



Time taken to achieve registration

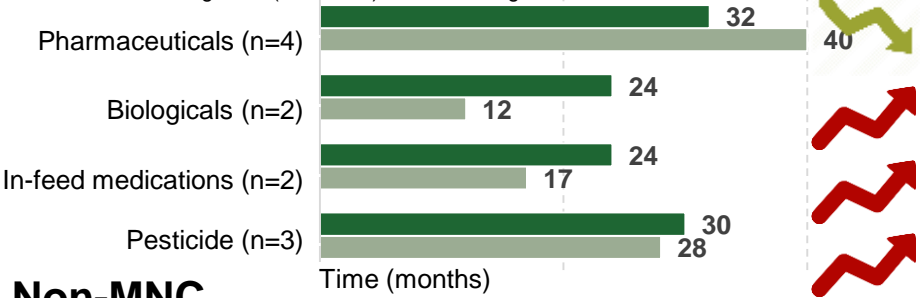


In general, the time taken to registered AH products have increased in 2018 vs. 2014, with the exception of pharmaceutical by MNC companies due to external regulatory process

MNC

Base, N=5 ■ 2018 ■ 2014

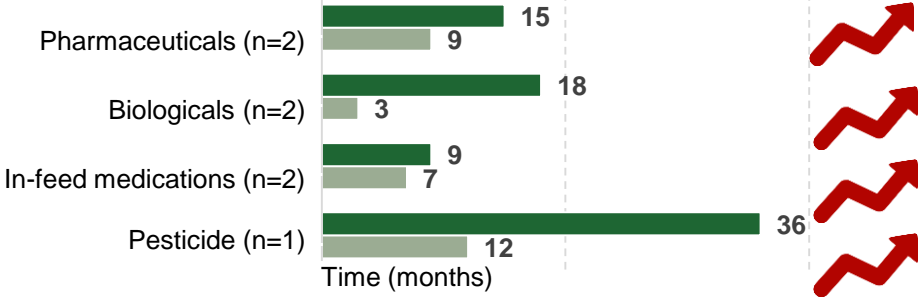
Data showed the avg. time (in months) to achieve registration



Non-MNC

Base, N=4 ■ 2018 ■ 2014

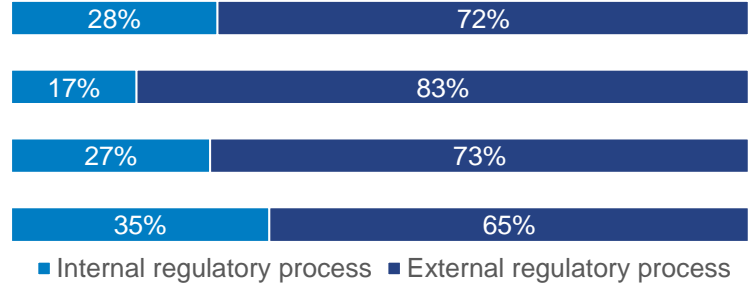
Data showed the avg. time (in months) to achieve registration



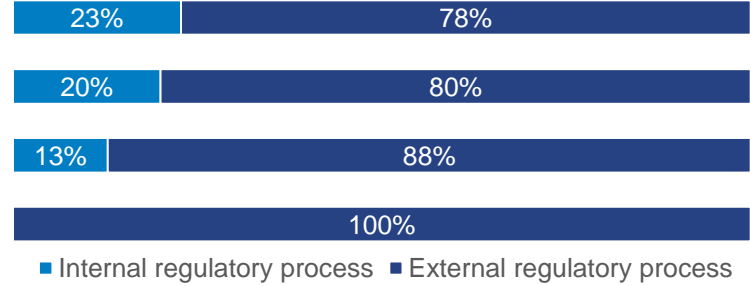
Internal regulatory processes: All activities required for your company to manage the regulatory activity after the dossier has been submitted

External regulatory processes: All activities of the regulatory agency after the dossier has been submitted

Proportion of change in time taken (between 2018 vs. 2014) caused by internal vs external



Proportion of change in time taken (between 2018 vs. 2014) caused by internal vs external



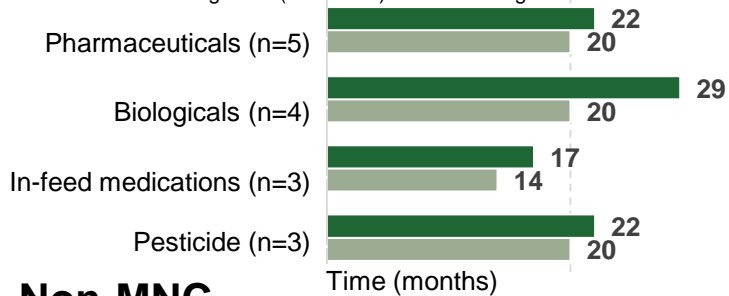
C1a1. Can you tell me what the typical time is for you to achieve registration for AH products for your country/ASEAN currently? C1b. What about vs/ 2014? C1c. What proportion of these changes (between 2014 vs. 2018) has been caused by internal regulatory processes and what proportion by external regulatory processes?

In general, the time taken to registered AH products have increased in 2018 vs. 2014, with the exception of pharmaceutical by MNC companies due to external regulatory process

MNC

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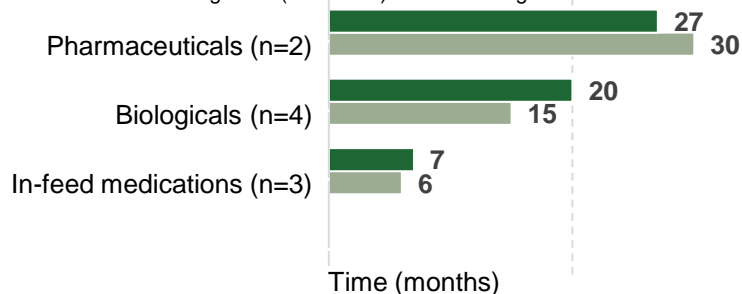
Data showed the avg. time (in months) to achieve registration



Non-MNC

Base, N=4 ■ 2018 ■ 2014

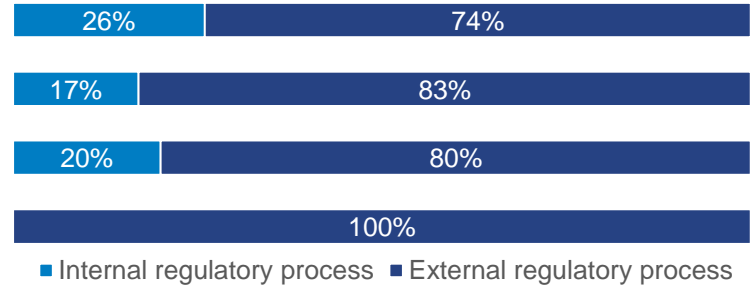
Data showed the avg. time (in months) to achieve registration



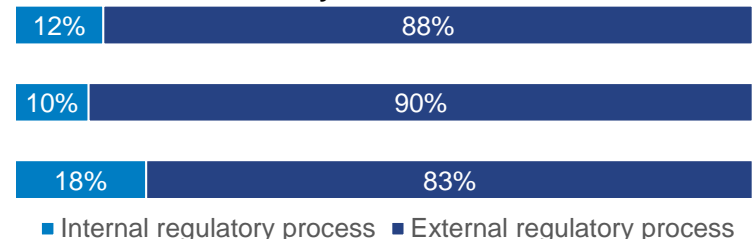
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Proportion of change in time taken (between 2018 vs. 2014) caused by internal vs external



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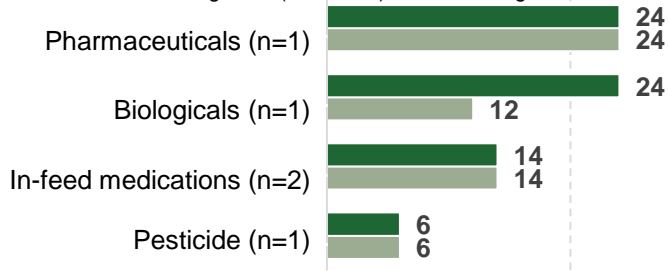


For aqua & other products the time taken to get product registration have not change, except biological...which timeline had improved (decreased)

MNC

Base, N=5 ■ 2018 ■ 2014

Data showed the avg. time (in months) to achieve registration



Internal regulatory processes: All activities required for your company to manage the regulatory activity after the dossier has been submitted

External regulatory processes: All activities of the regulatory agency after the dossier has been submitted

Proportion of change in time taken (between 2018 vs. 2014) caused by internal vs external



■ Internal regulatory process ■ External regulatory process

MALAYSIA SUMMARY: Typical time for registration for different categories of product registration

Pharmaceutical			Biologicals			In-feed medications			Pesticides		
Category	No of months		Category	No of months		Category	No of months		Category	No of months	
	MNC	Non-MNC		MNC	Non-MNC		MNC	Non-MNC		MNC	Non-MNC
New product	36	--	New product	24	24	New product	--	--	New product	--	36
Generic	24	--	Generic	24	--	Generic	--	--	Generic	--	--
Major variation	12	--	Major variation	6	--	Major variation	--	--	Major variation	--	--
Minor variation	6	--	Minor variation	2	--	Minor variation	--	--	Minor variation	--	--
Re-registration	6	1	Re-registration	6	1	Re-registration	--	1	Re-registration	12	12

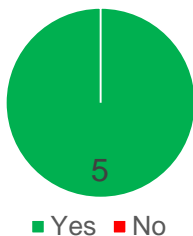
NOTE: Not all managers provide us detailed timeline by product categories. We have recorded down all the answers given. Hence, the base is very small. Use with caution

MALAYSIA – PHARMACEUTICALS: Typical time for registration for different categories of product registration

Are there significant differences in typical time for registration for [THERAPEUTIC AREA] between different categories (new products vs. generic products vs. major variation vs. minor variations vs. re-registration)?

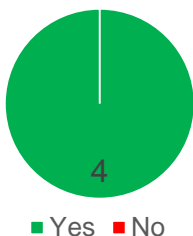
Base, n=5

MNC



Base, n=4

Non-MNC



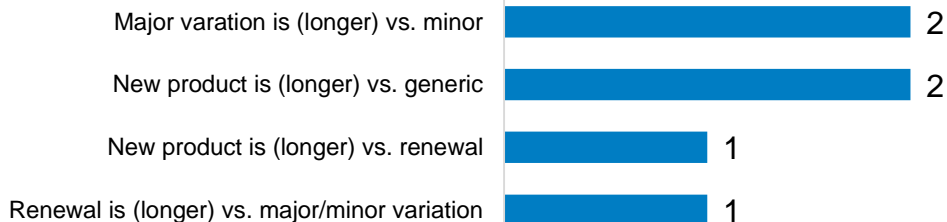
Comparison between timeline for registration on different category of product registration

Base, n=5, Data shown no. of mentions



Comparison between timeline for registration on different category of product registration

Base, n=4, Data shown no. of mentions



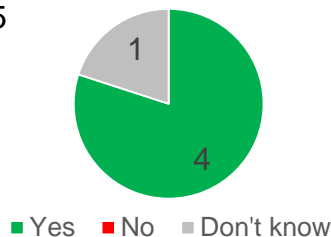
C1a: Are there significant differences in terms of typical time for registration of Pharmaceuticals for your country / ASEAN for different categories of product registration (new products vs. generic products vs. major variation vs. minor variation vs. re-registration)

MALAYSIA – BIOLOGICALS: Typical time for registration for different categories of product registration

Are there significant differences in typical time for registration for [THERAPEUTIC AREA] between different categories (new products vs. generic products vs. major variation vs. minor variations vs. re-registration)?

