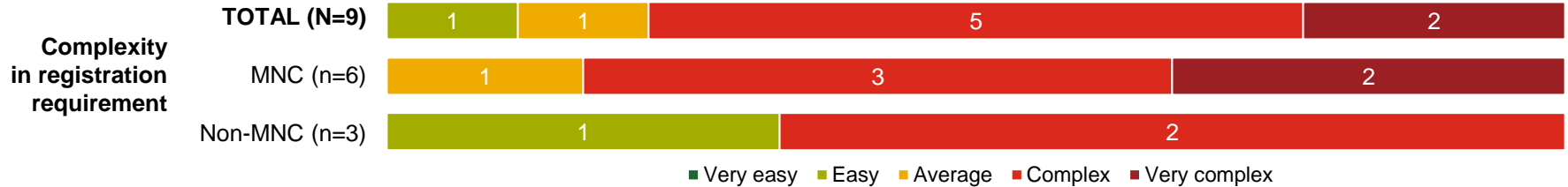
Almost all MNC and Non-MNCs think registration requirement is very complex and is seen as a step back to 5 years before 



Base, N=9

Data shown no. of mentions

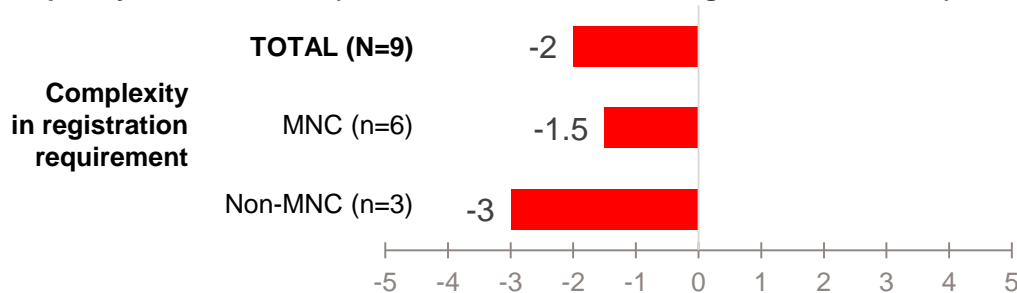
Current product registration complexity



Base, N=9

Data shown mean score

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



F2. Thinking about CURRENT PRODUCT REGISTRATION COMPLEXITY, how well do you consider it is conducted/done based on: science based, consistent & predictable review process, honest, independent & free from political / commercial influence

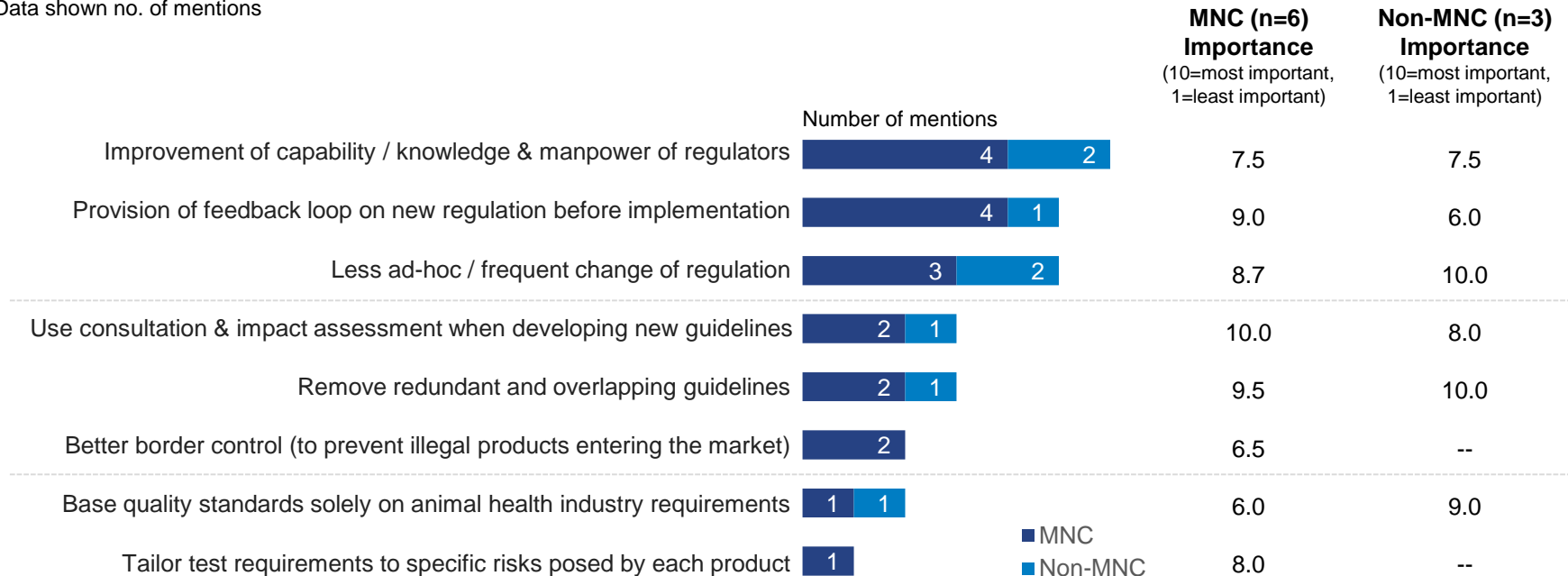
F2b: COMPARE TO 2014 and NOW on PRODUCT REGISTRATION COMPLEXITY, how well do you consider it is conducted/done based on:

PHILIPPINES: Issues that have occurred, and would have (positive) impact product registration achievement...(1)

# Both MNC and non-MNC consider improvement in capability/knowledge and manpower of regulators to have the most positive impact on product registration achievement



Base, N=9 (combined both MNC & Non-MNC)  
Data shown no. of mentions



F3a. The following have been identified as ISSUES that would have impact on PROUDCT REGISTRATION ACHIEVEMENT – which of these have occurred, and which have had or might still have the greatest positive impact on your ability to ACHIEVE PROUDCT REGISTRATION?

