

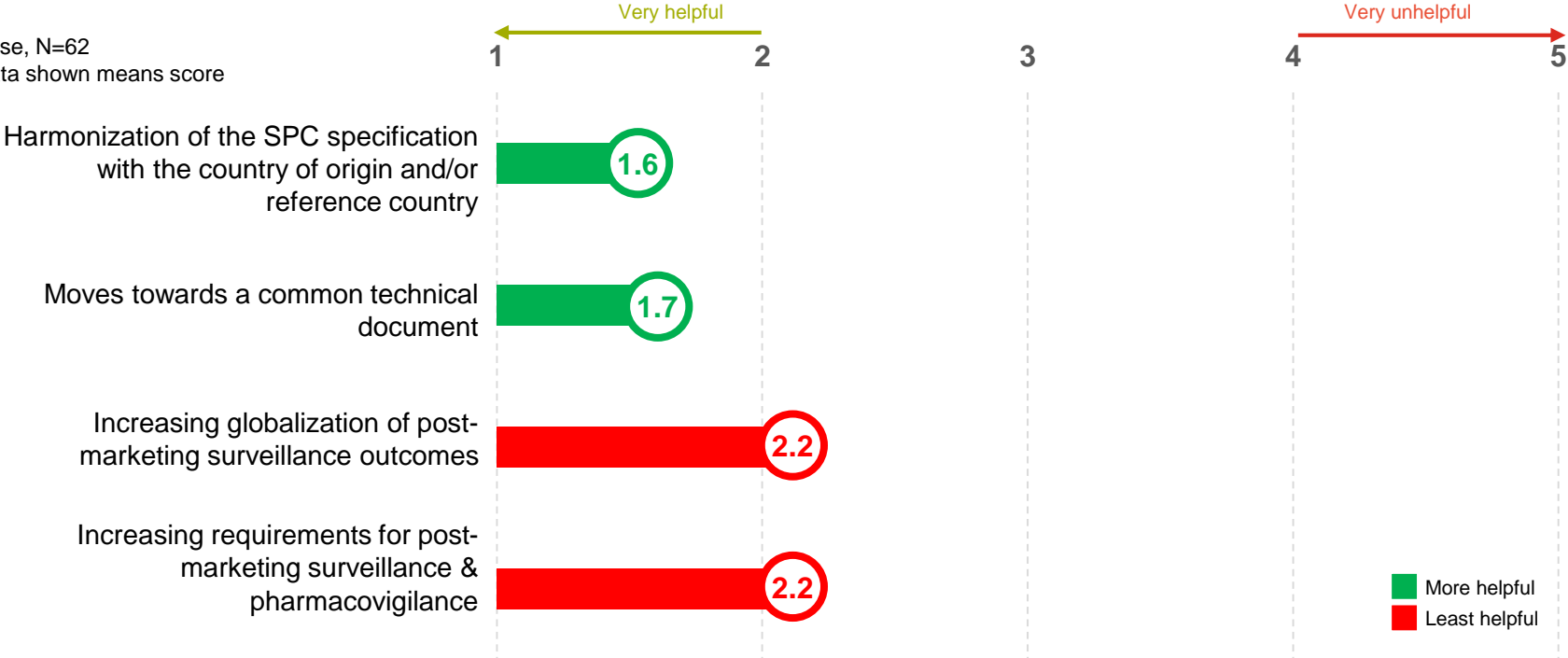


# Hopes & expectations for the next 5 years

XX

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

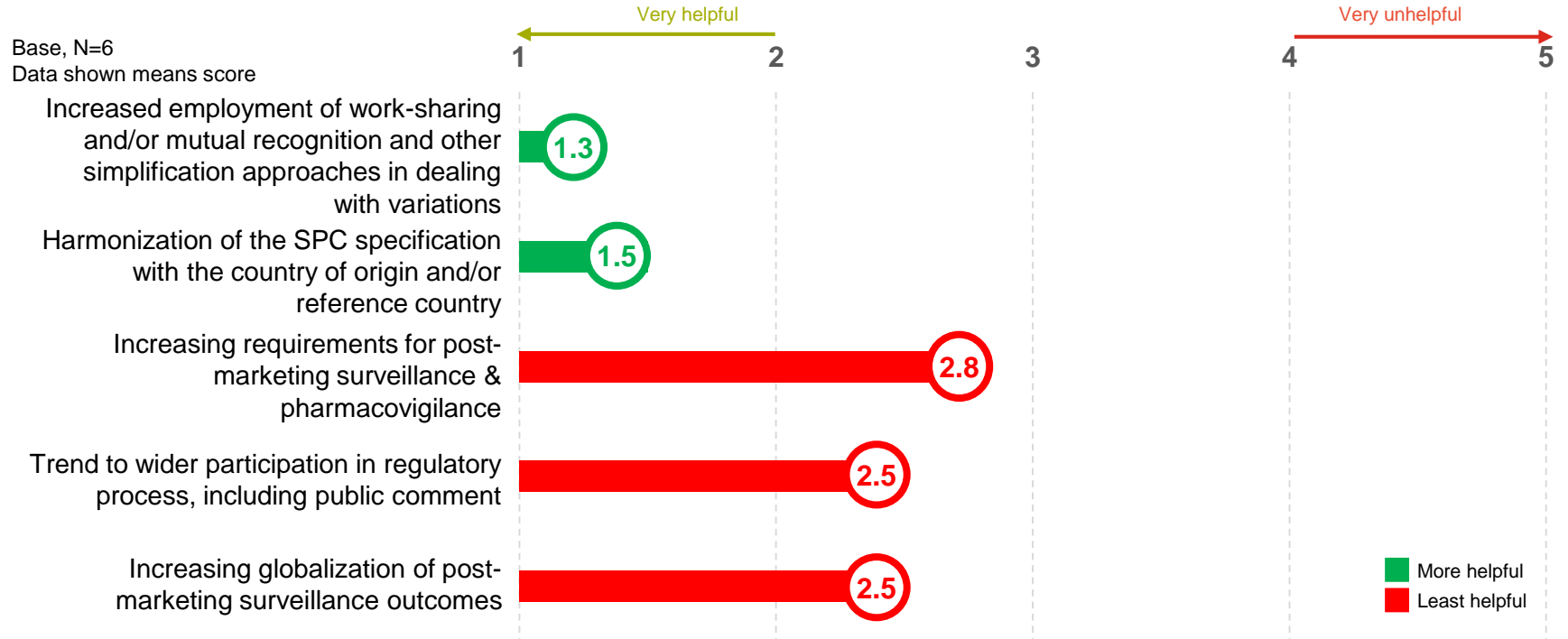
Base, N=62  
Data shown means score



In the next 5 years, increased employment of work-sharing and/or mutual recognition and other simplification approaches in dealing with variations and harmonization of the SPC specification with the country of origin and/or reference country are deemed helpful to AH business. In contrast, increasing requirement for post-marketing surveillance & pharmacovigilance is not helpful



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



In Malaysia, harmonization of the SPC requirement with country of origin and/or reference country will be helpful to AH business in the future, whilst increase globalization of post-marketing surveillance outcome will make it more challenging.