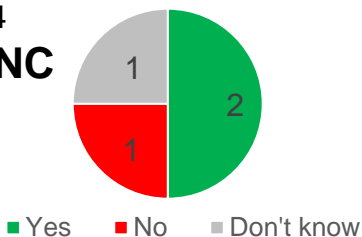
Base, n=5

MNC



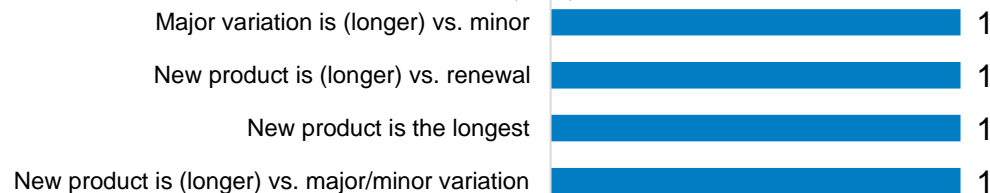
Base, n=4

Non-MNC



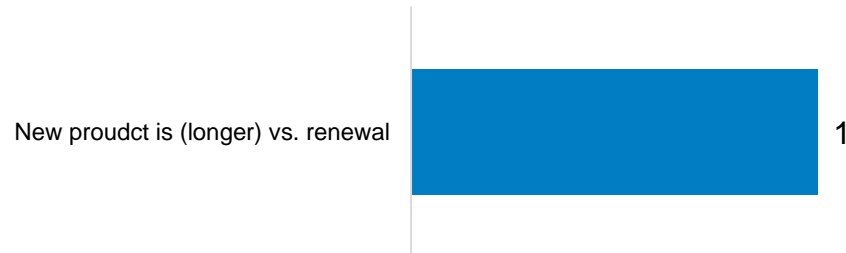
Comparison between timeline for registration on different category of product registration

Base, n=4, Data shown no. of mentions



Comparison between timeline for registration on different category of product registration

Base, n=1, Data shown no. of mentions

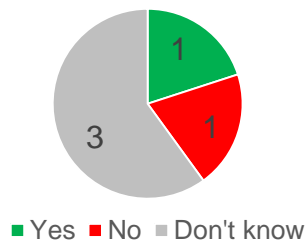


C2a: Are there significant differences in terms of typical time for registration of Biologicals for your country / ASEAN for different categories of product registration (new products vs. generic products vs. major variation vs. minor variation vs. re-registration)

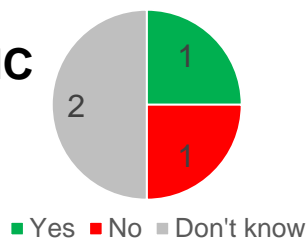
MALAYSIA – IN-FEED MEDICATIONS: Typical time for registration for different categories of product registration

Are there significant differences in typical time for registration for [THERAPEUTIC AREA] between different categories (new products vs. generic products vs. major variation vs. minor variations vs. re-registration)?

Base, n=5
MNC



Base, n=4
Non-MNC



Comparison between timeline for registration on different category of product registration

Base, n=1, Data shown no. of mentions



Comparison between timeline for registration on different category of product registration

Base, n=1, Data shown no. of mentions



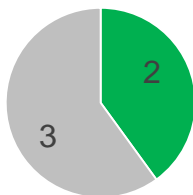
C3a: Are there significant differences in terms of typical time for registration of In-feed medications for your country / ASEAN for different categories of product registration (new products vs. generic products vs. major variation vs. minor variation vs. re-registration)

MALAYSIA – PESTICIDES: Typical time for registration for different categories of product registration

Are there significant differences in typical time for registration for [THERAPEUTIC AREA] between different categories (new products vs. generic products vs. major variation vs. minor variations vs. re-registration)?

Base, n=5

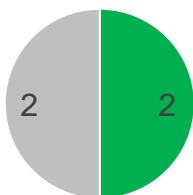
MNC



■ Yes ■ No ■ Don't know

Base, n=4

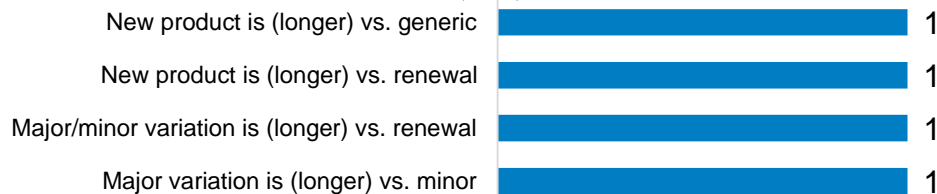
Non-MNC



■ Yes ■ No ■ Don't know

Comparison between timeline for registration on different category of product registration

Base, n=2, Data shown no. of mentions



Comparison between timeline for registration on different category of product registration

Base, n=2, Data shown no. of mentions



C4a: Are there significant differences in terms of typical time for registration of Pesticides for your country / ASEAN for different categories of product registration (new products vs. generic products vs. major variation vs. minor variation vs. re-registration)

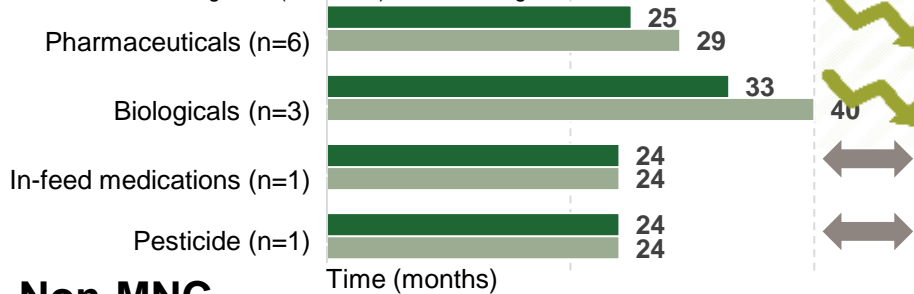


According to the managers, time taken to achieved registration had reduced for pharmaceutical and biologicals. No change to in-feed medications and pesticides

MNC

Base, N=6 ■ 2018 ■ 2014

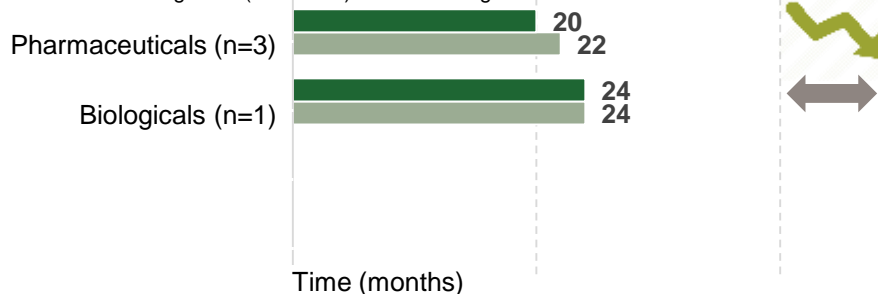
Data showed the avg. time (in months) to achieve registration



Non-MNC

Base, N=6 ■ 2018 ■ 2014

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Internal regulatory processes: All activities required for your company to manage the regulatory activity after the dossier has been submitted

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Proportion of change in time taken (between 2018 vs. 2014) caused by internal vs external



■ Internal regulatory process ■ External regulatory process

Proportion of change in time taken (between 2018 vs. 2014) caused by internal vs external



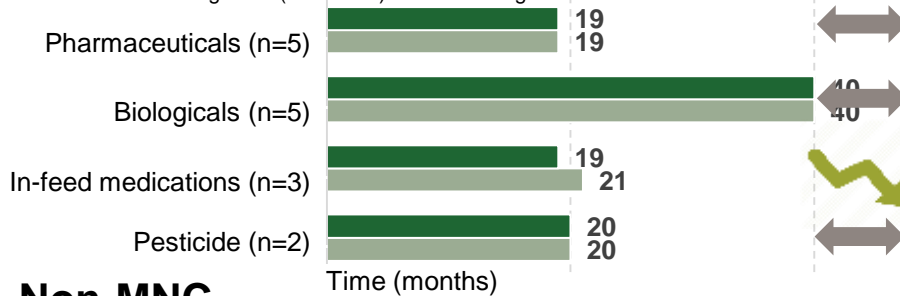
■ Internal regulatory process ■ External regulatory process

MNC and non-MNC disagreed on the time taken to for AH product registration. MNC said the timeline has reduced, while non-MNC said increased in timeline

MNC

Base, N=6 ■ 2018 ■ 2014

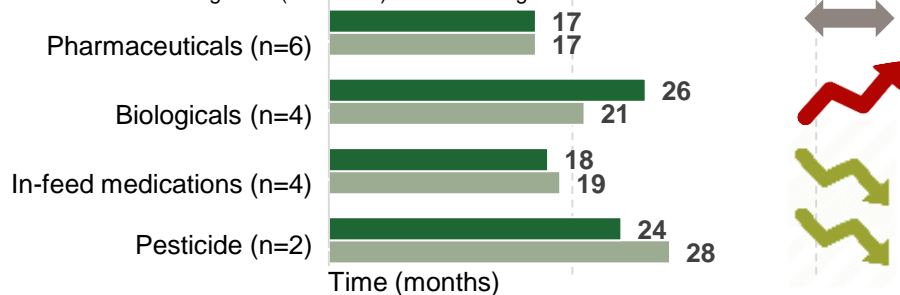
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Non-MNC

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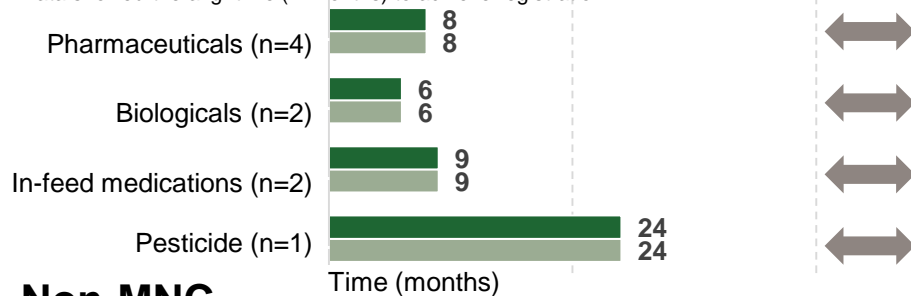
INDONESIA – AQUA & OTHERS: Time taken to achieve new animal health product registration (months)

No change to the timeline of aqua and other products in Indonesia

MNC

Base, N=6 ■ 2018 ■ 2014

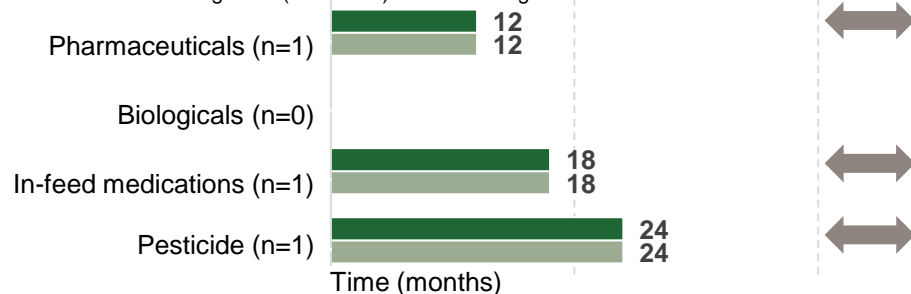
Data showed the avg. time (in months) to achieve registration



Non-MNC

Base, N=6 ■ 2018 ■ 2014

Data showed the avg. time (in months) to achieve registration



INDONESIA SUMMARY: Typical time for registration for different categories of product registration