## Both MNC and non-MNC consider improvement in capability/knowledge and manpower of regulators to have the most positive impact on product registration achievement



Base, N=9 (combined both MNC & Non-MNC)

Data shown no. of mentions

	Number of mentions	MNC (n=6) Importance (10=most important, 1=least important)	Non-MNC (n=3) Importance (10=most important, 1=least important)
Change test requirements only with scientific justification	1	3.0	--
Provision of a comprehensive data protection package covering all major investments in product enhancements other than p	1	7.0	--
Less local protectionism (e.g. same standard applies to both local and MNC companies)	1	--	9.0
<hr/>			
Harmonize test or guideline interpretation and implementation within ASEAN	1	7.0	--
Remove political involvement in testing and approval	1	--	7.0
Harmonize test requirements internationally/ regionally	1	--	9.0
<hr/>			
Accept relevant/high quality test results from other sectors, species or regions	1	5.0	--
Adapt test requirements to reflect small size of markets	1	4.0	--

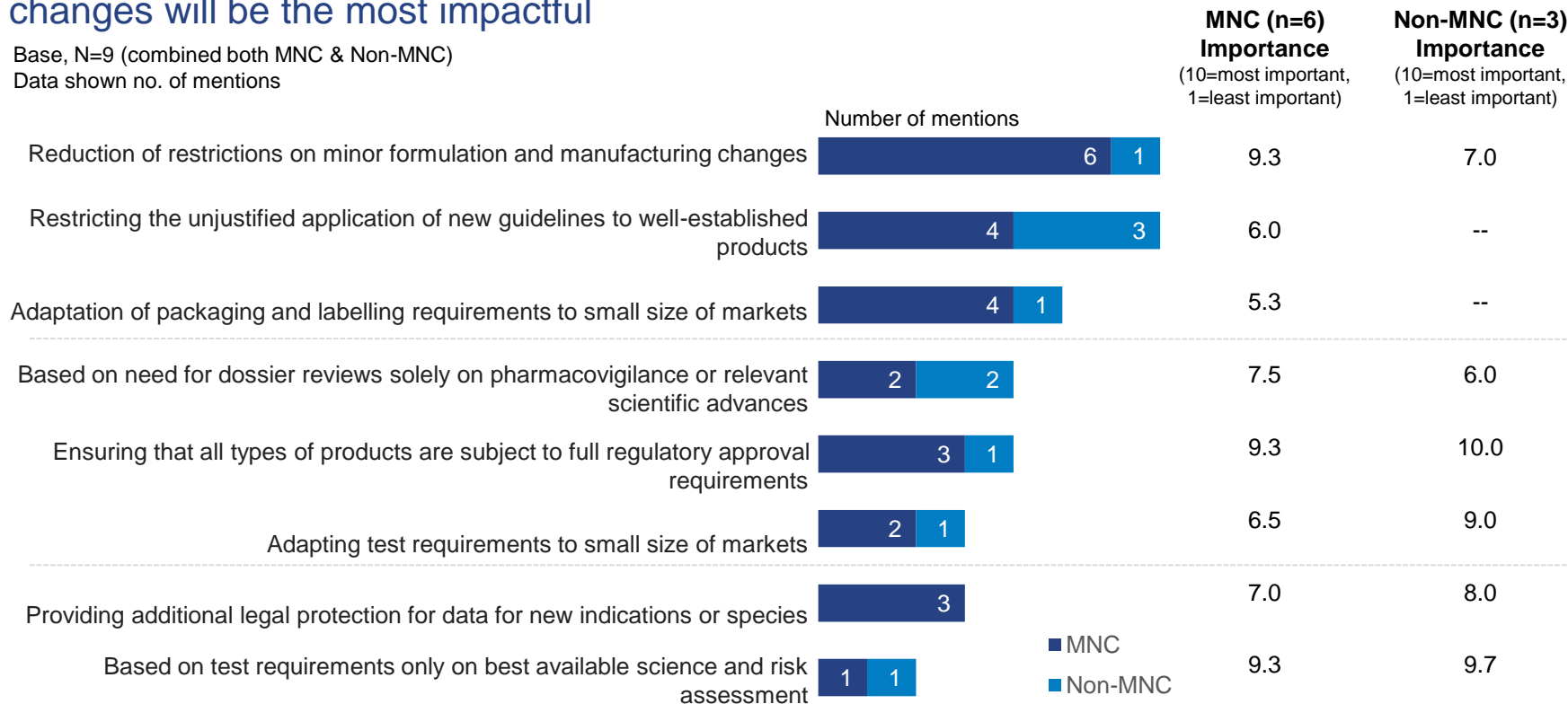
■ MNC  
■ Non-MNC

F3a. The following have been identified as ISSUES that would have impact on PROUDCT REGISTRATION ACHIEVEMENT – which of these have occurred, and which have had or might still have the greatest positive impact on your ability to ACHIEVE PROUDCT REGISTRATION?

## To help ease the maintaining the registration of existing products, most companies agree that reduction of restrictions on minor formulation and manufacturing changes will be the most impactful



Base, N=9 (combined both MNC & Non-MNC)  
Data shown no. of mentions



F3b. The following have been identified as ISSUES that would have impact on the industry's ability to PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS – which of these have occurred, and which have had or might still have the greatest positive impact on your ability to PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS?



Change of registration flow process to speed up registration time is most expected regulatory framework change but this has not occurred since 2014.