In Indonesia, electronic submission and increase transparency will be helpful for future AH business

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

Base, N=6

Data shown means score



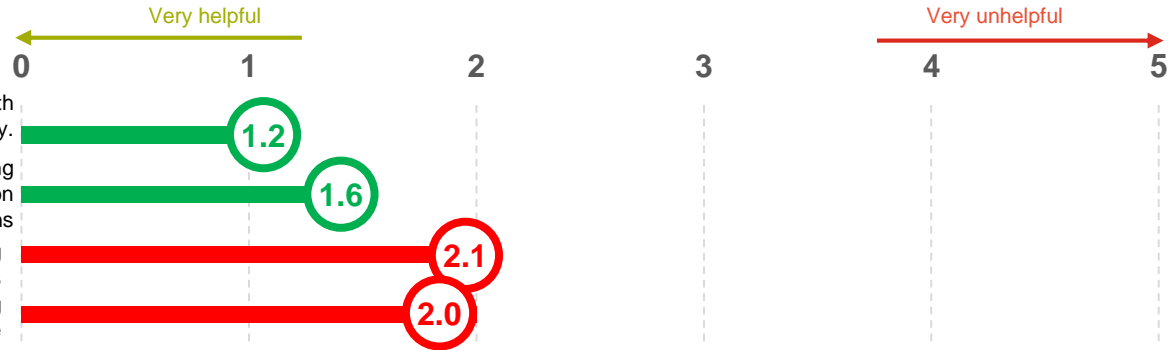
Malaysia

Harmonization of the SPC specification with country of origin and/or reference country.

Increased employment of work-sharing and/or mutual recognition, other simplification approaches dealing with variations

Increasing globalization of post-marketing surveillance outcomes

Increasing requirements for post-marketing surveillance & pharmacovigilance



Base, N=6

Data shown means score



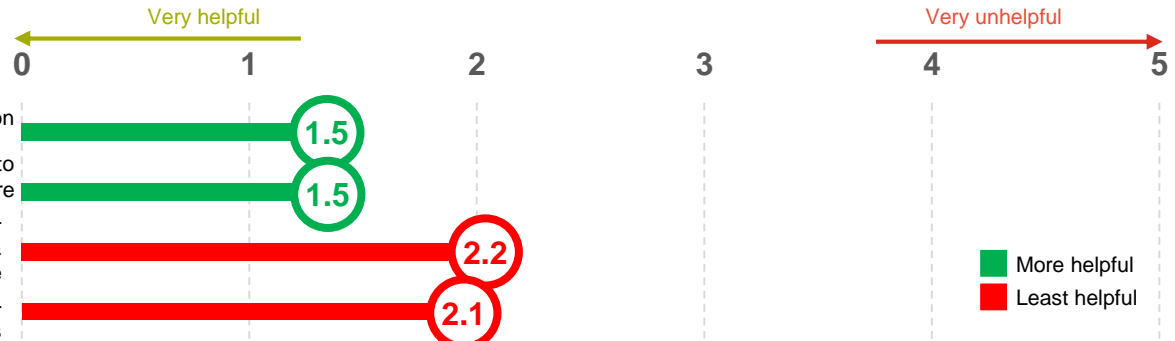
Indonesia

Moves towards electronic submission

Increasing transparency with respect to data disclosure

Increasing requirements for post-marketing surveillance & pharmacovigilance

Increasing globalization of post-marketing surveillance outcomes

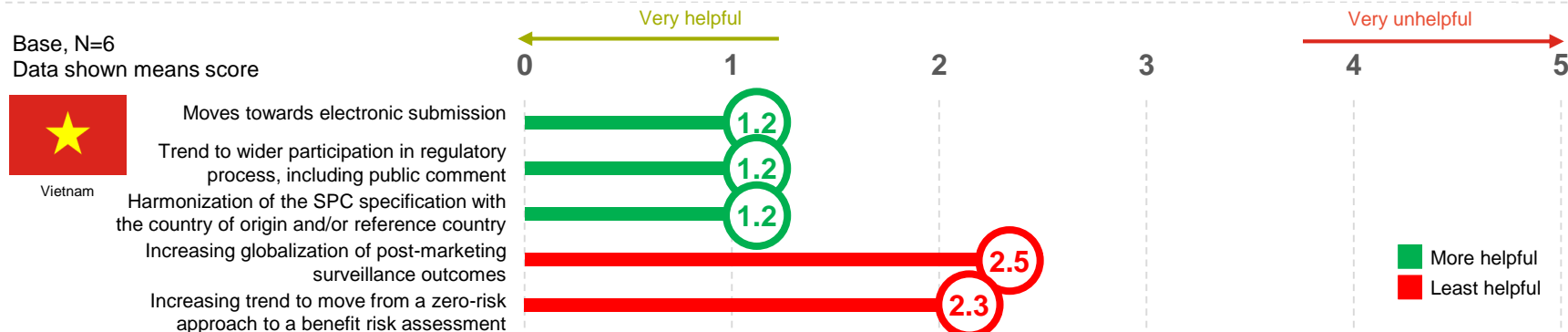
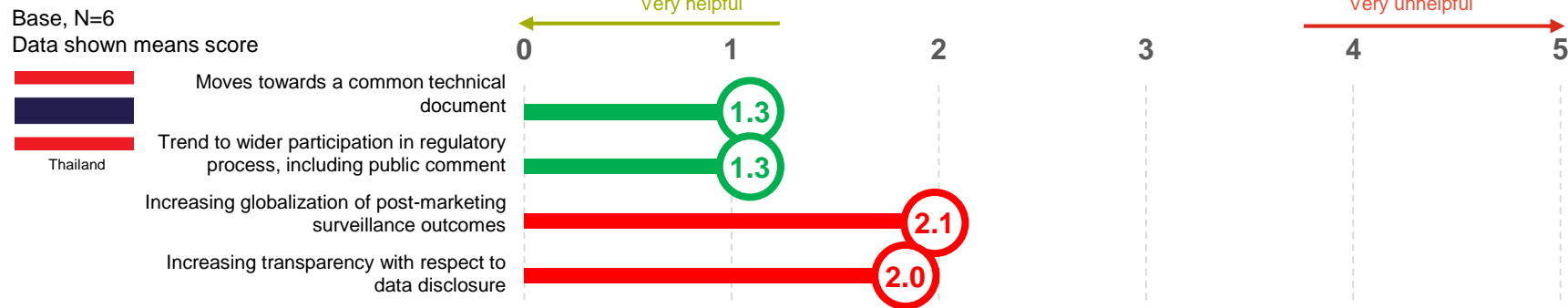


More helpful  
Least helpful

Move towards a common technical document and wider participation in regulatory process will be helpful for AH business in the next 5 years in Thailand. 

Vietnamese regulatory managers considered electronic submission, wider participation in regulatory process and harmonization of SPC specification will improve business in the future