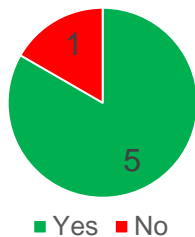
Pharmaceutical			Biologicals			In-feed medications			Pesticides		
Category	No of months		Category	No of months		Category	No of months		Category	No of months	
	MNC	Non-MNC		MNC	Non-MNC		MNC	Non-MNC		MNC	Non-MNC
New product	24	24	New product	24	24	New product	18	24	New product	18	36
Generic	18	12	Generic	18	--	Generic	15	12	Generic	12	12
Major variation	6	8	Major variation	6	8	Major variation	6	8	Major variation	6	12
Minor variation	3	3	Minor variation	3	3	Minor variation	3	3	Minor variation	3	6
Re-registration	12	18	Re-registration	12	18	Re-registration	--	18	Re-registration	--	24

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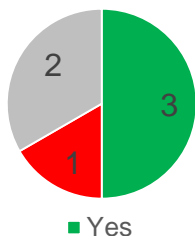
INDONESIA – PHARMACEUTICALS: Typical time for registration for different categories of product registration

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Base, n=6
MNC

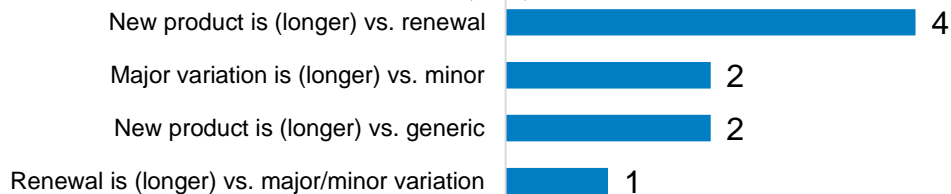


Base, n=6
Non-MNC



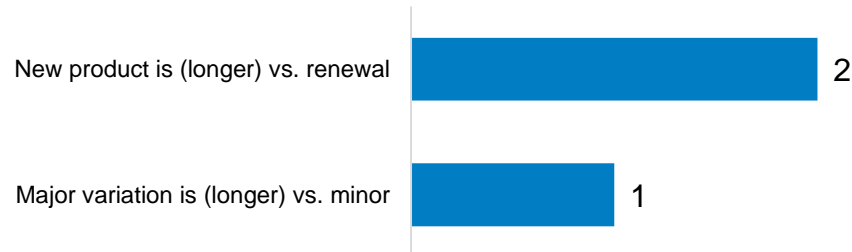
Comparison between timeline for registration on different category of product registration

Base, n=5, Data shown no. of mentions



Comparison between timeline for registration on different category of product registration

Base, n=3, Data shown no. of mentions



C1a: Are there significant differences in terms of typical time for registration of Pharmaceuticals for your country / ASEAN for different categories of product registration (new products vs. generic products vs. major variation vs. minor variation vs. re-registration)

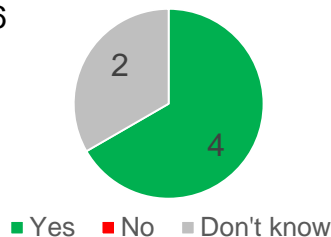
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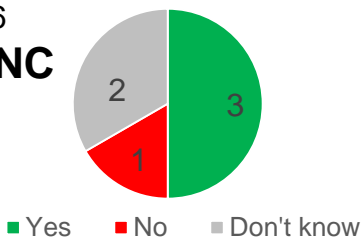
Base, n=6

MNC



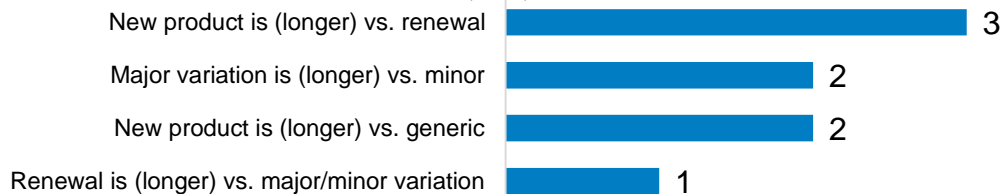
Base, n=6

Non-MNC



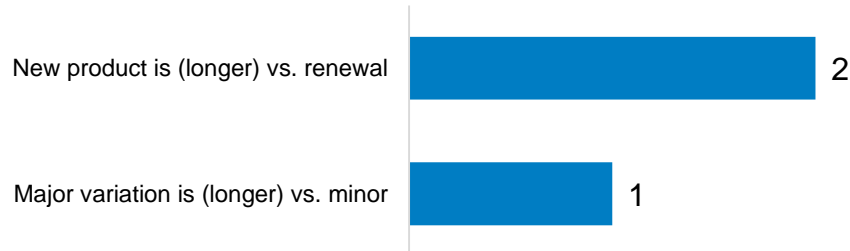
Comparison between timeline for registration on different category of product registration

Base, n=4, Data shown no. of mentions



Comparison between timeline for registration on different category of product registration

Base, n=3, Data shown no. of mentions

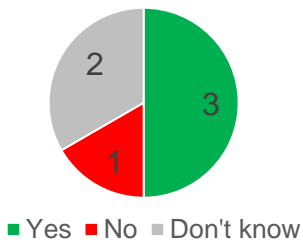


C2a: Are there significant differences in terms of typical time for registration of Biologicals for your country / ASEAN for different categories of product registration (new products vs. generic products vs. major variation vs. minor variation vs. re-registration)

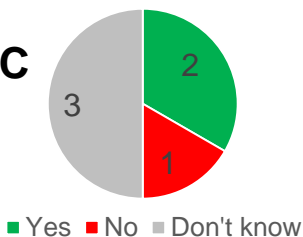
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Base, n=6
MNC



Base, n=6
Non-MNC



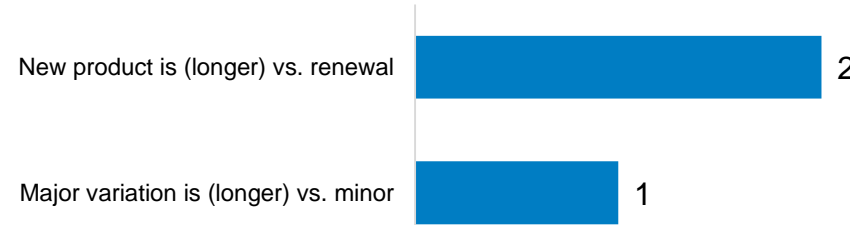
Comparison between timeline for registration on different category of product registration

Base, n=3, Data shown no. of mentions



Comparison between timeline for registration on different category of product registration

Base, n=2, Data shown no. of mentions



C3a: Are there significant differences in terms of typical time for registration of in-feed medications for your country / ASEAN for different categories of product registration (new products vs. generic products vs. major variation vs. minor variation vs. re-registration)

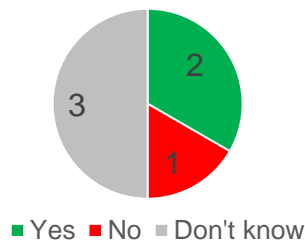
INDONESIA – PESTICIDES: Typical time for registration for different categories of product registration



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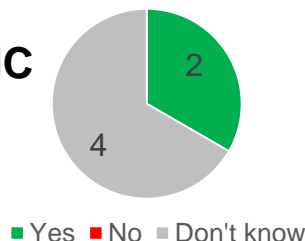
Base, n=6

MNC



Base, n=6

Non-MNC



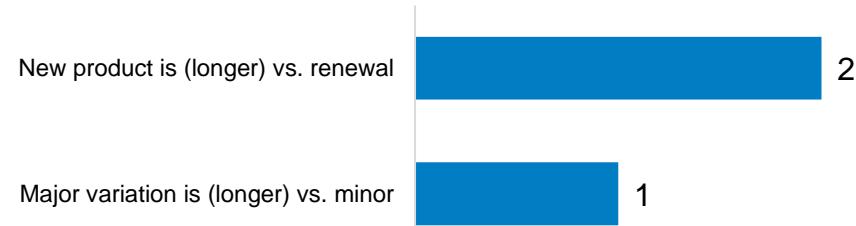
Comparison between timeline for registration on different category of product registration

Base, n=2, Data shown no. of mentions



Comparison between timeline for registration on different category of product registration

Base, n=2, Data shown no. of mentions



C4a: Are there significant differences in terms of typical time for registration of Pesticides for your country / ASEAN for different categories of product registration (new products vs. generic products vs. major variation vs. minor variation vs. re-registration)

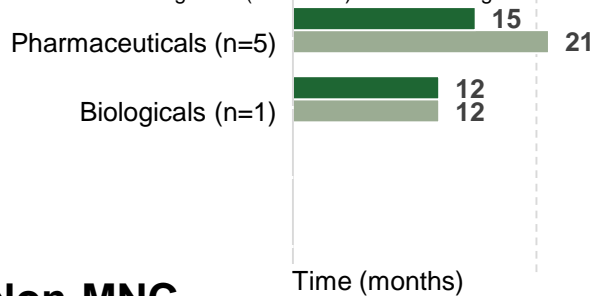


In general the timeline needed for product registration has reduced for all most of the therapeutic areas

MNC

Base, N=6 ■ 2018 ■ 2014

Data showed the avg. time (in months) to achieve registration



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Proportion of change in time taken (between 2018 vs. 2014) caused by internal vs external

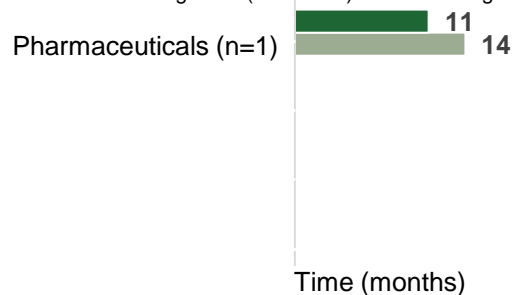


■ Internal regulatory process ■ External regulatory process

Non-MNC

Base, N=2 ■ 2018 ■ 2014

Data showed the avg. time (in months) to achieve registration



Proportion of change in time taken (between 2018 vs. 2014) caused by internal vs external



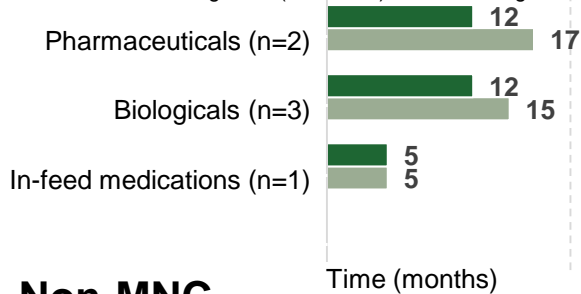
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MNC

Base, N=6 ■ 2018 ■ 2014

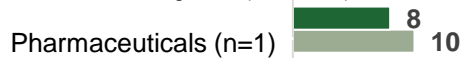
Data showed the avg. time (in months) to achieve registration



Non-MNC

Base, N=2 ■ 2018 ■ 2014

Data showed the avg. time (in months) to achieve registration



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Proportion of change in time taken (between 2018 vs. 2014) caused by internal vs external



■ Internal regulatory process ■ External regulatory process

Proportion of change in time taken (between 2018 vs. 2014) caused by internal vs external



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THAILAND SUMMARY: Typical time for registration for different categories of product registration