Data shown no. of mentions

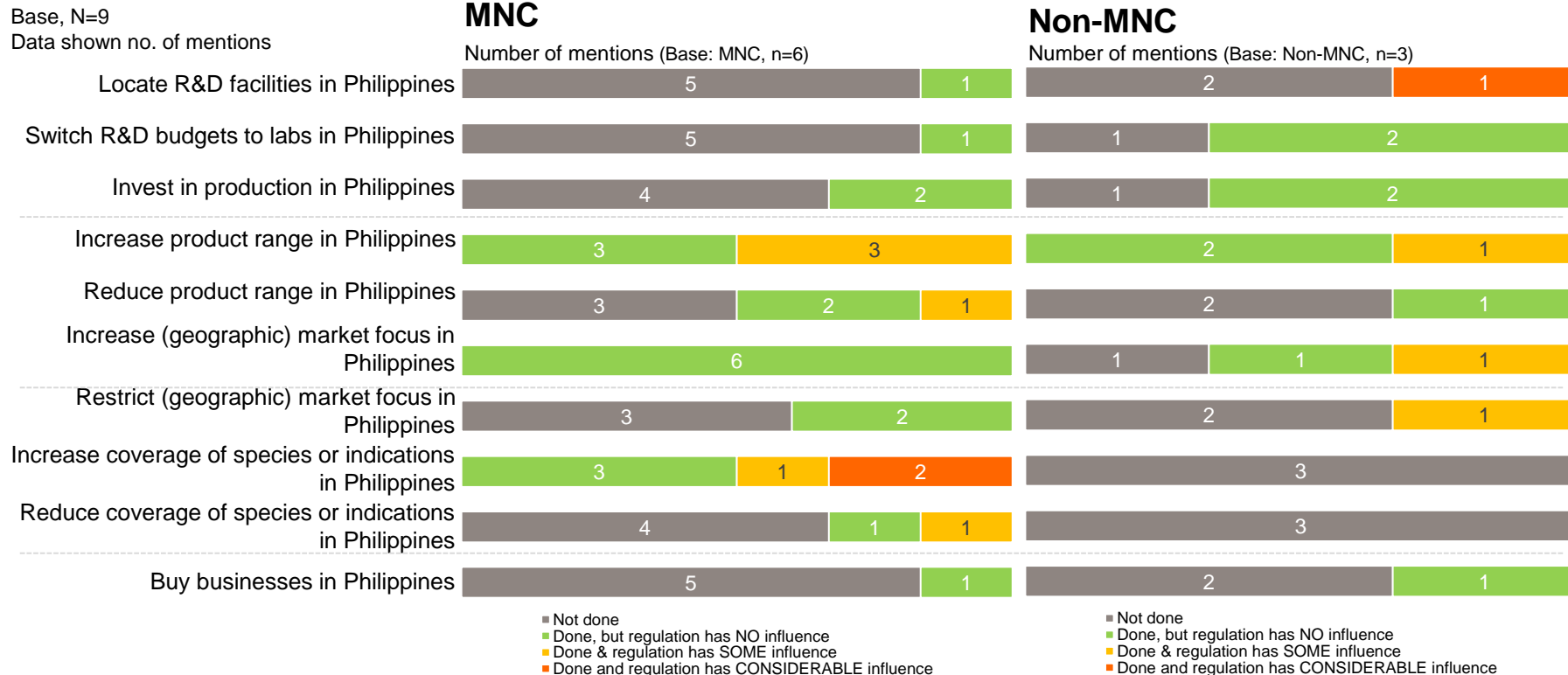
Expected regulatory framework changes that have not occurred since 2014	No. of mentions		
	TOTAL (N=9)	MNC (n=6)	Non – MNC (n=3)
Change of registration flow process to speed up registration time	4	2	2
Harmonization of requirements among the ASEAN countries	3	2	1
Improvement of quality of evaluation of products from the government agency	3	3	--
Increase in fee for faster service	1	1	--
Updating of registration guidelines specific for animal industry	1	1	--

## All non-MNC and more than half of the MNC managers faced problem with consistency and speed of dossier evaluation due to lack of skilled dossier readers

Data shown no. of mentions

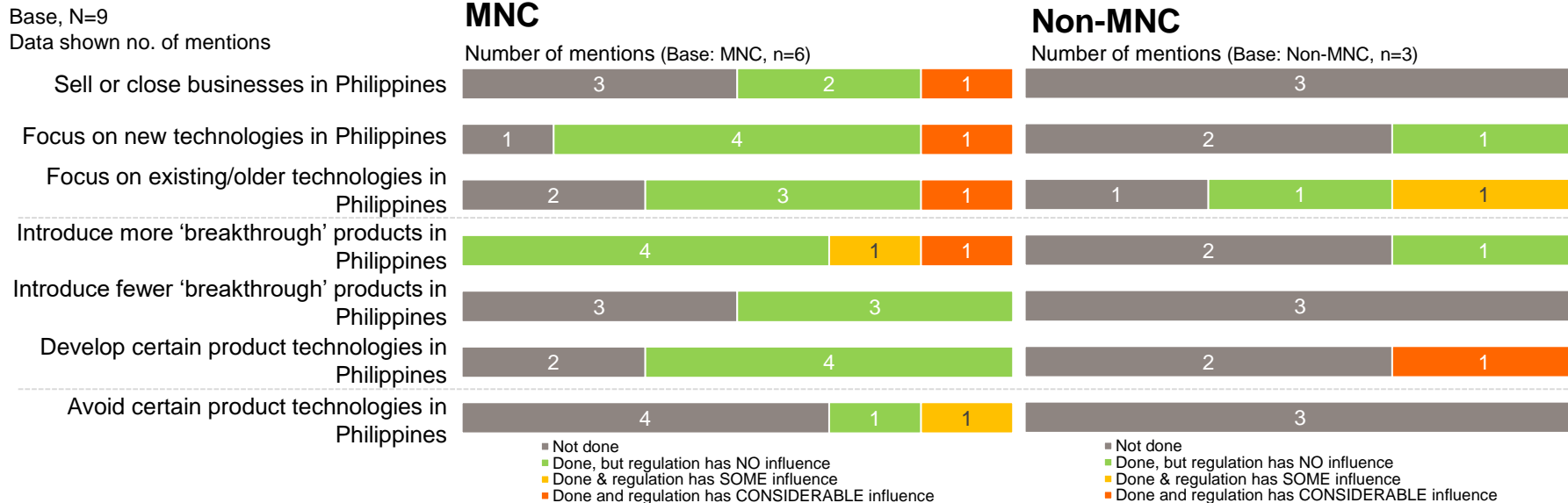
Regulatory change since 2014 that has given most problems	No. of mentions		
	TOTAL (N=9)	MNC (n=6)	Non – MNC (n=3)
Lack of skilled dossier readers which affects consistency and speed of dossier evaluation	7	4	3
Difficult GMP clearance	3	1	2
Constant change of regulations itself and implements regulations without considering the public opinions and their own capabilities	1	--	1
No face to face with the evaluators gives no chance to ask, clarify and follow-up status of application.	1	1	--
The implementation of ASEAN VARIATION requirements , where in fact ASEAN Harmonization guidelines/ requirements has not been in place	1	--	1

# Major decisions take by MNCs due to regulations in place are increasing coverage of species or indications and introducing 'breakthrough' products



F6. Have regulations played a major role in influencing you to take any of the following major decisions over the last five years?