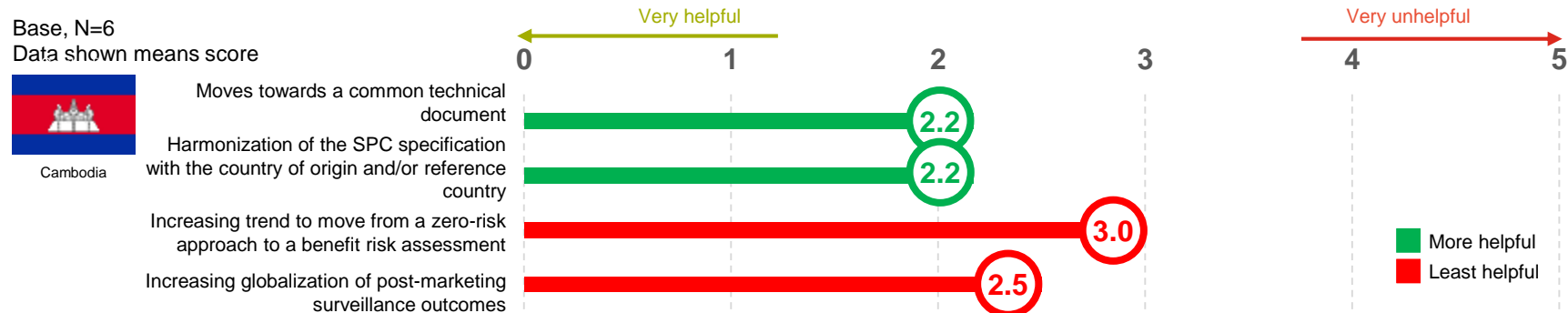
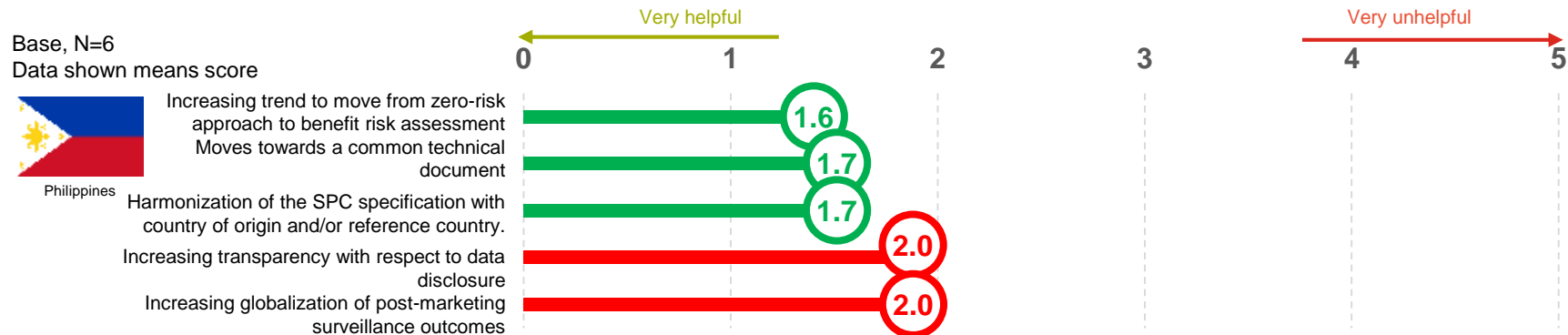
Top trends that more and least helpful in the next 5 years that can impact your business



For Philippines, increasing trend to move from zero-risk approach to benefit risk assessment, move towards a common technical document and harmonization of SPC specification will have good impact on future business.

For Cambodia, a move towards common technical document and harmonization of SPC specification are considered positive move.

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



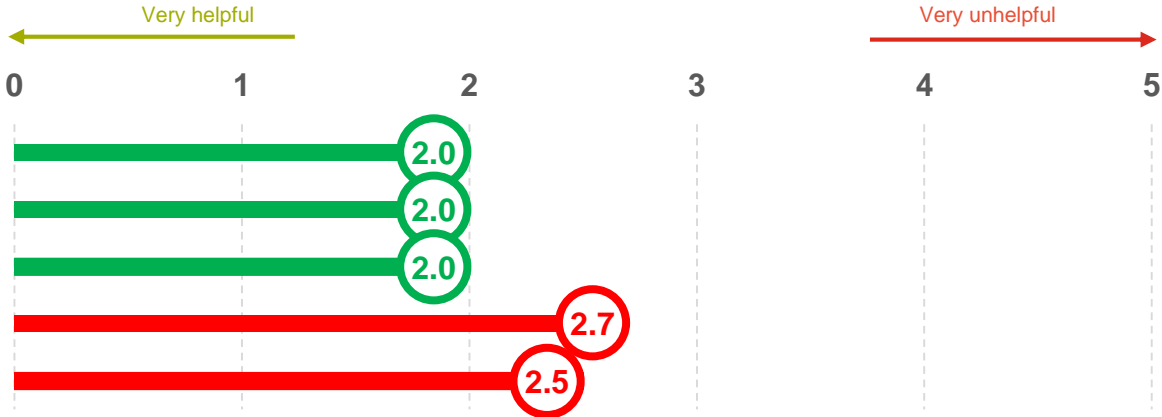
For Myanmar, local managers said electronic submission, a common technical document and harmonization of the SPC specification with the country of origin and/or reference country in the next 5 years will be helpful for their business.

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

Base, N=6  
Data shown means score

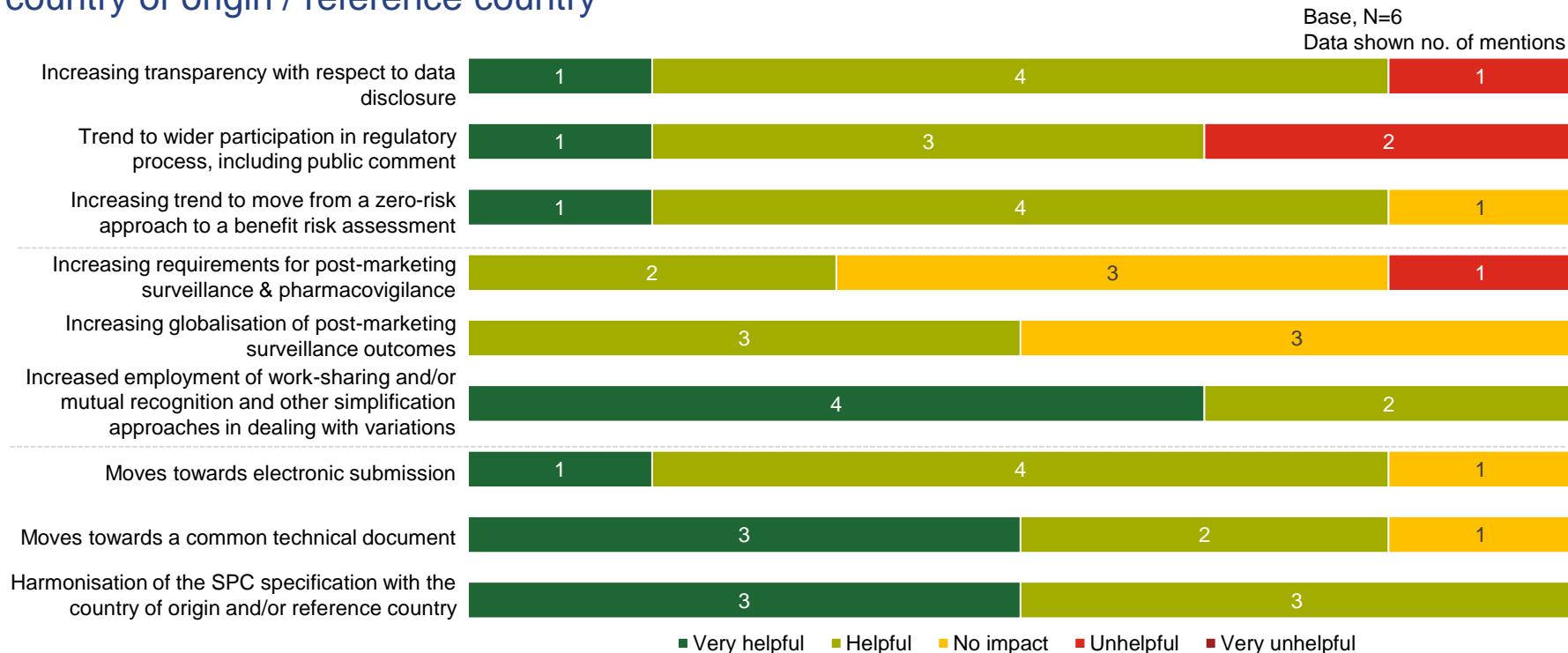


Myanmar



More helpful  
Least helpful

Two key trends in the future that have positive impact on the industry are: increased employment of work-sharing and/or mutual recognition and other simplification approaches in dealing with variations and harmonization of the SPC specification with country of origin / reference country



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?