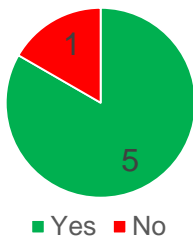
Pharmaceutical			Biologicals			In-feed medications			Pesticides		
Category	No of months		Category	No of months		Category	No of months		Category	No of months	
	MNC	Non-MNC		MNC	Non-MNC		MNC	Non-MNC		MNC	Non-MNC
New product	12	11	New product	--	--	New product	--	--	New product	4	--
Generic	8	8	Generic	8	--	Generic	--	--	Generic	--	--
Major variation	6	5	Major variation	8	--	Major variation	--	--	Major variation	2	--
Minor variation	3	3	Minor variation	3	--	Minor variation	--	--	Minor variation	2	--
Re-registration	--	--	Re-registration	--	--	Re-registration	--	--	Re-registration	--	--

NOTE: Not all managers provide us detailed timeline by product categories. We have recorded down all the answers given. Hence, the base is very small. Use with caution

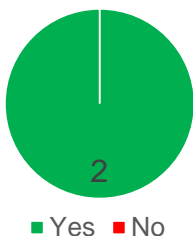
THAILAND – PHARMACEUTICALS: Typical time for registration for different categories of product registration

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Base, n=6
MNC

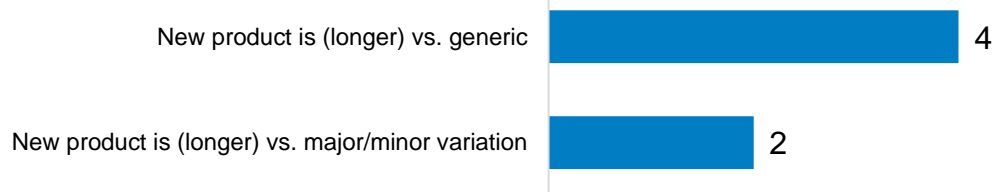


Base, n=2
Non-MNC



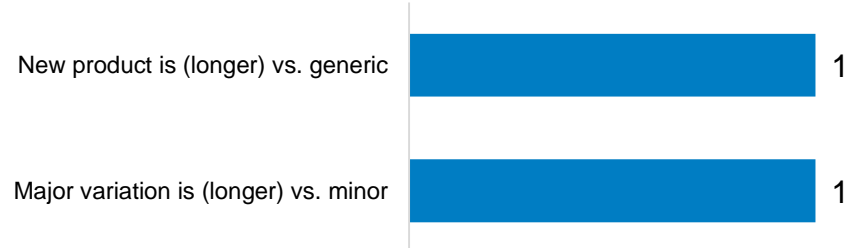
Comparison between timeline for registration on different category of product registration

Base, n=5, Data shown no. of mentions



Comparison between timeline for registration on different category of product registration

Base, n=2, Data shown no. of mentions

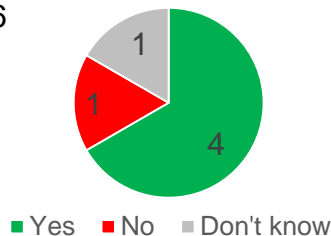


C1a: Are there significant differences in terms of typical time for registration of Pharmaceuticals for your country / ASEAN for different categories of product registration (new products vs. generic products vs. major variation vs. minor variation vs. re-registration)

THAILAND – BIOLOGICALS: Typical time for registration for different categories of product registration

Are there significant differences in typical time for registration for [THERAPEUTIC AREA] between different categories (new products vs. generic products vs. major variation vs. minor variations vs. re-registration)?

Base, n=6
MNC

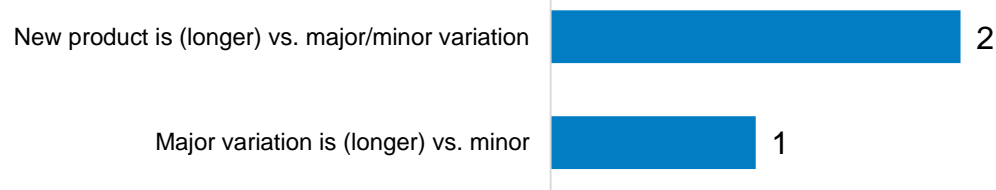


Base, n=2
Non-MNC



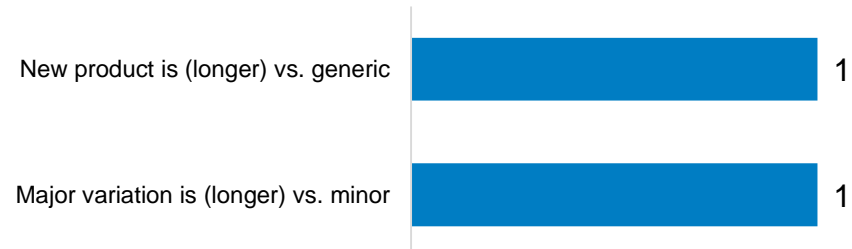
Comparison between timeline for registration on different category of product registration

Base, n=4, Data shown no. of mentions



Comparison between timeline for registration on different category of product registration

Base, n=2, Data shown no. of mentions



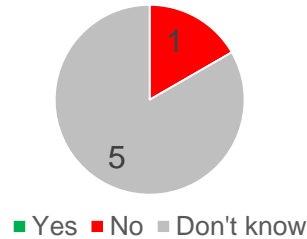
C2a: Are there significant differences in terms of typical time for registration of Biologicals for your country / ASEAN for different categories of product registration (new products vs. generic products vs. major variation vs. minor variation vs. re-registration)

THAILAND – IN-FEED MEDICATIONS: Typical time for registration for different categories of product registration

Are there significant differences in typical time for registration for [THERAPEUTIC AREA] between different categories (new products vs. generic products vs. major variation vs. minor variations vs. re-registration)?

Base, n=6

MNC



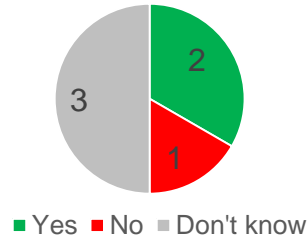
C3a: Are there significant differences in terms of typical time for registration of In-feed medications for your country / ASEAN for different categories of product registration (new products vs. generic products vs. major variation vs. minor variation vs. re-registration)

THAILAND – PESTICIDES: Typical time for registration for different categories of product registration

Are there significant differences in typical time for registration for [THERAPEUTIC AREA] between different categories (new products vs. generic products vs. major variation vs. minor variations vs. re-registration)?

Base, n=6

MNC



Comparison between timeline for registration on different category of product registration

Base, n=2, Data shown no. of mentions

New product is (longer) vs. major/minor variation



C4a: Are there significant differences in terms of typical time for registration of Pesticides for your country / ASEAN for different categories of product registration (new products vs. generic products vs. major variation vs. minor variation vs. re-registration)

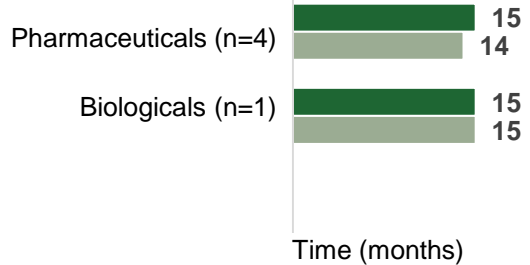
In general the timeline needed for product registration has increased for all most of the therapeutic areas for companion and production animals



Companion animal

Base, N=6 ■ 2018 ■ 2014

Data showed the avg. time (in months) to achieve registration



Companion animal



Internal regulatory processes: All activities required for your company to manage the regulatory activity after the dossier has been submitted

External regulatory processes: All activities of the regulatory agency after the dossier has been submitted

Proportion of change in time taken (between 2018 vs. 2014) caused by internal vs external

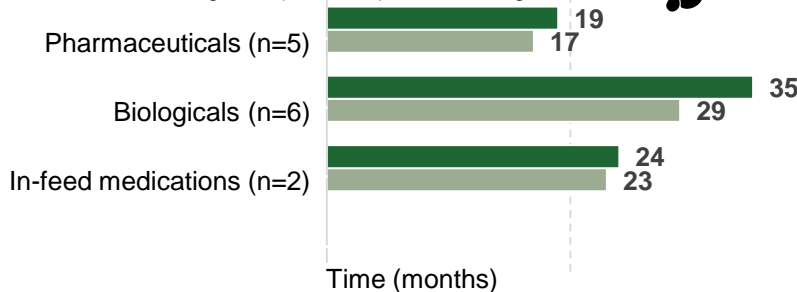


■ Internal regulatory process ■ External regulatory process

Production animal

Base, N=6 ■ 2018 ■ 2014

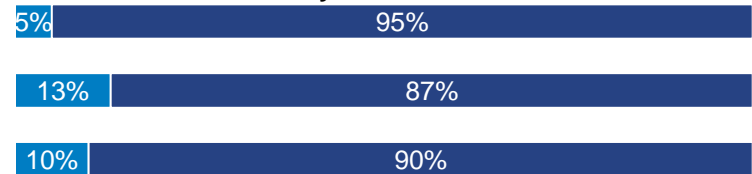
Data showed the avg. time (in months) to achieve registration



Production animal



Proportion of change in time taken (between 2018 vs. 2014) caused by internal vs external



■ Internal regulatory process ■ External regulatory process

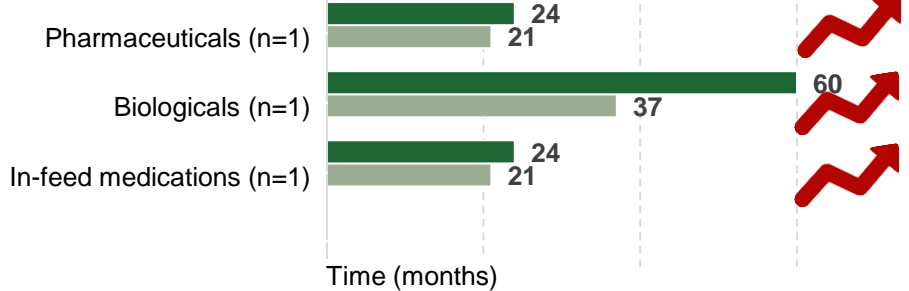
In general the timeline needed for product registration has increased for all most of the therapeutic areas for aqua and others



Aqua & others

Base, N=6 ■ 2018 ■ 2014

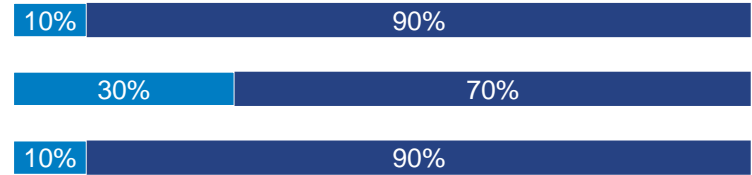
Data showed the avg. time (in months) to achieve registration



Internal regulatory processes: All activities required for your company to manage the regulatory activity after the dossier has been submitted

External regulatory processes: All activities of the regulatory agency after the dossier has been submitted

Proportion of change in time taken (between 2018 vs. 2014) caused by internal vs external



■ Internal regulatory process ■ External regulatory process

VIETNAM SUMMARY: Typical time for registration for different categories of product registration



Pharmaceutical			Biologicals			In-feed medications			Pesticides		
Category	No of months		Category	No of months		Category	No of months		Category	No of months	
	MNC	Non-MNC		MNC	Non-MNC		MNC	Non-MNC		MNC	Non-MNC
New product	42	--	New product	48	--	New product	38	--	New product	40	--
Generic	24	--	Generic	24	--	Generic	12	--	Generic	12	--
Major variation	6	--	Major variation	9	--	Major variation	6	--	Major variation	8	--
Minor variation	2	--	Minor variation	5	--	Minor variation	3	--	Minor variation	2	--
Re-registration	3	--	Re-registration	6	--	Re-registration	6	--	Re-registration	--	--

NOTE: Not all managers provide us detailed timeline by product categories. We have recorded down all the answers given. Hence, the base is very small. Use with caution

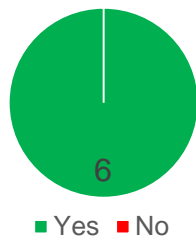
VIETNAM – MNC: Typical time for registration for different categories of product registration



Are there significant differences in typical time for registration for [THERAPEUTIC AREA] between different categories (new products vs. generic products vs. major variation vs. minor variations vs. re-registration)?