## Major decisions take by MNCs due to regulations in place are increasing coverage of species or indications and introducing 'breakthrough' products



# Companies find the poor consistency and predictability of review process to be a hindrance in product registration achievement. This issue has slightly worsened since 2014



Base, N=6 (combined both MNC & Non-MNC)

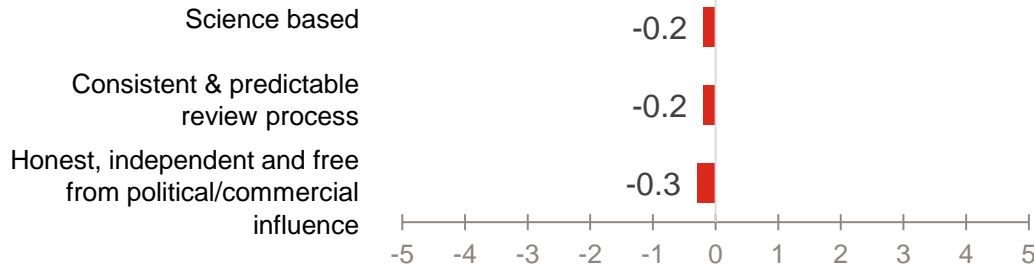
Data shown no. of mentions



Base, N=6

Data shown mean score

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

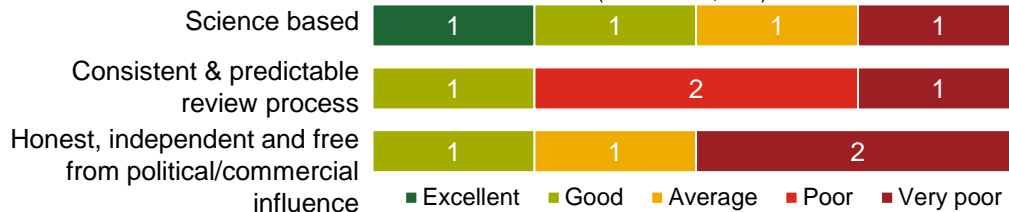


F1. Thinking about CURRENT PRODUCT REGISTRATION ACHIEVEMENT, how well do you consider it is conducted/done based on: science based, consistent & predictable review process, honest, independent & free from political / commercial influence. F1b: COMPARE TO 2014 and NOW on PRODUCT REGISTRATION ACHIEVEMENT, how well do you consider it is conducted/done based on:

While all MNCs think the current climate on product registration achievement has slightly worsened compared to 2104, the non-MNCs do not see any difference

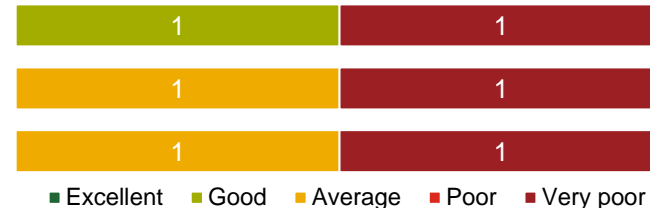
### MNC Current product registration achievement

Number of mentions (Base: MNC, n=4)



### Non-MNC Current product registration achievement

Number of mentions (Base: Non-MNC, n=2)

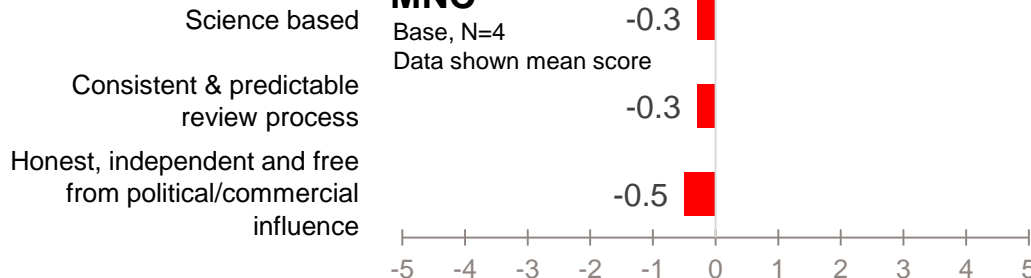


In comparison with 2014 (benchmark), is current product registration achievement better or worst (-5 = A lot worse, 0 = No change; +5=A lot better)

### MNC

Base, N=4

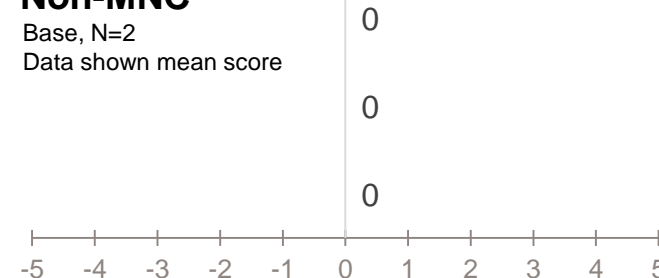
Data shown mean score



### Non-MNC

Base, N=2

Data shown mean score



F1. Thinking about CURRENT PRODUCT REGISTRATION ACHIEVEMENT, how well do you consider it is conducted/done based on: science based, consistent & predictable review process, honest, independent & free from political / commercial influence. F1b: COMPARE TO 2014 and NOW on PRODUCT REGISTRATION ACHIEVEMENT, how well do you consider it is conducted/done based on:

Most companies think the product registration is easy but non-MNCs think it has become increasingly more complex compared to 2015. This could be due to the political involvement in registrations approvals



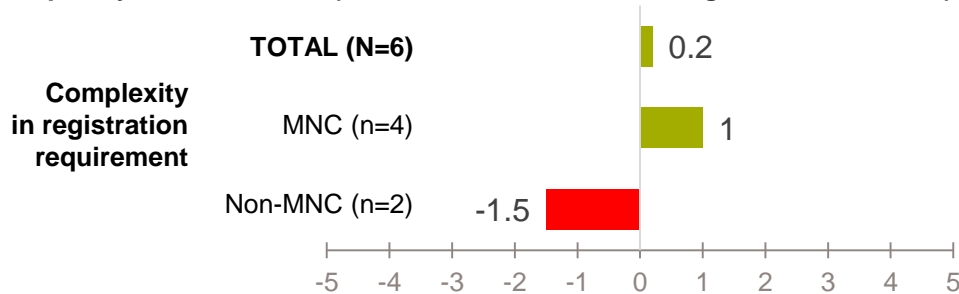
Base, N=6  
Data shown no. of mentions

Current product registration complexity



Base, N=6  
Data shown mean score

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



F2. Thinking about CURRENT PRODUCT REGISTRATION COMPLEXITY, how well do you consider it is conducted/done based on: science based, consistent & predictable review process, honest, independent & free from political / commercial influence. F2b: COMPARE TO 2014 and NOW on PRODUCT REGISTRATION COMPLEXITY, how well do you consider it is conducted/done based on:

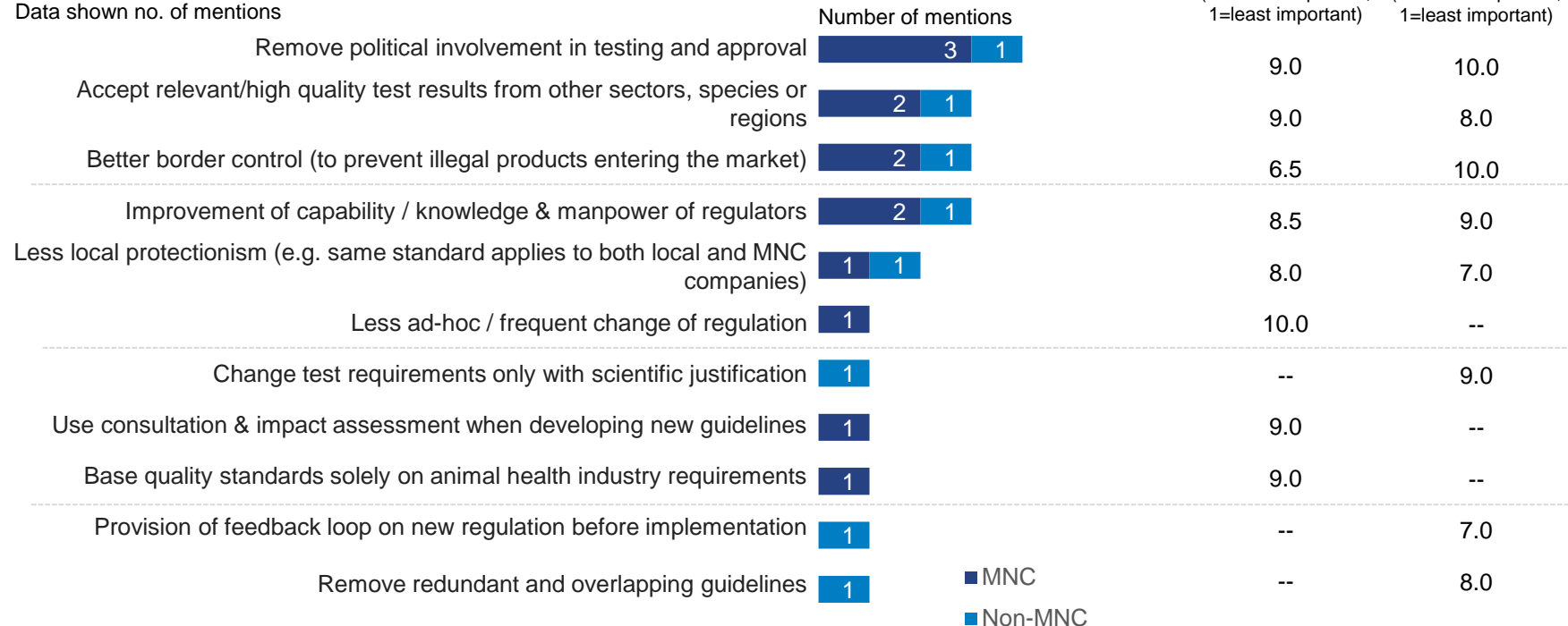
## CAMBODIA: Issues that have occurred, and would have (positive) impact product registration achievement

# Removal of political involvement in testing and approval is highly critical to bring about positive impact of product registration achievement



Base, N=6 (combined both MNC & Non-MNC)

Data shown no. of mentions

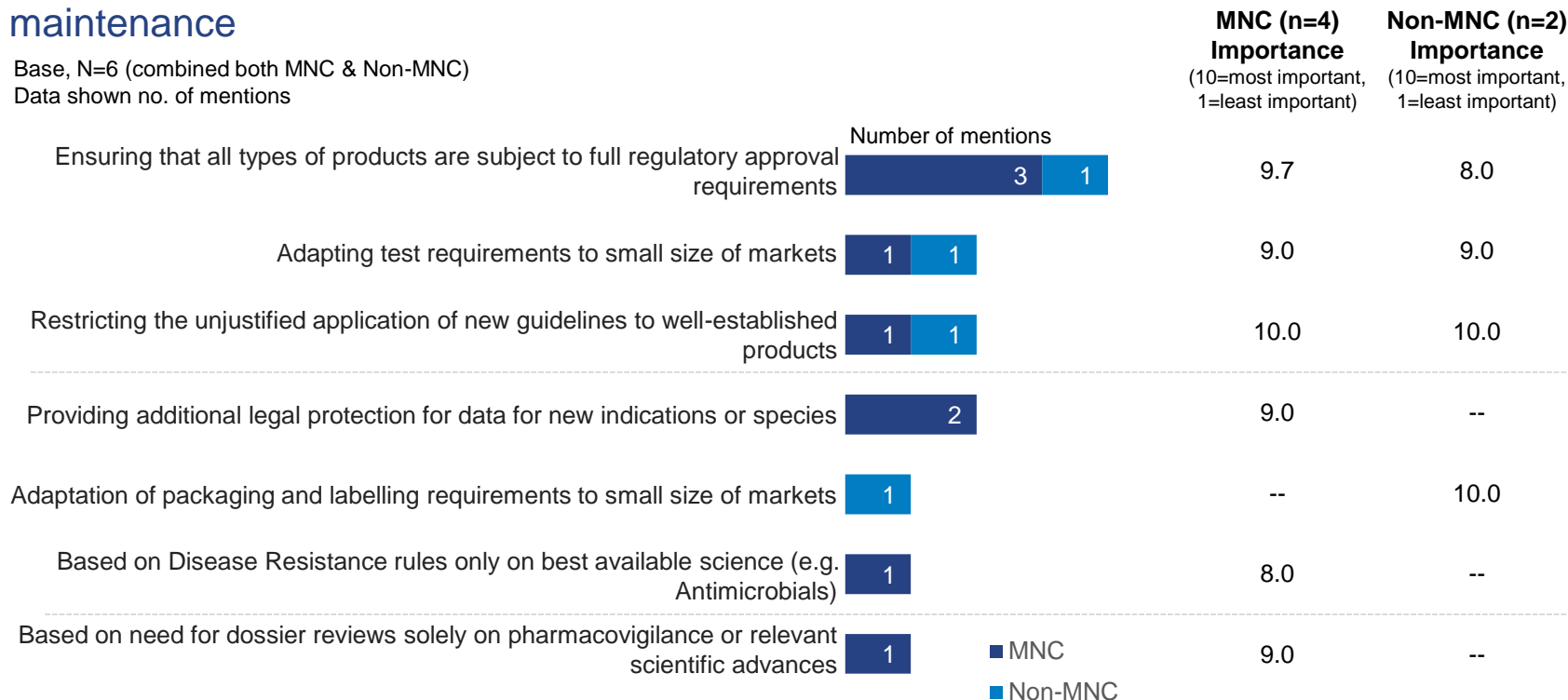


F3a. The following have been identified as ISSUES that would have impact on PROUDCT REGISTRATION ACHIEVEMENT – which of these have occurred, and which have had or might still have the greatest positive impact on your ability to ACHIEVE PROUDCT REGISTRATION?