## REGIONAL: How the new veterinary product regulations (currently in draft) will affect business? >> Increase efficiency in registration and alignment with regional and global guidelines



Base, N=6

Data shown no. of mentions

How the new veterinary product regulations (currently in draft) will affect business?	No of mentions
This will increase the efficiency of AH product registration	3
Increase alignment to regional and global guidelines (i.e. harmonization)	2
In general new regulations are not clear and interpretation/implementation varies from one person to another, that most of the time it slow down processes.	1
Increase clarity about registration process and requirements	1
Strengthen the importance of science-based evidence rather than political influence	1
Other changes that have had positive impact on business	No of mentions
Out right rejection of application if any lacking requirement which limits backlogs of pending registration application	1
Reduced time in reviewing process since they collected government fees	1
Extending the licenses validity period - save time and cost	1
No answer	3

The key changes these regional regulatory manager desired is >> harmonization of registration process and mutual recognition, leading to reduction of redundancy

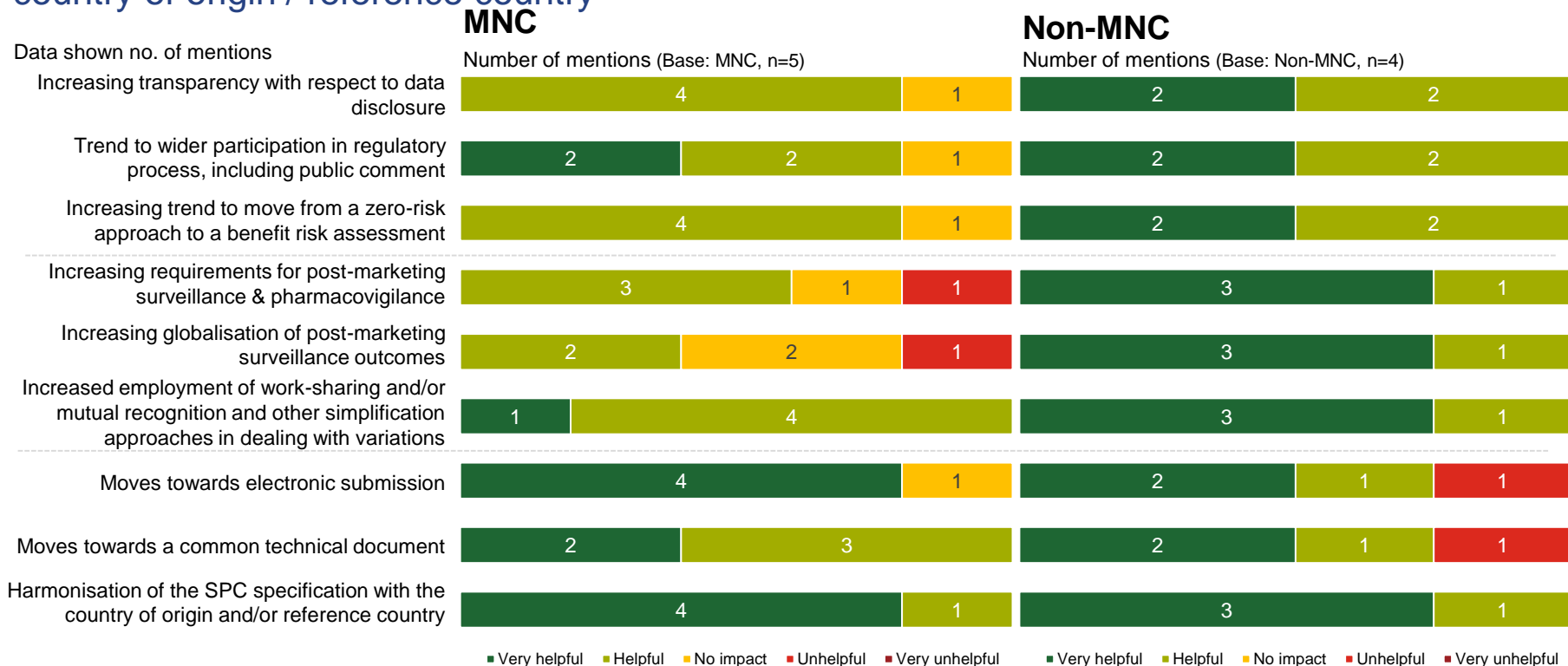


Base, N=6

Data shown no. of mentions

Other changes that are still needed / pending	No of mentions
Harmonized registration process and some sort of mutual recognition to enhance efficiency and reduce redundancy	3
Consistency in requirements	1
Ability to have dialogue with authorities	1
Less non-scientific protectionism / A well developed Registration Process and free from political / commercial influences	1
More qualified dossier evaluators	1
Removal for need for FSC or at least ability to supplement mid-application and not to have to wait for FSC before possible to submit	1
Separate procedure and requirement for borderline products (e.g. comfort, hygiene products)	1

Two key trends in the future that have positive impact on the industry are: increased employment of work-sharing and/or mutual recognition and other simplification approaches in dealing with variations and harmonization of the SPC specification with country of origin / reference country



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?

**MALAYSIA: How the new veterinary product regulations (currently in draft) will affect business? >> Determine the no. of products sell in the market.**



**MALAYSIA: Other changes that can have positive impact on business? >> Change in organization structure to help clear backlogs of product submission and speed up evaluation process**

Data shown no. of mentions

How the new veterinary product regulations (currently in draft) will affect business?	No. of mentions		
	TOTAL (N=9)	MNC (n=5)	Non – MNC (n=4)
It determines how many products that our company can sell	2	1	1
Companies will be able to reduce time and resource needed in registration and focus more on R&D for new product	1	--	1
It might increase the duration of the registration process for veterinary medicines	1	1	--
New Veterinary Product Act will hopefully bring all veterinary related products under a roof of one regulatory agency	1	1	--
Increases clarity about registration process and requirements	1	1	--
Increases alignment to regional and global guidelines (i.e. harmonization)	1	1	--

Other changes that have had positive impact on business	No. of mentions		
	TOTAL (N=9)	MNC (n=5)	Non – MNC (n=4)
New organizational structure which helps to clear the back logs product submissions and speed up evaluation process	3	3	--
Veterinary medicine's quality check has improved to a certain extent to limit fake and low-quality products	1	--	2
Exemption list for unregistered product which allows companies to bring in pending approval veterinary medicines while registration is in the progress	1	--	1
No answer	3	3	--

# MNC and non-MNC agreed that more qualified dossier evaluators in regulatory bodies and provide clearer guidelines with easier access will be needed for the future

Data shown no. of mentions

Other changes that are still needed / pending	No. of mentions		
	TOTAL (N=9)	MNC (n=5)	Non – MNC (n=4)
More qualified dossier evaluators	4	2	2
All requirements to be stated clearly on guideline which can be reviewed online	3	1	2
Harmonized registration process and some sort of mutual recognition to enhance efficiency and reduce redundancy	2	2	--
Consistent timeline is followed as stated in the guidelines	2	1	1
A more focused or stand-alone entity or Office/ Regulatory agency to handle licensing & registration of animal health products.	1	1	--
Consistency in requirements	1	--	1
All the reviewing officer of registration dossier should not be changed or transferred out every 2-3 years	1	1	--
Vet drugs registration should not be evaluated as stringent as human drugs	1	--	1

# Managers felt that electronic submission and move towards a common technical documents will be helpful for the next 5 years in bringing more positive value to their business