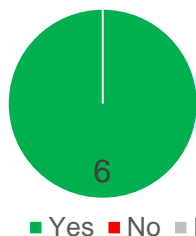
Base, n=6

Pharmaceuticals



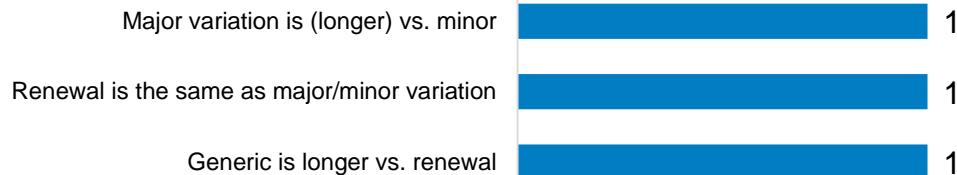
Base, n=6

Biologicals



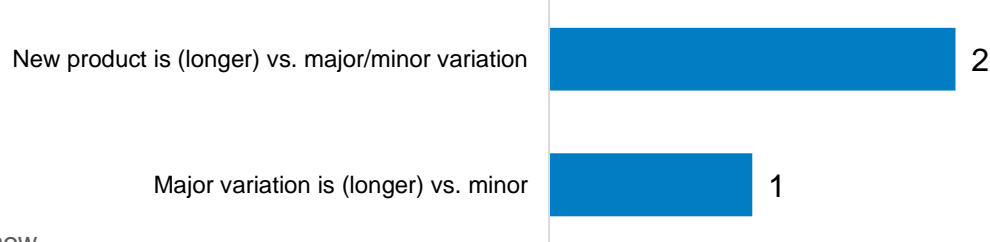
Comparison between timeline for registration on different category of product registration

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



Comparison between timeline for registration on different category of product registration

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



C1a: Are there significant differences in terms of typical time for registration of Pharmaceuticals for your country / ASEAN for different categories of product registration (new products vs. generic products vs. major variation vs. minor variation vs. re-registration)

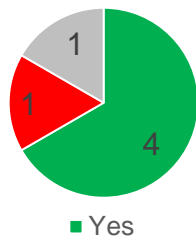
VIETNAM – MNC: Typical time for registration for different categories of product registration



Are there significant differences in typical time for registration for [THERAPEUTIC AREA] between different categories (new products vs. generic products vs. major variation vs. minor variations vs. re-registration)?

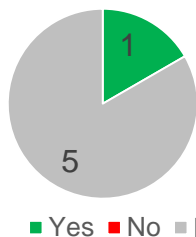
Base, n=6

In-feed medications



Base, n=6

Biologicals



■ Yes ■ No ■ Don't know

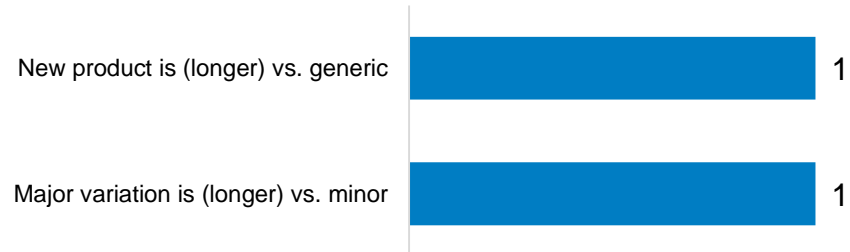
Comparison between timeline for registration on different category of product registration

Base, n=4, Data shown no. of mentions



Comparison between timeline for registration on different category of product registration

Base, n=1, Data shown no. of mentions



C1a: Are there significant differences in terms of typical time for registration of Pharmaceuticals for your country / ASEAN for different categories of product registration (new products vs. generic products vs. major variation vs. minor variation vs. re-registration)

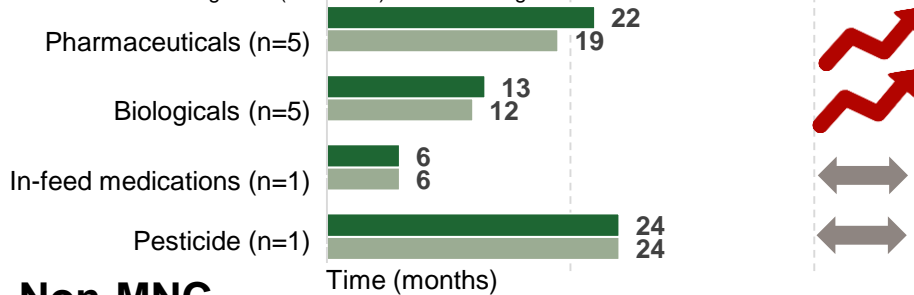


In general the timeline needed for product registration has reduced or remains the same all most of the therapeutic areas for companion animals

MNC

Base, N=6 ■ 2018 ■ 2014

Data showed the avg. time (in months) to achieve registration



Internal regulatory processes: All activities required for your company to manage the regulatory activity after the dossier has been submitted

External regulatory processes: All activities of the regulatory agency after the dossier has been submitted

Proportion of change in time taken (between 2018 vs. 2014) caused by internal vs external

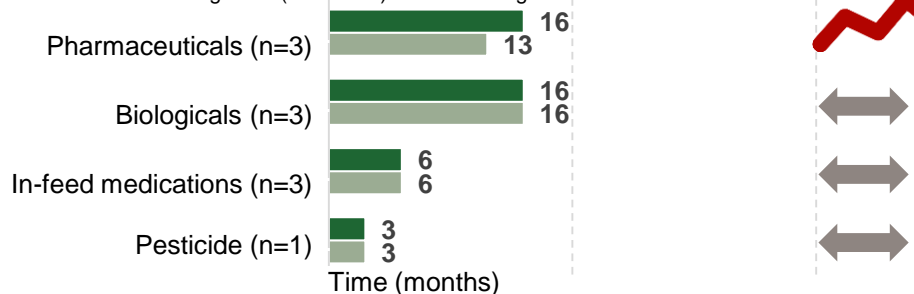


■ Internal regulatory process ■ External regulatory process

Non-MNC

Base, N=3 ■ 2018 ■ 2014

Data showed the avg. time (in months) to achieve registration



Proportion of change in time taken (between 2018 vs. 2014) caused by internal vs external



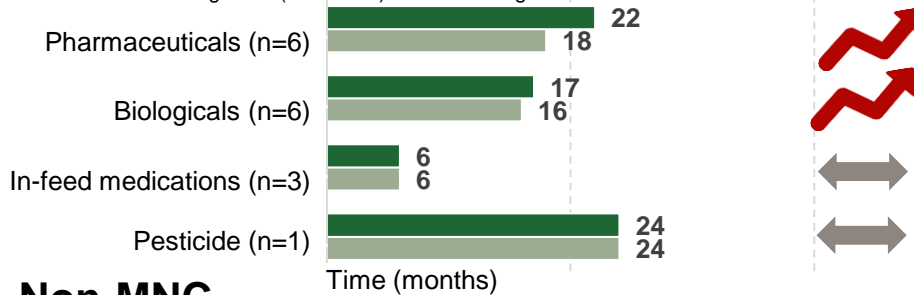
■ Internal regulatory process ■ External regulatory process

Different of views from MNC vs. non-MNC on timeline taken to achieve registration for pharmaceuticals and biologicals

MNC

Base, N=6 ■ 2018 ■ 2014

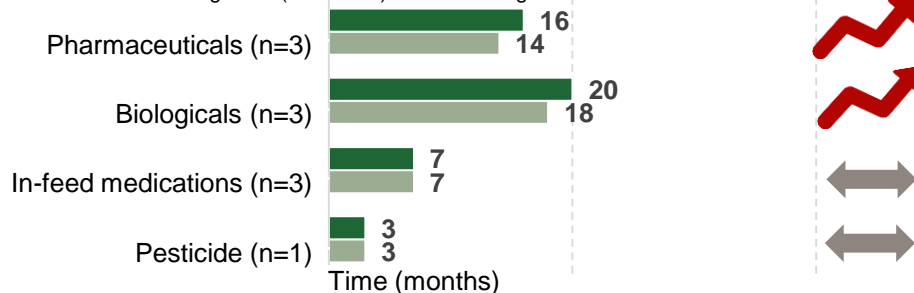
Data showed the avg. time (in months) to achieve registration



Non-MNC

Base, N=3 ■ 2018 ■ 2014

Data showed the avg. time (in months) to achieve registration



Internal regulatory processes: All activities required for your company to manage the regulatory activity after the dossier has been submitted

External regulatory processes: All activities of the regulatory agency after the dossier has been submitted

Proportion of change in time taken (between 2018 vs. 2014) caused by internal vs external



■ Internal regulatory process ■ External regulatory process

Proportion of change in time taken (between 2018 vs. 2014) caused by internal vs external



■ Internal regulatory process ■ External regulatory process

C1a1. Can you tell me what the typical time is for you to achieve registration for AH products for your country/ASEAN currently? C1b. What about vs/ 2014? C1c. What proportion of these changes (between 2014 vs. 2018) has been caused by internal regulatory processes and what proportion by external regulatory processes?

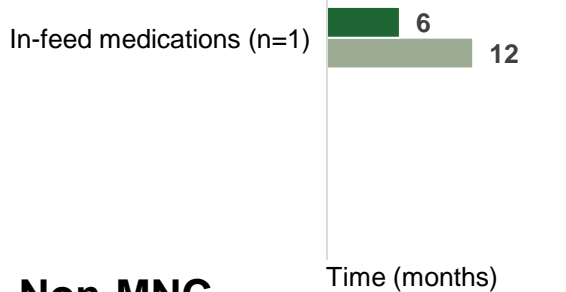


MNC felt that the time taken to achieved new registration in aqua and others are now shorter...

MNC

Base, N=6 ■ 2018 ■ 2014

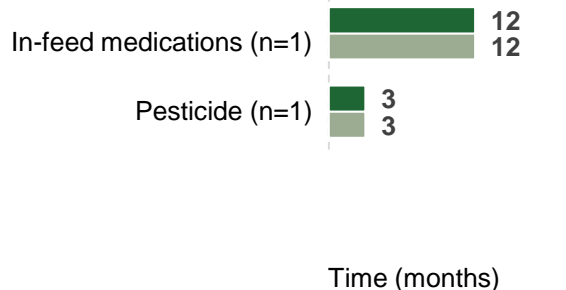
Data showed the avg. time (in months) to achieve registration



Non-MNC

Base, N=3 ■ 2018 ■ 2014

Data showed the avg. time (in months) to achieve registration



Internal regulatory processes: All activities required for your company to manage the regulatory activity after the dossier has been submitted

External regulatory processes: All activities of the regulatory agency after the dossier has been submitted

Proportion of change in time taken (between 2018 vs. 2014) caused by internal vs external



■ Internal regulatory process ■ External regulatory process

PHILIPPINES SUMMARY: Typical time for registration for different categories of product registration

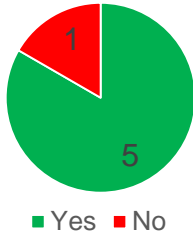
Pharmaceutical			Biologicals			In-feed medications			Pesticides		
Category	No of months		Category	No of months		Category	No of months		Category	No of months	
	MNC	Non-MNC		MNC	Non-MNC		MNC	Non-MNC		MNC	Non-MNC
New product	24	18	New product	24	24	New product	24	--	New product	24	--
Generic	12	6	Generic	12	12	Generic	12	--	Generic	--	--
Major variation	12	18	Major variation	6	--	Major variation	12	6	Major variation	6	--
Minor variation	6	12	Minor variation	3	--	Minor variation	12	--	Minor variation	3	--
Re-registration	12	12	Re-registration	3	--	Re-registration	6	6	Re-registration	24	--

NOTE: Not all managers provide us detailed timeline by product categories. We have recorded down all the answers given. Hence, the base is very small. Use with caution

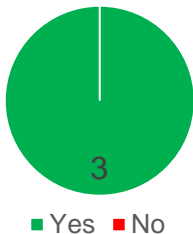
PHILIPPINES – PHARMACEUTICALS: Typical time for registration for different categories of product registration

Are there significant differences in typical time for registration for [THERAPEUTIC AREA] between different categories (new products vs. generic products vs. major variation vs. minor variations vs. re-registration)?