## Most companies mentioned that ensuring all types of products are subject to full regulatory approval requirements to bring positive impact in product registration maintenance

Base, N=6 (combined both MNC & Non-MNC)  
Data shown no. of mentions



F3b. The following have been identified as ISSUES that would have impact on the industry's ability to PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS – which of these have occurred, and which have had or might still have the greatest positive impact on your ability to PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS?

## Some non-MNC expected to have reduction in registration fees to match with market opportunity but this change has not occurred since 2014

Base, N=6

Data shown no. of mentions

Expected regulatory framework changes that have not occurred since 2014	No. of mentions		
	TOTAL (N=6)	MNC (n=4)	Non – MNC (n=2)
Reduction in registration fees to match with market opportunity	1	--	1
Don't know	5	4	1

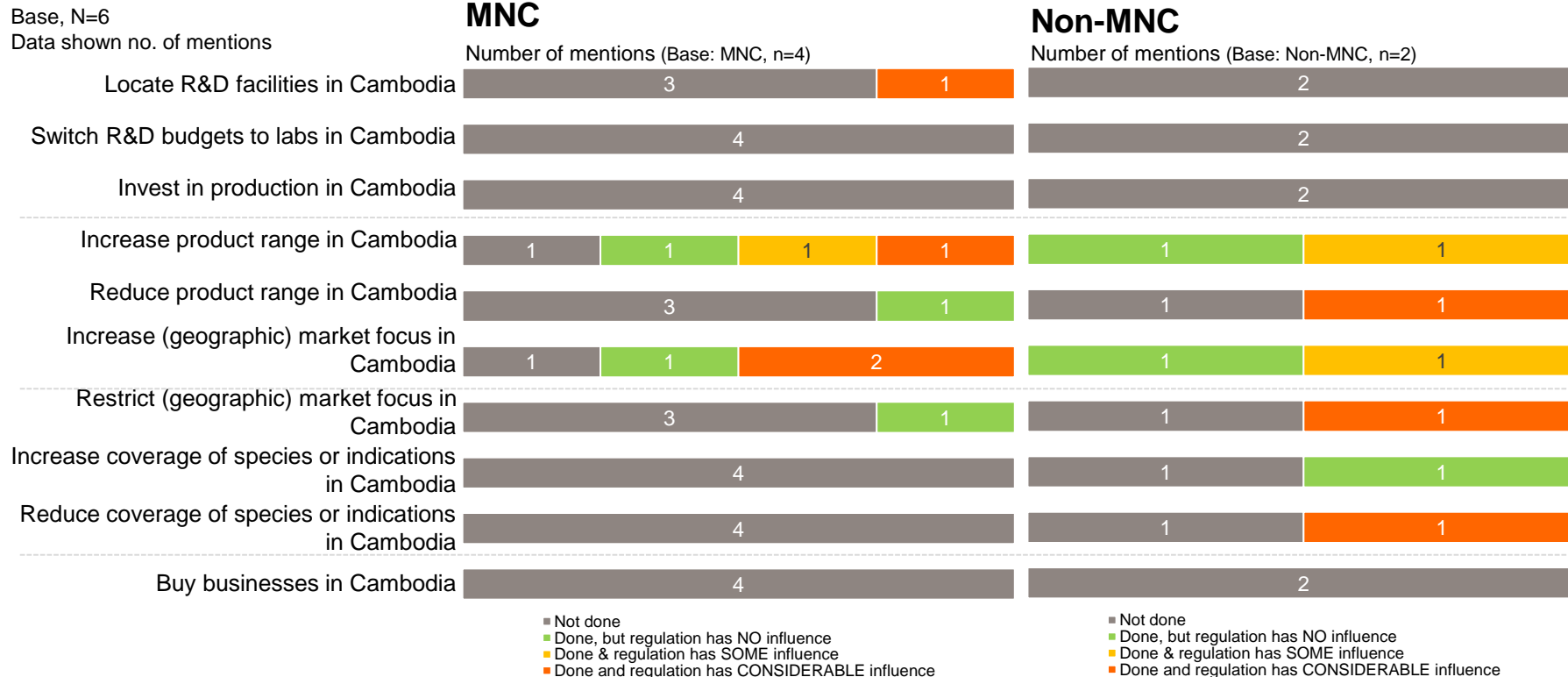
  

Regulatory change since 2014 that has given most problems	No. of mentions		
	TOTAL (N=6)	MNC (n=4)	Non – MNC (n=2)
No change in regulatory framework since 2014	2	1	1
None	4	3	1

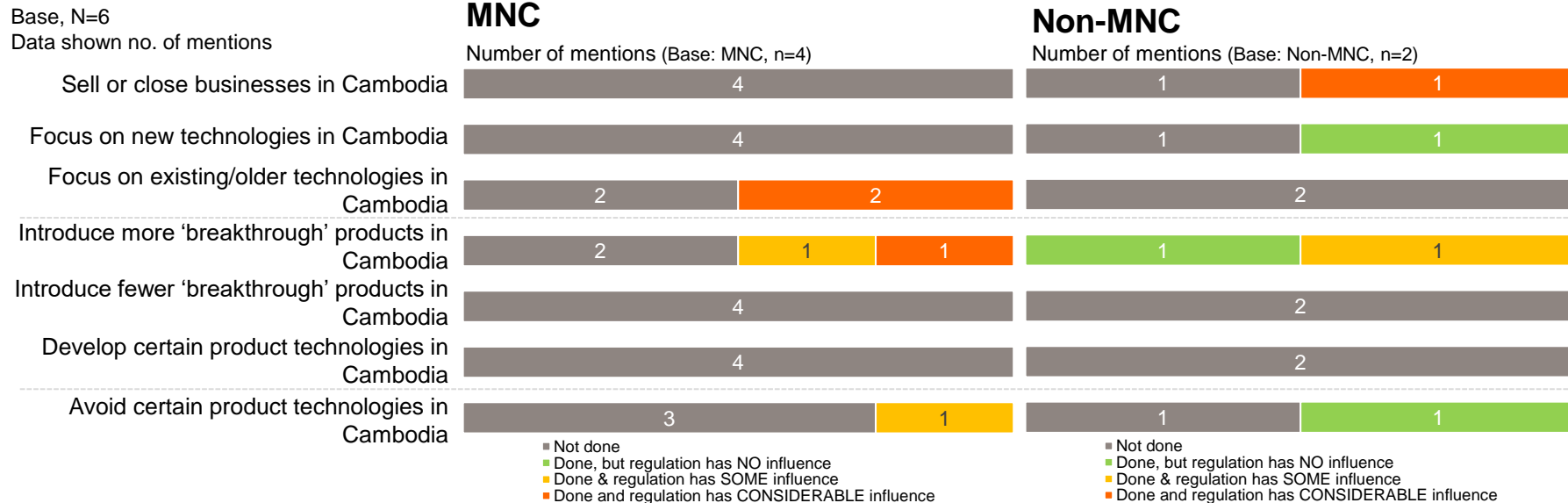
F4. What expected changes have NOT occurred in regulatory frameworks SINCE 2014 despite of expectations of change?