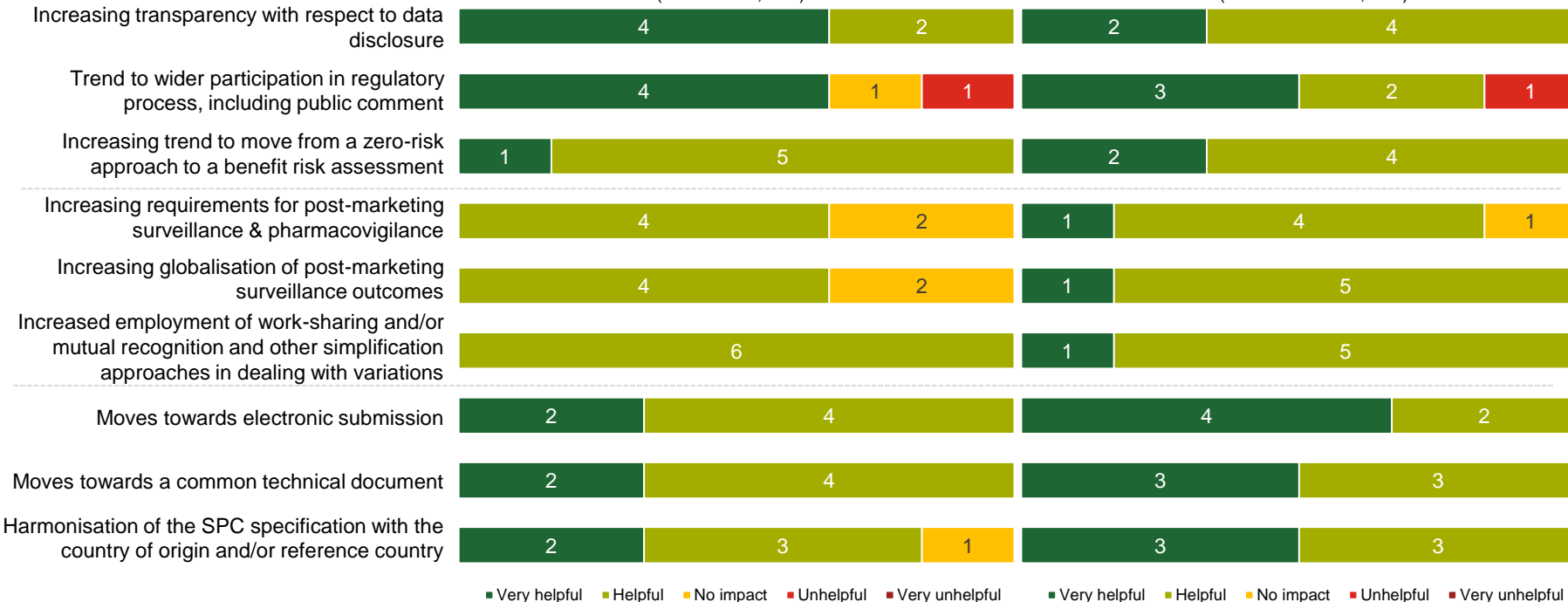
Base, N=12 (combined both MNC & Non-MNC)  
Data shown no. of mentions

## MNC

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

## Non-MNC

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



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?

## INDONESIA: How the new veterinary product regulations (currently in draft) will affect business? >> Such action will force manufacturers to do technology transfer to local production

Data shown no. of mentions

How the new veterinary product regulations (currently in draft) will affect business?	No. of mentions		
	TOTAL (N=12)	MNC (n=6)	Non – MNC (n=6)
It will force manufacturers to do the technology transfer to local production	4	2	2
The limitation of Growth Promoter antibiotics products	1	--	1
Approval process will be faster and able to adhere to the time frame, it will give our business a better forecast and prediction of our marketing strategy	1	1	--
Many guidance or definition are not science based would definitely impact business	1	1	--
It might increase the duration of the registration process for veterinary medicines	1	1	--
Transfer of technology might limit the innovative products and end users will face difficulties to obtain the innovative animal medicine that they need	1	1	--

## INDONESIA: Other changes that can have positive impact on business? >> Online registration will make registration process speedier and help prevent lost of dossiers

Data shown no. of mentions

Other changes that have had positive impact on business	No. of mentions		
	TOTAL (N=12)	MNC (n=6)	Non – MNC (n=6)
The online registration made quicker registration process and helped in prevention of dossier loss	5	2	3
Pending new regulation on distribution which was never regulated before may bring positive influence toward the distribution of animal medicine	1	1	--
New regulation under the Ministry of Environmental is more coordinated and time efficient for leading the discussion on GM products	1	1	--
New organizational structure which helps to clear the back logs product submissions and speed up evaluation process	1	--	1
Pending new regulation on export oriented product, expected to overcome the barrier on long registration process of export oriented new product	1	--	1
Role/function rotation in government staffs/ personnel with proper qualifications has improved the registration process.	1	1	--
Since the controlled usage of AGP in feed, this has prevented AMR	1	--	1
Nothing significant	1	1	--



## MNC claimed more qualified dossier evaluators in regulatory bodies will increase future efficiency in the AH industry.

Data shown no. of mentions

Other changes that are still needed / pending	No. of mentions		
	TOTAL (N=12)	MNC (n=6)	Non – MNC (n=6)
More qualified dossier evaluators	2	2	--
Make the registration period shorter	1	--	1
The change of specification requirements on herbal product	1	--	1
Simplify registration procedures.	1	--	1
Authorities to welcome new technologies in larger regions	1	1	--
Consistency in requirements	1	1	--
More efficient registration procedures like parallel document submission	1	1	--
Consistent timeline is followed as stated in the guidelines	1	--	1
Better quality and capabilities of designated laboratories for evaluation	1	1	--
Authorities to move from zero-risk approach to benefit-assessment approach in product registration restriction	1	1	--
All requirements should be able to be reviewed online	1	--	1

# The move towards a common technical document and wider participation in regulatory process, including public comments will enhance the AH industry in the future.



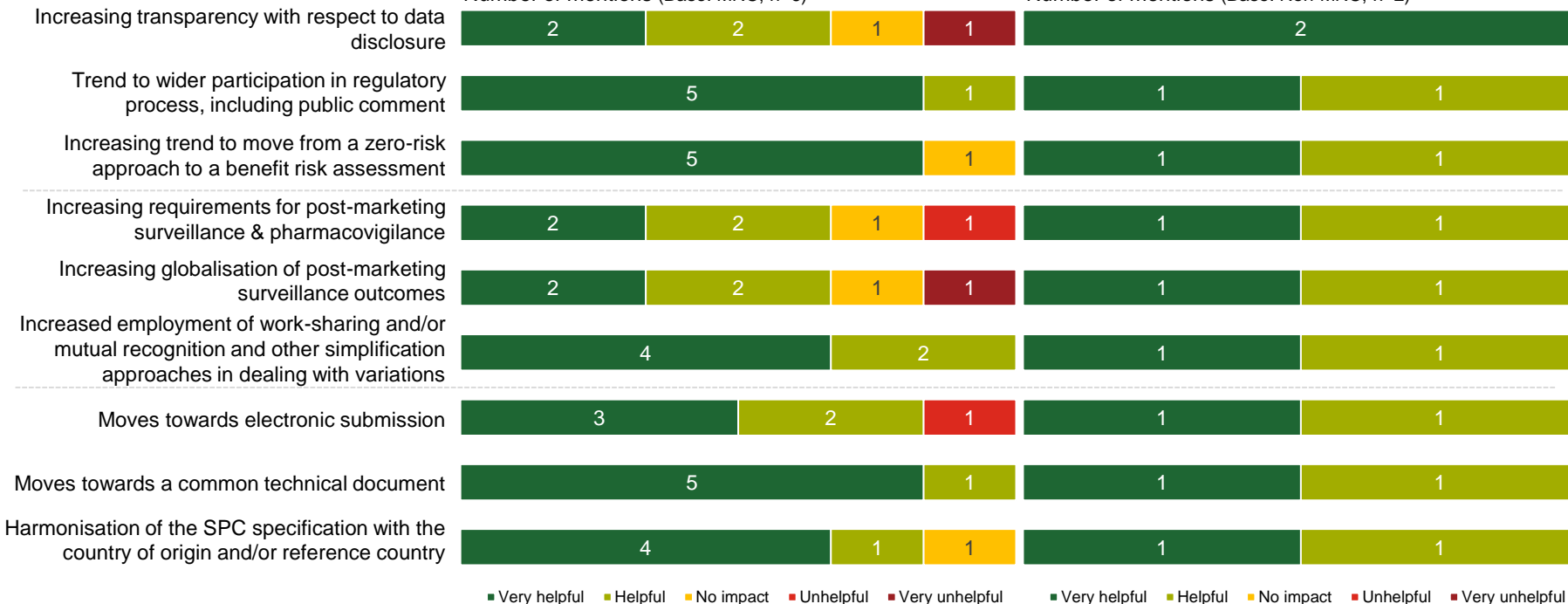
Base, N=8 (combined both MNC & Non-MNC)  
Data shown no. of mentions

## MNC

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

## Non-MNC

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



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?