Base, n=6
MNC

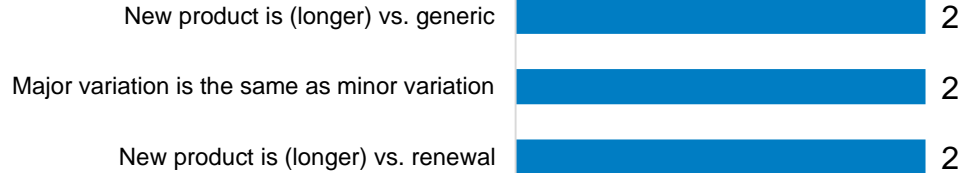


Base, n=3
Non-MNC



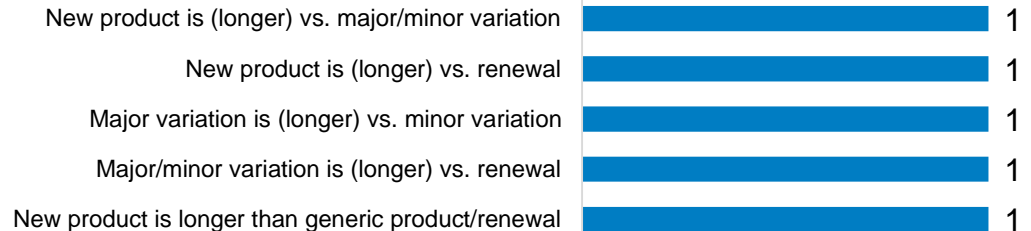
Comparison between timeline for registration on different category of product registration

Base, n=5, Data shown no. of mentions



Comparison between timeline for registration on different category of product registration

Base, n=3, Data shown no. of mentions



C1a: Are there significant differences in terms of typical time for registration of Pharmaceuticals for your country / ASEAN for different categories of product registration (new products vs. generic products vs. major variation vs. minor variation vs. re-registration)

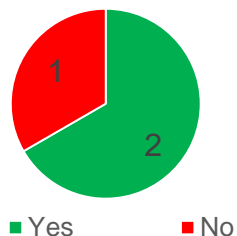
PHILIPPINES – BIOLOGICALS: Typical time for registration for different categories of product registration

Are there significant differences in typical time for registration for [THERAPEUTIC AREA] between different categories (new products vs. generic products vs. major variation vs. minor variations vs. re-registration)?

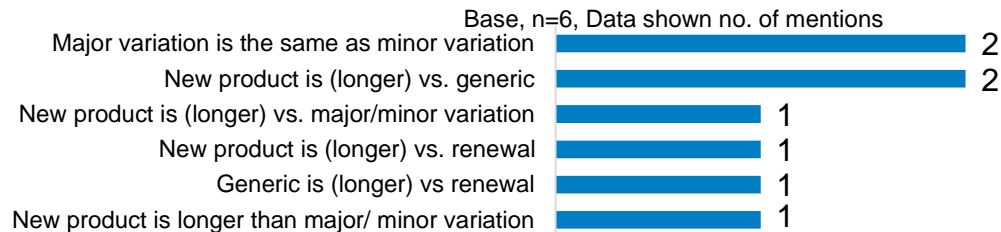
Base, n=6
MNC



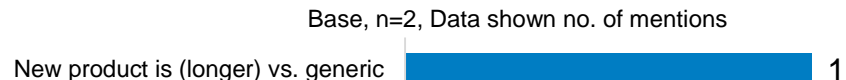
Base, n=3
Non-MNC



Comparison between timeline for registration on different category of product registration



Comparison between timeline for registration on different category of product registration

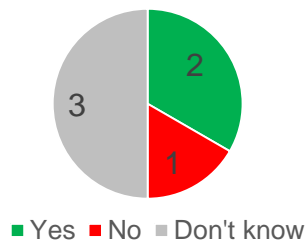


C2a: Are there significant differences in terms of typical time for registration of Biologicals for your country / ASEAN for different categories of product registration (new products vs. generic products vs. major variation vs. minor variation vs. re-registration)

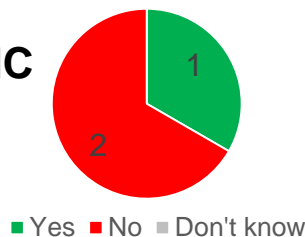
PHILIPPINES – IN-FEED MEDICATIONS: Typical time for registration for different categories of product registration

Are there significant differences in typical time for registration for [THERAPEUTIC AREA] between different categories (new products vs. generic products vs. major variation vs. minor variations vs. re-registration)?

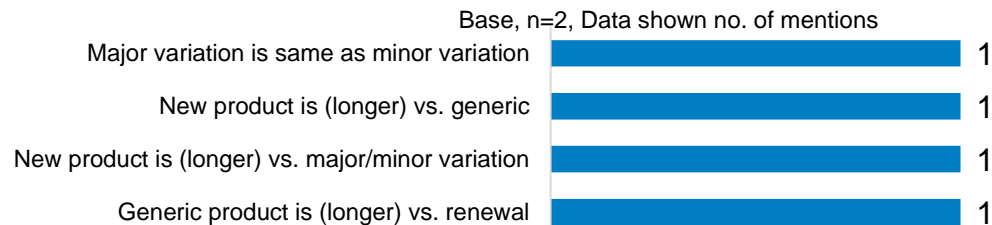
Base, n=6
MNC



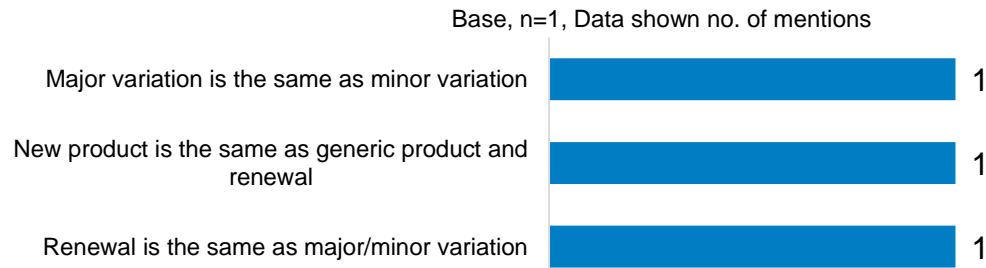
Base, n=3
Non-MNC



Comparison between timeline for registration on different category of product registration



Comparison between timeline for registration on different category of product registration



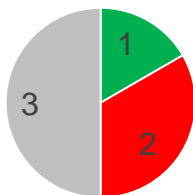
C3a: Are there significant differences in terms of typical time for registration of In-feed medications for your country / ASEAN for different categories of product registration (new products vs. generic products vs. major variation vs. minor variation vs. re-registration)

PHILIPPINES – IN-FEED MEDICATIONS: Typical time for registration for different categories of product registration

Are there significant differences in typical time for registration for [THERAPEUTIC AREA] between different categories (new products vs. generic products vs. major variation vs. minor variations vs. re-registration)?

Base, n=6

MNC



■ Yes ■ No ■ Don't know

Base, n=3

Non-MNC



■ Yes ■ No ■ Don't know

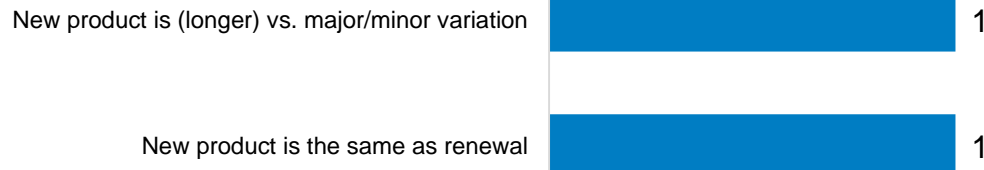
Comparison between timeline for registration on different category of product registration

Base, n=1, Data shown no. of mentions



Comparison between timeline for registration on different category of product registration

Base, n=1, Data shown no. of mentions



C3a: Are there significant differences in terms of typical time for registration of In-feed medications for your country / ASEAN for different categories of product registration (new products vs. generic products vs. major variation vs. minor variation vs. re-registration)

Timeline taken to achieved registration for both companion and production animals are same vs. 2014

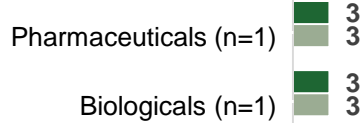


There is no significant differences between different categories (new products vs. generic products vs. major variation vs. minor variations vs. re-registration)

COMPANION ANIMALS - MNC

Base, N=4 ■ 2018 ■ 2014

Data showed the avg. time (in months) to achieve registration



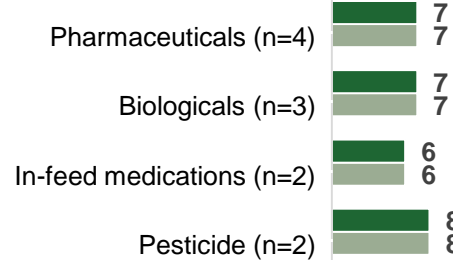
Companion animal



PRODUCTION ANIMALS - MNC

Base, N=4 ■ 2018 ■ 2014

Data showed the avg. time (in months) to achieve registration



Production animal



Companion animal



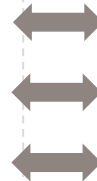
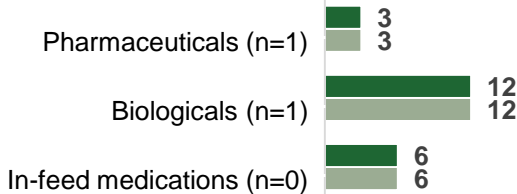
Time (months)

Time (months)

COMPANION ANIMALS - Non-MNC

Base, N=2 ■ 2018 ■ 2014

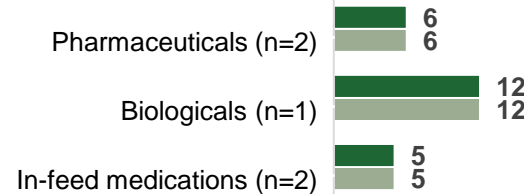
Data showed the avg. time (in months) to achieve registration



PRODUCTION ANIMALS - Non-MNC

Base, N=2 ■ 2018 ■ 2014

Data showed the avg. time (in months) to achieve registration



Production animal



Time (months)

Time (months)

Timeline taken to achieved registration for both companion, production animals and aqua are same vs. 2014