F5. What regulatory changes SINCE 2014 have given you the most problems and why?

# The regulations in placed has influenced some companies to increase market focus and product range in Cambodia



# The regulations in placed has influenced some companies to increase market focus and product range in Cambodia



# More than half thinks that the current climate of product registration is good and has improved in all areas since 2014



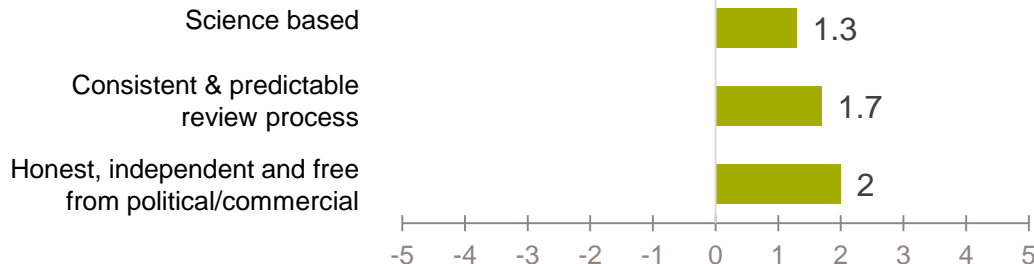
Base, N=6 (combined both MNC & Non-MNC)  
Data shown no. of mentions



Base, N=6

Data shown mean score

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



F1. Thinking about CURRENT PRODUCT REGISTRATION ACHIEVEMENT, how well do you consider it is conducted/done based on: science based, consistent & predictable review process, honest, independent & free from political / commercial influence. F1b: COMPARE TO 2014 and NOW on PRODUCT REGISTRATION ACHIEVEMENT, how well do you consider it is conducted/done based on:

# Complexity of product registration is quite average with some nominal improvement over the past 5 years

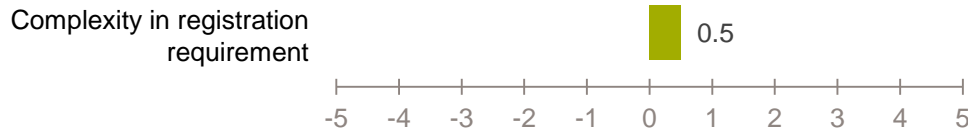


Base, N=6  
Data shown no. of mentions



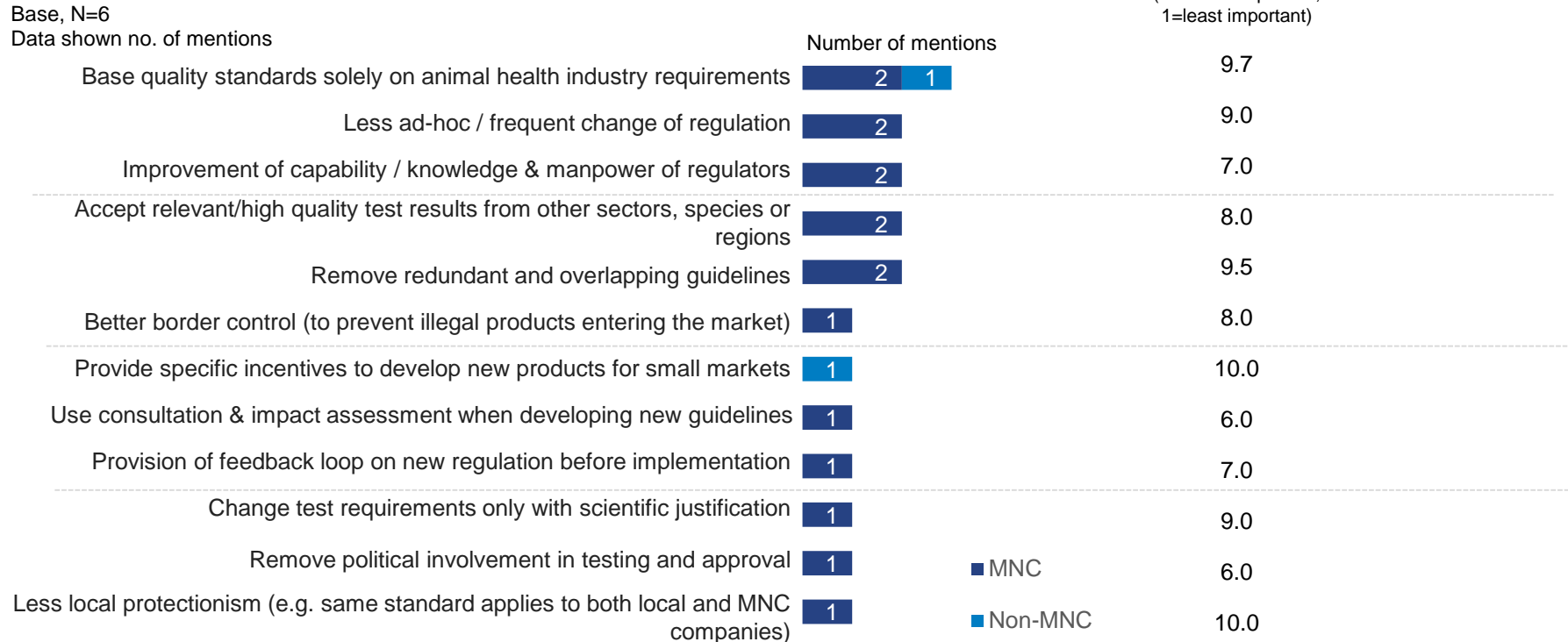
Base, N=6  
Data shown mean score

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



F2. Thinking about CURRENT PRODUCT REGISTRATION COMPLEXITY, how well do you consider it is conducted/done based on: science based, consistent & predictable review process, honest, independent & free from political / commercial influence. F2b: COMPARE TO 2014 and NOW on PRODUCT REGISTRATION COMPLEXITY, how well do you consider it is conducted/done based on:

## Basing quality standards solely on animal health industry requirements is seen as the most important factor that would bring positive impact to product registration achievement



F3a. The following have been identified as ISSUES that would have impact on PROUDCT REGISTRATION ACHIEVEMENT – which of these have occurred, and which have had or might still have the greatest positive impact on your ability to ACHIEVE PROUDCT REGISTRATION?