THAILAND: How the new veterinary product regulations (currently in draft) will affect business? >> None have much comment on this aspect.

THAILAND: Other changes that can have positive impact on business? >> None have much comment on this aspect.

Data shown no. of mentions

How the new veterinary product regulations (currently in draft) will affect business?	No. of mentions		
	TOTAL (N=8)	MNC (n=6)	Non – MNC (n=2)
Minor/No impact	2	2	--
It should be more clear and more specific to animal health products, rather than just follow human guidelines which are sometimes not fit to our implementation.	1	1	--
Would get more difficult to register Animal related products as Thailand and international standards are different	1	--	1
Renewal of the very old products that may require an update of the entire dossier	1	1	--
Negative impact is that this can potentially increase the cost of products	1	1	--
Don't Know	2	1	1

Other changes that have had positive impact on business	No. of mentions		
	TOTAL (N=8)	MNC (n=6)	Non – MNC (n=2)
Clearer requirements	1	1	--
Less complex requirements	1	1	--
Reduced time in reviewing process since they collected government fees	1	--	1
Nothing significant	5	4	1

G2. G3.

## Clearer guidelines that can be review online, reduce the registration standard of AH products (not following human health standard) and reduce the registration period are improvement regulatory managers are seeking

Data shown no. of mentions

Other changes that are still needed / pending	No. of mentions		
	TOTAL (N=8)	MNC (n=6)	Non – MNC (n=2)
All requirements to be stated clearly on guideline which can be reviewed online	3	2	1
Vet drugs registration should not be evaluated as stringent as human drugs	3	2	--
Make the registration period shorter	2	1	1
A more focused or stand-alone entity or Office/ Regulatory agency to handle licensing & registration of animal health products	1	1	--
Thai FDA to request for TRD that really impacts on quality, safety and efficacy of the products, not the unnecessary details	1	1	--
More qualified dossier evaluators	1	1	--
Foresee impact of all new regulations and, in advance, prepare answers to the companies' questions so that companies can have a clear picture and minimize the negative impacts in time	1	1	--

## Increase trend to move from a zero risk approach to a benefit risk assessment is considered by MNCs to be helpful in their business in the future. Non-MNC focused on electronic submission, a common technical document and harmonization of SPC specification

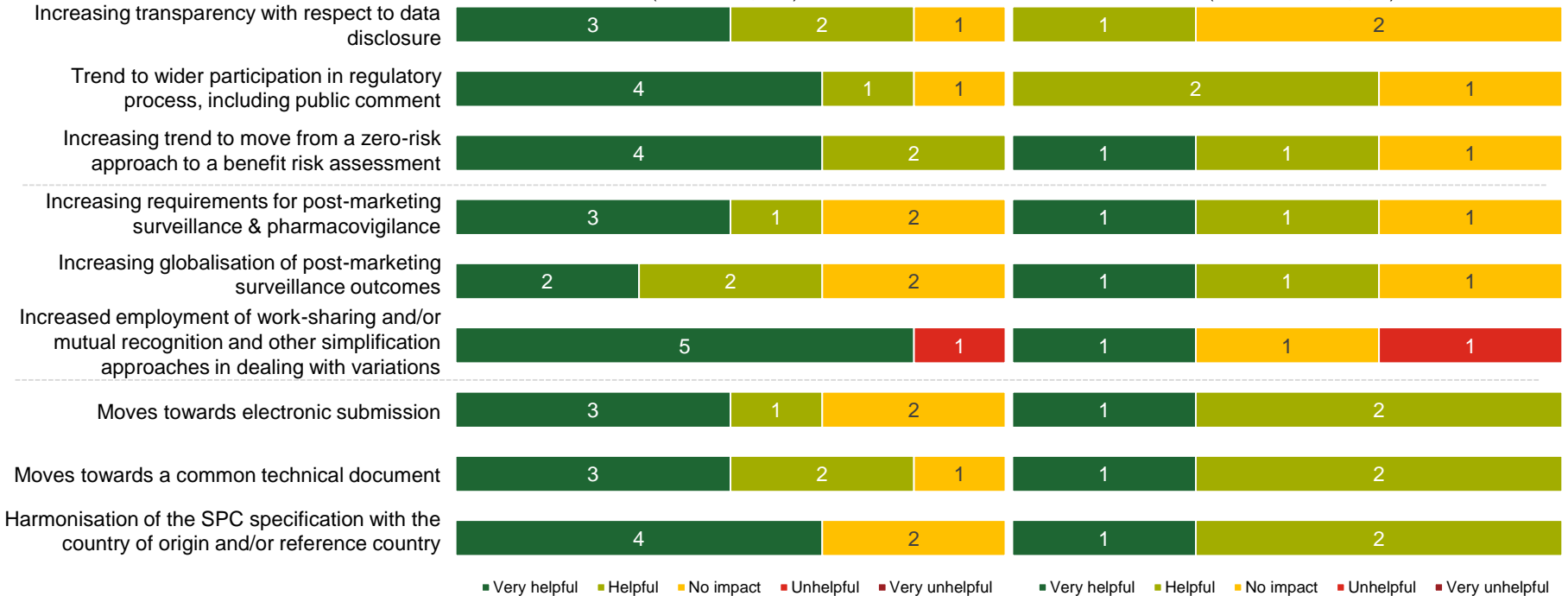
Base, N=9 (combined both MNC & Non-MNC)  
Data shown no. of mentions

### MNC

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

### Non-MNC

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



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?

PHILIPPINES: How the new veterinary product regulations (currently in draft) will affect business? >> Could potentially have changes in requirements for product registration if another regulatory body is doing registration (instead of JAO)



Data shown no. of mentions

How the new veterinary product regulations (currently in draft) will affect business?	No. of mentions		
	TOTAL (N=9)	MNC (n=6)	Non – MNC (n=3)
If the JAO will be discontinued there might be transfer of registration to another authorities which has likely have different requirements	2	1	1
Once it is approved and might proceed to immediate implementation, it will impact all products submitted even before the implementation	1	1	--
New Veterinary Product Act will hopefully bring all veterinary related products under a roof of one regulatory agency	1	--	1
Companies will be able to reduce time and resource needed in registration and focus more on R&D for new product	1	1	--
In general new regulations are not clear and interpretation/implementation varies from one person to another	1	1	--
Potentially increase the cost of products	1	--	1

G2. In your opinion, do you think the NEW VETERINARY PRODUCT REGULATIONS (currently in draft) will affect your business and why?