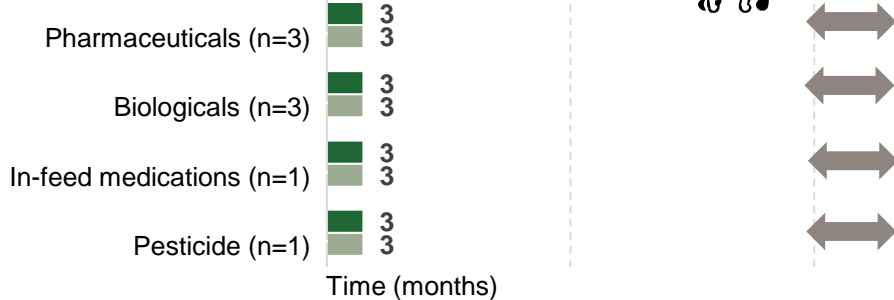


There is no significant differences between different categories (new products vs. generic products vs. major variation vs. minor variations vs. re-registration)

COMPANION ANIMALS - MNC

Base, N=5 ■ 2018 ■ 2014

Data showed the avg. time (in months) to achieve registration



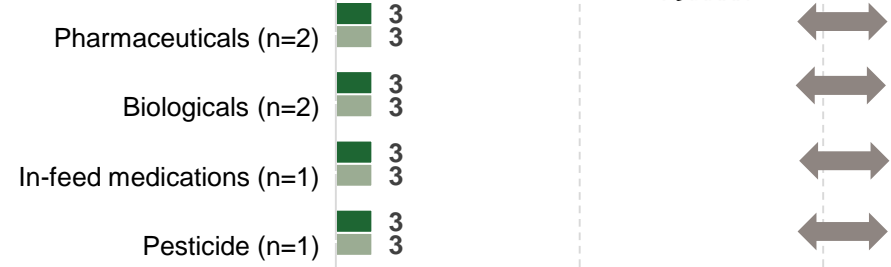
Companion animal



AQUA & OTHERS - MNC

Base, N=5 ■ 2018 ■ 2014

Data showed the avg. time (in months) to achieve registration



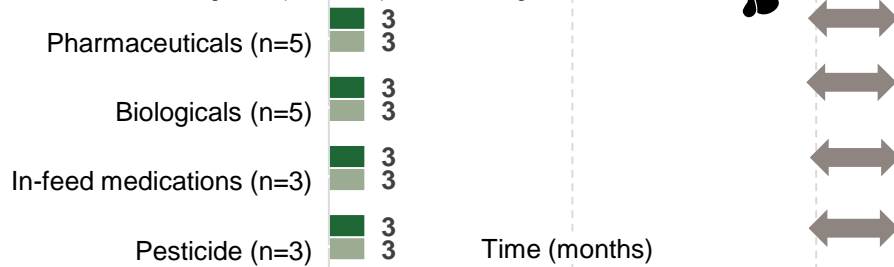
Aqua & others



PRODUCTION ANIMALS - MNC

Base, N=5 ■ 2018 ■ 2014

Data showed the avg. time (in months) to achieve registration



Production animal

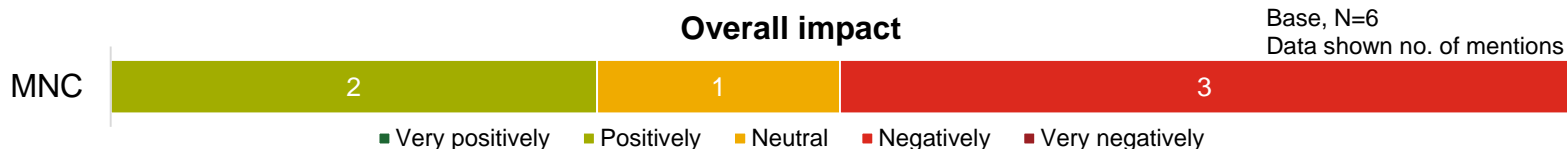




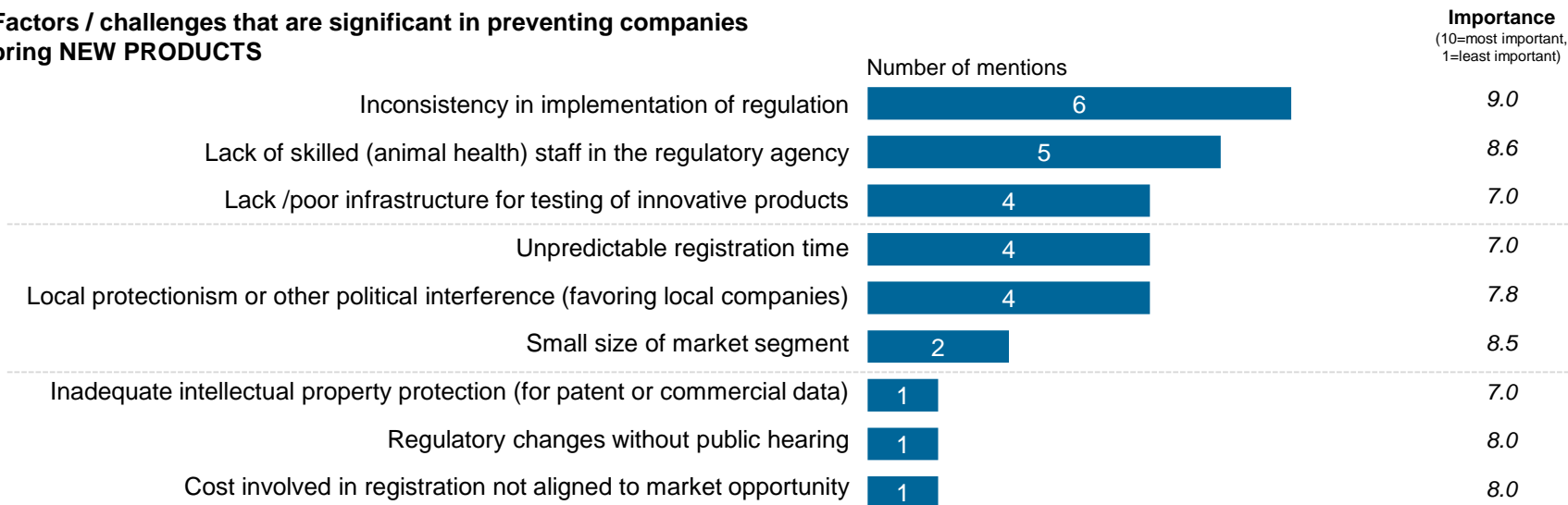
Bringing new AH products to market – challenges faced

REGIONAL: Impact of regulatory environment in bringing new AH animal health product:

By and large, regional regulatory manager do not find the regulatory environment favorable for new product registration. The main challenges seems to be inconsistency in implementation of regulation and lack of skilled staff in regulatory agency



Factors / challenges that are significant in preventing companies bring NEW PRODUCTS



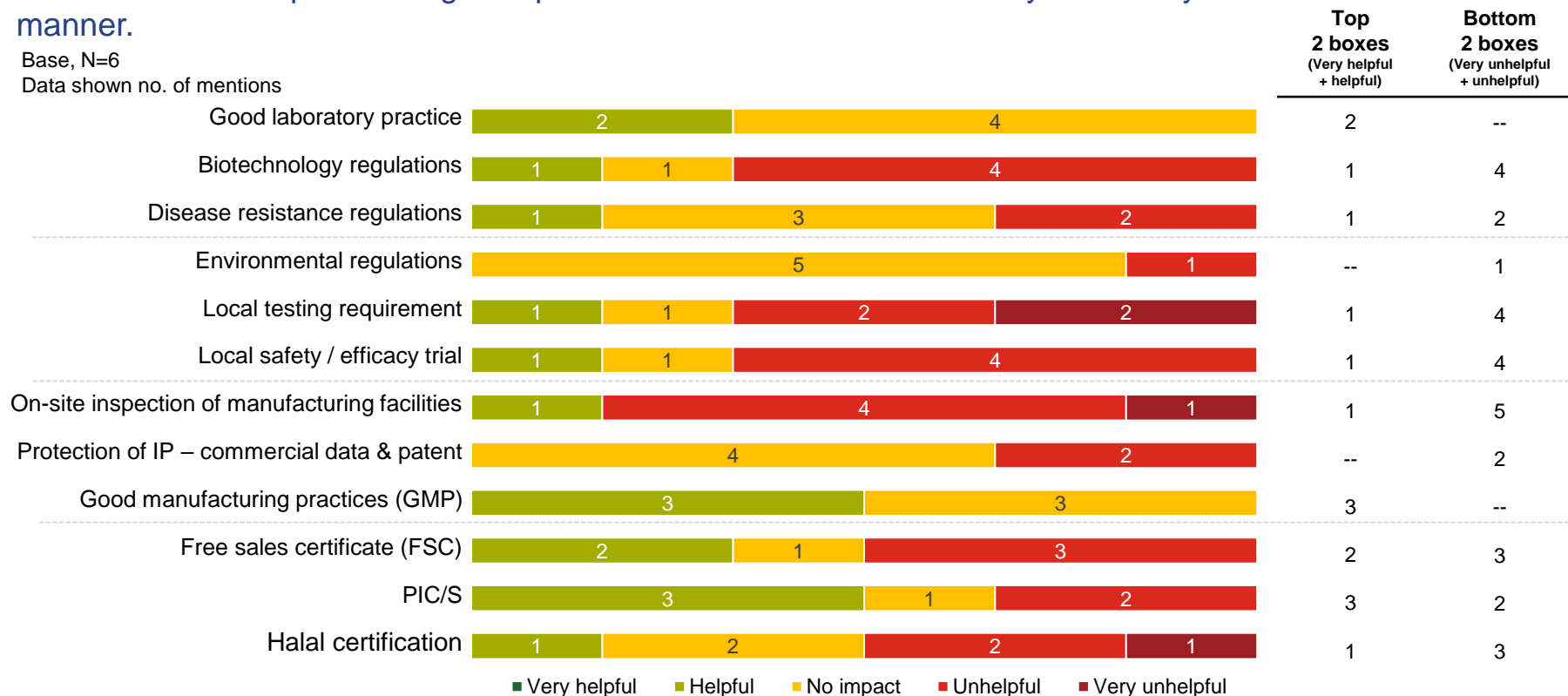
D1. How does the regulatory environment in your country/ASEAN impact your ability to BRING NEW PRODUCT TO MARKET?

D2. Which of these, if any, are significant in preventing you to BRING NEW PRODUCT to your country/ASEAN?

REGIONAL: Impact of govt. regulation on ability to bring new AH product successfully and timely manner to market
 On-site inspection of manufacturing facilities, local testing and safety requirements are hailed to be not helpful in bring new products to the market successfully and timely manner.