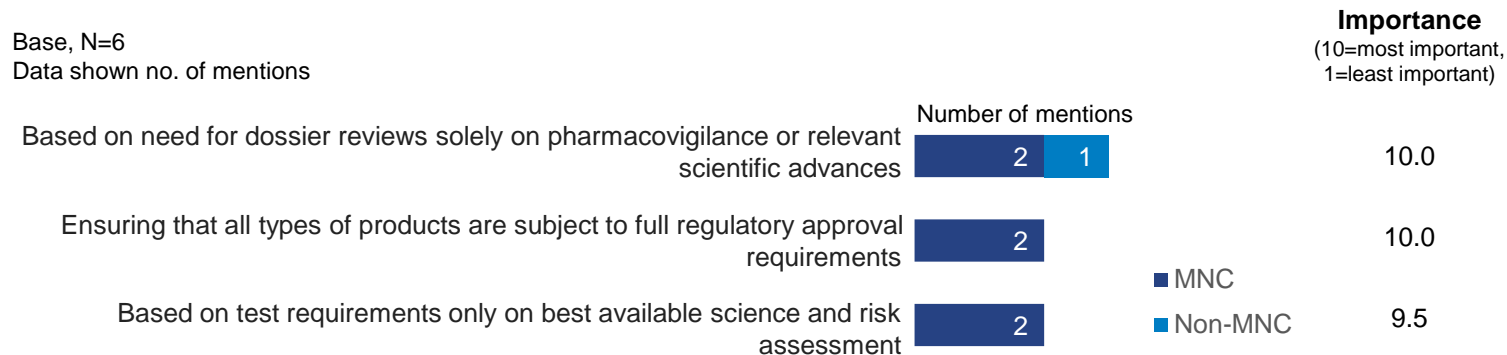
MYANMAR: Issues that have occurred, and would have (positive) impact on performing maintenance of registration of existing products



## Dossier reviews based solely on pharmacovigilance is the highly considered to be the most important factor to bring positive impact in product registration maintenance

Base, N=6

Data shown no. of mentions



F3b. The following have been identified as ISSUES that would have impact on the industry's ability to PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS – which of these have occurred, and which have had or might still have the greatest positive impact on your ability to PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS?



MYANMAR: Expected regulatory framework changes that have not occurred since 2014

Regulations in Cambodia have been unclear, possibly due to political issues – this has caused significant problems amongst some companies



Base, N=6

Data shown no. of mentions

Expected regulatory framework changes that have not occurred since 2014	No. of mentions
	TOTAL (N=6)
Resolving the issue of uncertainties of rules and regulations in veterinary sector	1
Better laboratory standard for checking products in government	1
Don't know	4

Regulatory change since 2014 that has given most problems	No. of mentions
	TOTAL (N=6)
No change in regulatory framework since 2014	1
Not have rules & regulations for making veterinary product registration in Myanmar because of political issue	1
None	4

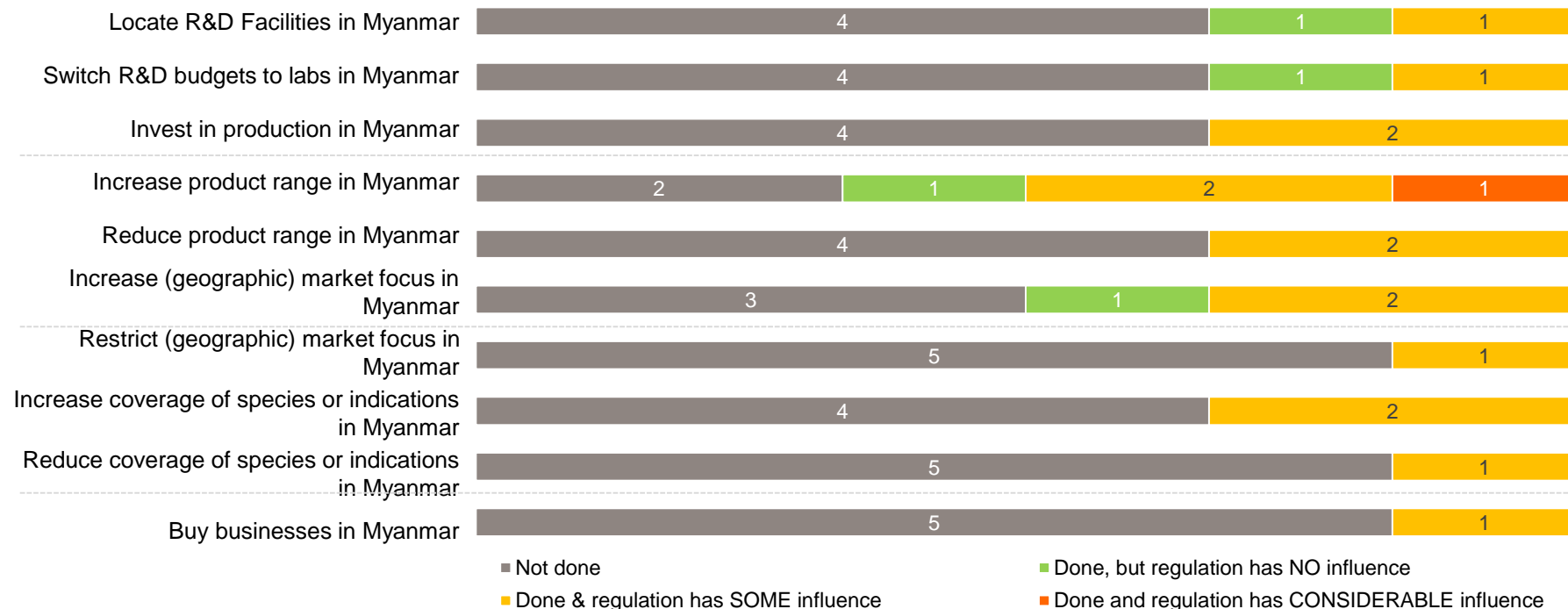
F4. What expected changes have NOT occurred in regulatory frameworks SINCE 2014 despite of expectations of change?

F5. What regulatory changes SINCE 2014 have given you the most problems and why?

# Regulations in Myanmar has brought considerable influence in companies to increase product range and focusing on existing or older technologies in Myanmar



Base, N=6  
Data shown no. of mentions



# Regulations in Myanmar has brought considerable influence in companies to increase product range and focusing on existing or older technologies in Myanmar



Base, N=6  
Data shown no. of mentions