## PHILIPPINES: Other changes that can have positive impact on business? >> Online registration will make registration process speedier and help prevent lost of dossiers

Data shown no. of mentions

Other changes that have had positive impact on business	No. of mentions		
	TOTAL (N=9)	MNC (n=6)	Non – MNC (n=3)
The online registration made quicker registration process and helped in prevention of dossier loss	2	2	--
Veterinary medicine's quality check has improved to a certain extent	1	--	1
Role/function rotation in government staffs/ personnel with proper qualifications has improved the registration process.	1	1	--
Clearer requirements	1	--	1
For pharmaceutical registration, the variation guidelines is quite helpful in the registration of changes even if adapted with the human regulation.	1	1	--

# Shorten registration period is considered most important change that still needed to happen.

Data shown no. of mentions

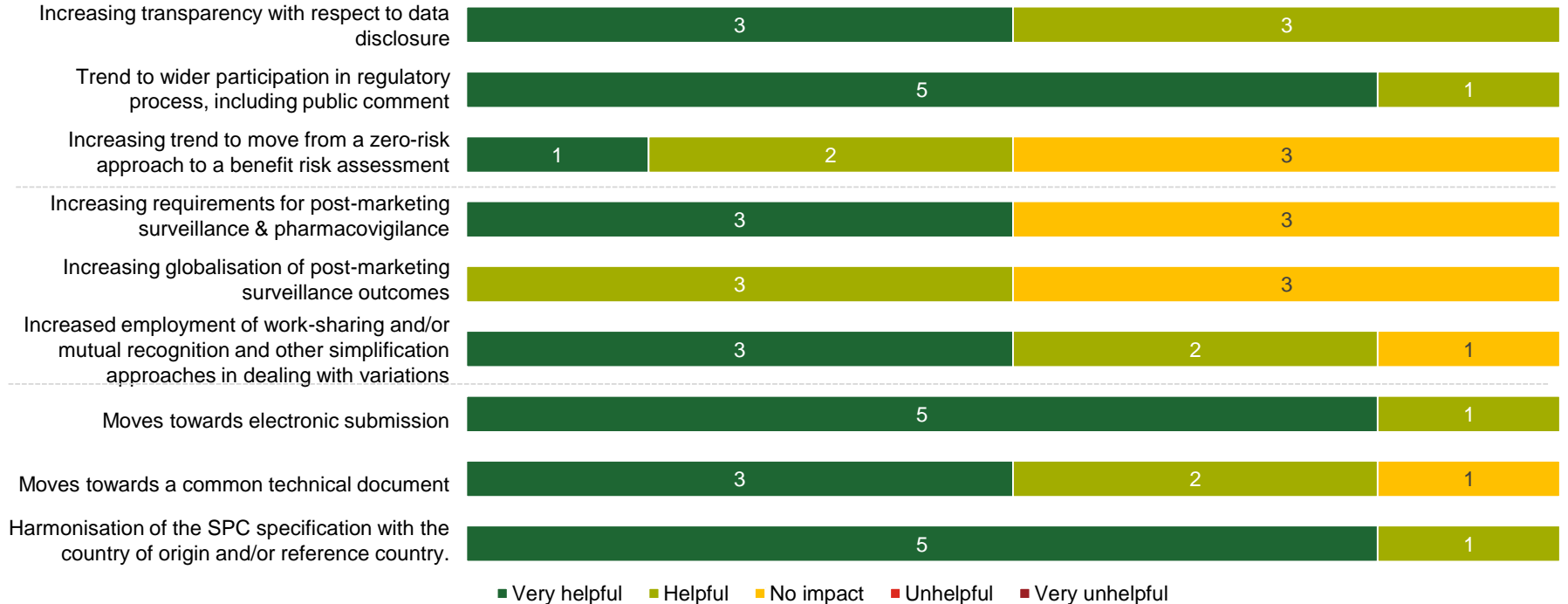
Other changes that are still needed / pending	No. of mentions		
	TOTAL (N=9)	MNC (n=6)	Non – MNC (n=3)
Make the registration period shorter	5	2	3
More qualified dossier evaluators	2	2	--
A more focused or stand-alone entity or Office/ Regulatory agency to handle licensing & registration of animal health products.	2	2	--
Vet drugs registration should not be evaluated as stringent as human drugs	1	1	--



## Increase transparency with respect to data disclosure, wider participation in regulatory process, including public comment and move towards electronic submission are key trends that will be helpful to AH business

Base, N=6 (only MNC)

Data shown no. of mentions



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?

## VIETNAM: How the new veterinary product regulations (currently in draft) will affect business? >> Increase the duration of product registration



## VIETNAM: Other changes that can have positive impact on business? >> Strict control of AH products will reduce fake and low-quality products

Base, N=6

Data shown no. of mentions

How the new veterinary product regulations (currently in draft) will affect business?	No of mentions
It might increase the duration of the registration process for veterinary medicines	2
2 years import license without the need for quality test	1
Spend more to change label according to new requirement	1
We have difficulty in registering for new products because of the limited list of permitted testing laboratories. With only two laboratories but huge workloads, registration progress is slow.	1
It will impact the registration but not sure for better or for worse	1
Minor/No impact	1

Other changes that have had positive impact on business	No of mentions
Strict control of veterinary medicine quality helps to limit fake and low-quality products	3
Accept manufacturer CoA if cant be tested in country	1
Extending the licenses validity period - save time and cost	1
Reduce time and cost due to reduce of quality test frequency	1

Acceptance manufacturers' test results of products in the event that the product cannot be tested in the country are what regulatory managers wanted to change in the future.

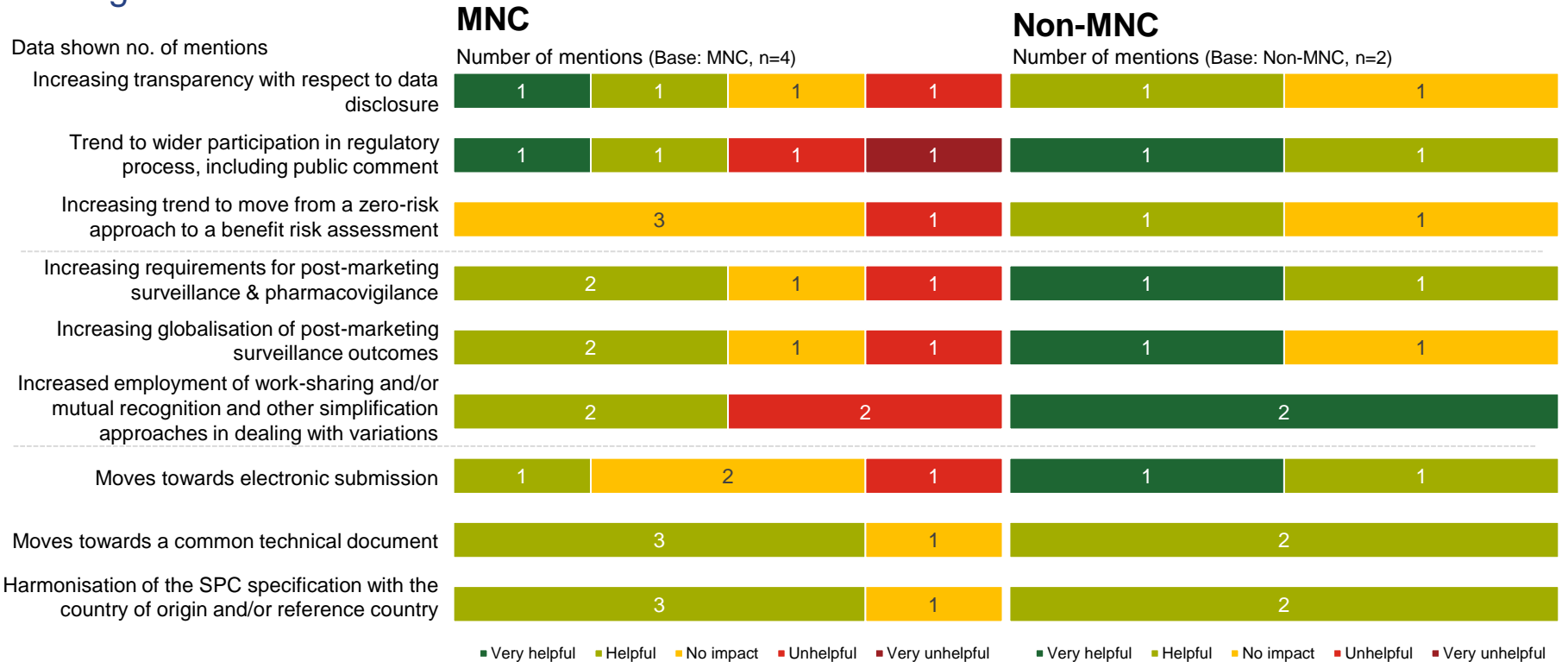


Base, N=6

Data shown no. of mentions

Other changes that are still needed / pending	No of mentions
Solution to register new products that can't be tested in the country/accept manufacturer/ related quality test result	4
Authorities to move from zero-risk approach to benefit-assessment approach in product registration restriction	2
Consistent timeline is followed as stated in the guidelines	2
Consistency in requirements	1
Simplify registration procedures.	1
Harmonized registration process and some sort of mutual recognition to enhance efficiency and reduce redundancy	1
Changes in the quality and capabilities of designated laboratories in order to be able to receive and receive new technology transfer in evaluating new product quality	1
Transparency in registration process and execution	1

Some MNC companies think that most of these trends/changes will not be helpful the industry in the future. Non-MNC seems more positive on 2 topics: Increased employment of work-sharing and move towards a common electronic submission



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?

CAMBODIA: How the new veterinary product regulations (currently in draft) will affect business? >> Most have much comment on this aspect.

CAMBODIA: Other changes that can have positive impact on business? >> Most have much comment on this aspect.

Data shown no. of mentions

How the new veterinary product regulations (currently in draft) will affect business?	No. of mentions		
	TOTAL (N=6)	MNC (n=4)	Non – MNC (n=2)
Minor/No impact	2	1	1
It will not affect as Registration Process is still not well developed in the country yet	1	1	--
Additionally, the IP protection in Cambodia will be better for the companies by preventing the illegal products from getting into the market easily	1	1	--
All A/H products are controlled by MOA, not MOH.	1	1	--
This will increase the efficiency of AH product registration	1	1	--
It might increase the duration of the registration process for veterinary medicines	1	1	--
Don't know	2	1	1
Other changes that have had positive impact on business	No. of mentions		
	TOTAL (N=6)	MNC (n=4)	Non – MNC (n=2)
No major challenges in AH product registration	1	1	--
Simple and quick regulatory system to bring in AH products for disease outbreak	1	1	--
More control on the usage of AGP, prevent AMR	1	1	--
Nothing significant	3	1	2

G2. G3.

## Transparency in registration process and execution, greater post-marketing surveillance, cheaper registration fee and support during registration are desired changes in the future for the industry



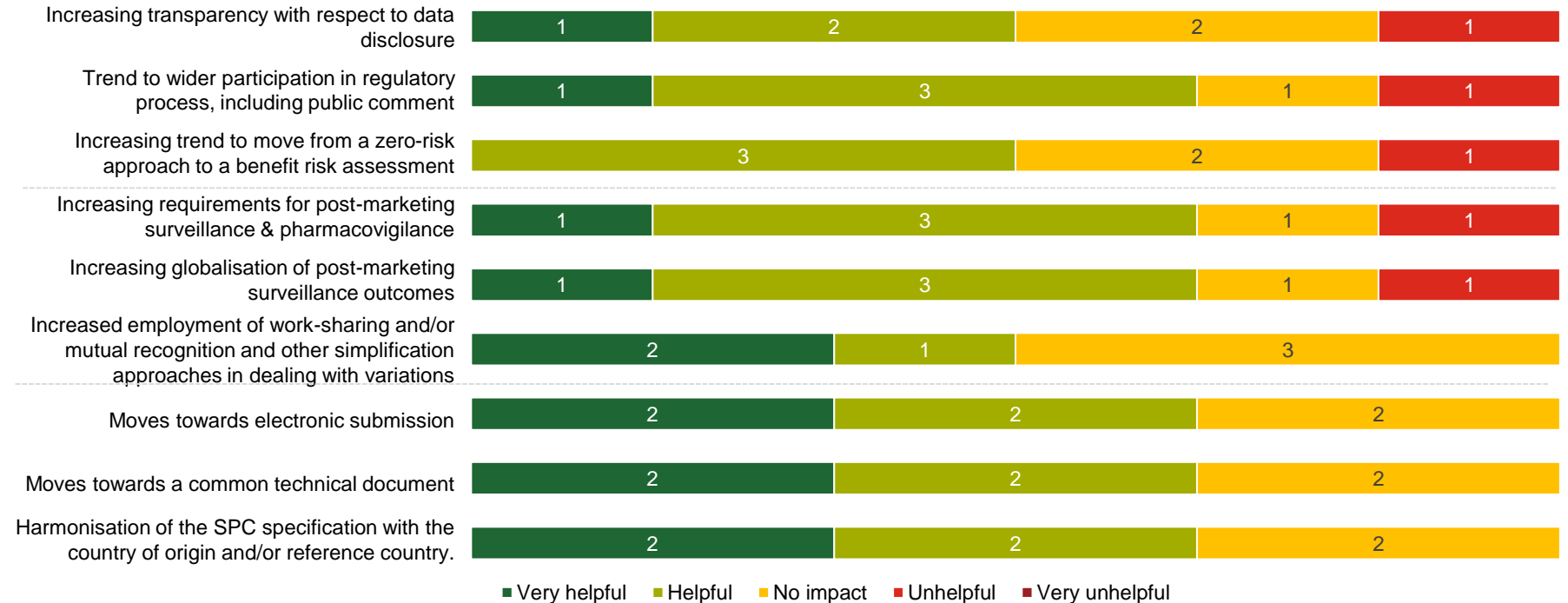
Data shown no. of mentions

Other changes that are still needed / pending	No. of mentions		
	TOTAL (N=6)	MNC (n=4)	Non – MNC (n=2)
Transparency in registration process and execution	1	1	--
Greater post-marketing surveillance to prevent non-registered products from entering the market.	1	--	1
Support foreign company in product registration in collaboration with local company	1	1	--
Registration fees commensurate with market size	1	--	1
A well developed Registration Process and free from political	1	1	--
NONE	2	1	1

# Managers considered electronic submission, common technical document and harmonization of the SPC specifications with the country of origin and/or reference country to be helpful in the future.



Base, N=6  
Data shown no. of mentions



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?

MYANMAR: How the new veterinary product regulations (currently in draft) will affect business? >> Most have much comment on this aspect.



MYANMAR: Other changes that can have positive impact on business? >> Most have much comment on this aspect.

Base, N=6

Data shown no. of mentions

How the new veterinary product regulations (currently in draft) will affect business?	No of mentions
Minor/No impact	4
Regulation in Myanmar is still in developing stage. It will take them years to be able to follow the New Veterinary Product Regulations	1
Don't Know	1
Other changes that have had positive impact on business	No of mentions
Simple and quick regulatory system to bring in AH products for disease outbreak	1
Requirement for more dossiers to prove product's quality helps reduce low quality products	1
No change in regulatory framework since 2014	1
Nothing significant	3



A more well developed registration process and free from political / commercial influences is what managers are looking for.

Base, N=6

Data shown no. of mentions

Other changes that are still needed / pending	No of mentions
Less non-scientific protectionism / A well developed Registration Process and free from political / commercial influences	2
Transparency in registration process and execution	1
Greater post-marketing surveillance to prevent non-registered products from entering the market.	1
All requirements to be stated clearly on guideline which can be reviewed online	1
Harmonized registration process and some sort of mutual recognition to enhance efficiency and reduce redundancy	1
None	2



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