Base, N=6
 Data shown no. of mentions



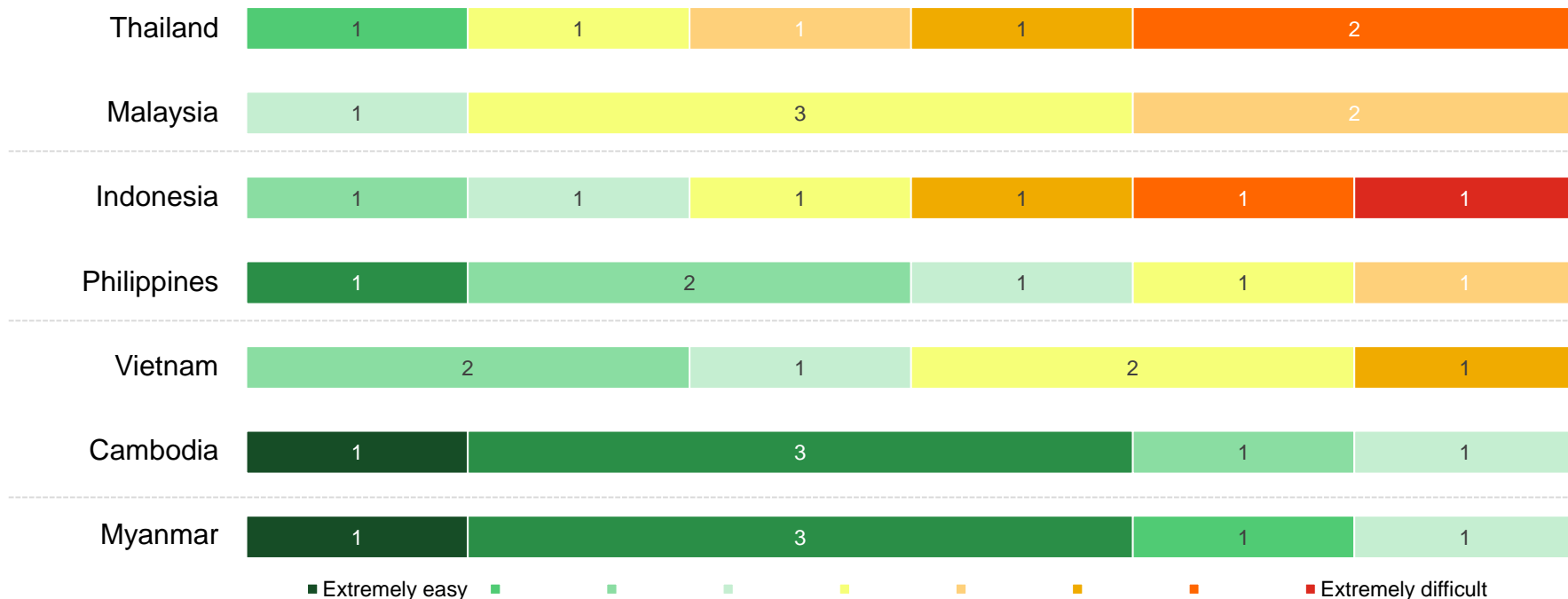
D3. Thinking about government regulations in your country/ASEAN, how would you assess the impact of each of the areas of regulation listed below on your ABILITY TO BRING NEW PRODUCT successfully and in a timely manner to your country/ASEAN?

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

Cambodia and Myanmar are deemed easy in term of product registration. Indonesia and lesser extent, Thailand are significantly more difficult to get AH product registered.



Base, N=6
Data shown no. of mentions



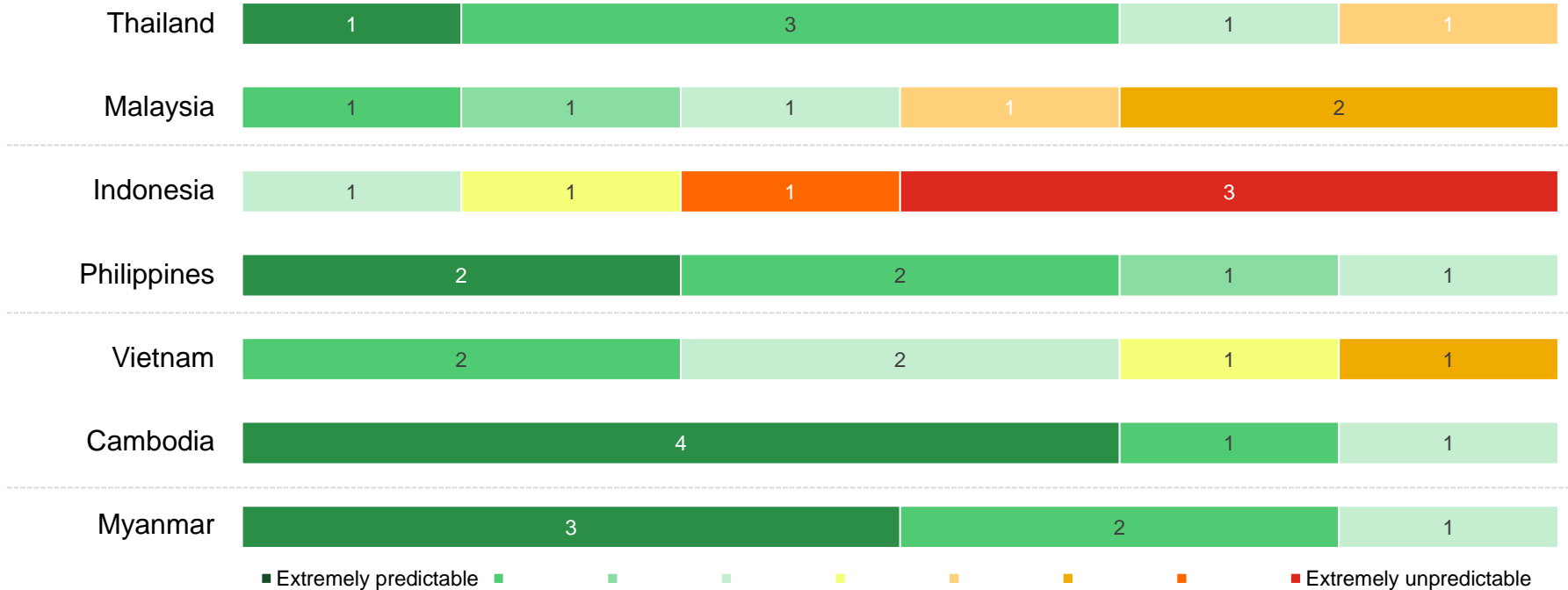
D4a. Thinking about the level of difficulty of product registration (IN TERMS OF PROCESS /PROTOCOL) of various AH products across ASEAN, how do you rate the level of difficulty across these 7 countries?

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

Expectedly, Indonesia is the most unpredictable (timeline) in getting AH products registered. Some companies are considered Malaysia and Vietnam product registration timeline a little unpredictable (too).

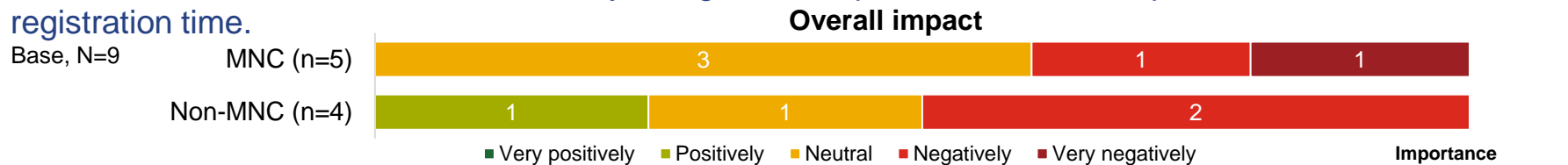


Base, N=6
Data shown no. of mentions



D4b. Thinking about the level of predictability of product registration (IN TERMS OF TIMELINE) of various AH products across ASEAN, how do you rate the level of predictability across these 7 countries?

3 in 5 MNC regulatory managers are do not considered the regulatory environment have a positive nor negative. 2 of 4 non-MNC regulatory managers considered the regulatory environment to have negative impact. The main challenges to bring new AH products to market are small size of the market, inconsistency in regulation implementation and unpredictable registration time.



Importance
(10=most important, 1=least important)

Factors / challenges that are significant in preventing companies bring NEW PRODUCTS

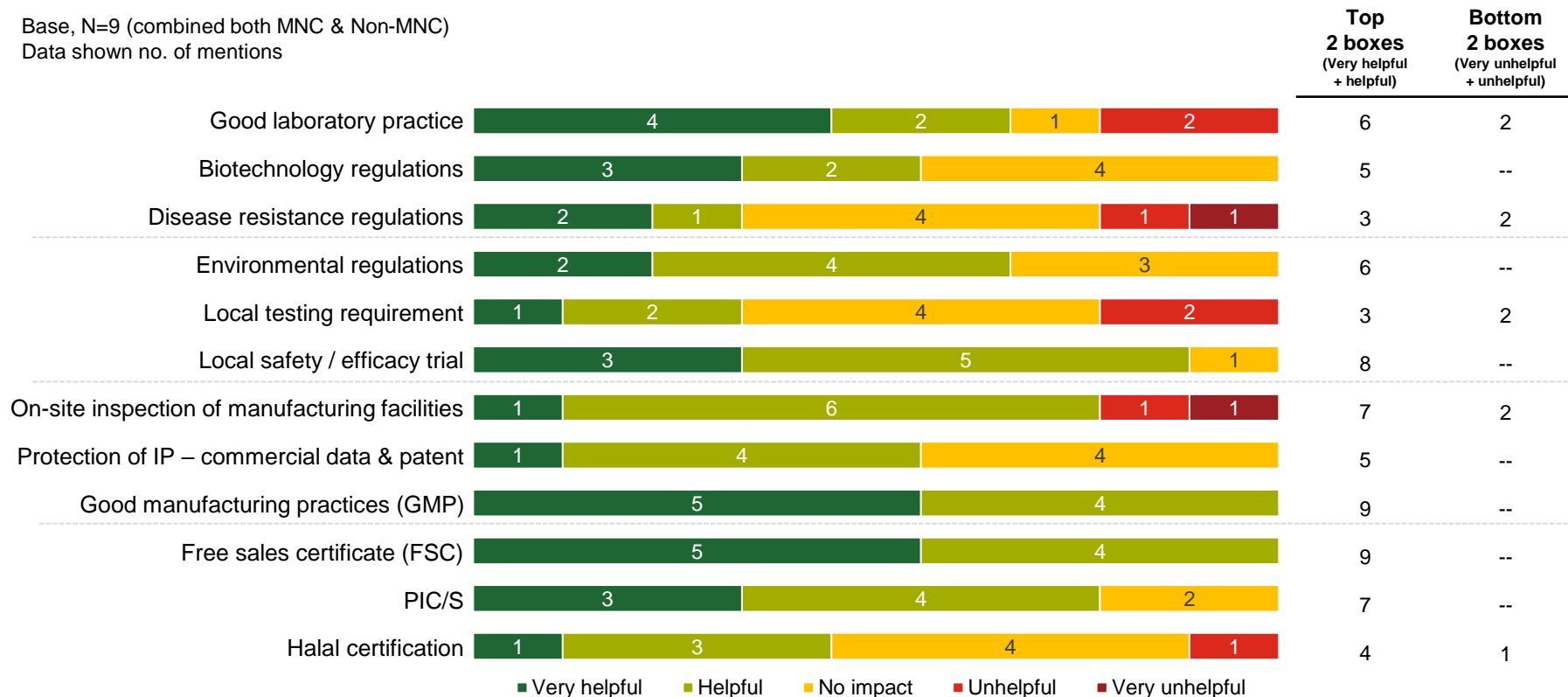
	Number of mentions (Base: MNC, n=5 ; Non-MNC, n=4)		MNC	Non-MNC
Small size of market segment	5	4	7.2	6.8
Inconsistency in implementation of regulation	5	4	7.0	7.0
Unpredictable registration time	5	4	9.5	9.0
Lack of skilled (animal health) staff in the regulatory agency	2	3	8.6	8.8
Negative consumer perceptions/attitudes	2	2	7.0	--
Lack /poor infrastructure for testing of innovative products	2	2	3.0	5.0
Cost involved in registration not aligned to market opportunity	1	2	3.5	4.0
Pressure competitions (including parallel imports and generics)	2	1	2.0	8.0
Local protectionism or other political interference (favoring local companies)	1	1	8.2	7.8
Internal company organizational or culture barriers	2		6.5	6.5
Insufficient experts to register vaccines	1		8.0	--
Post marketing surveillance	1		--	8.0

■ MNC
 ■ Non-MNC

GMP and FSC are considered helpful in bringing new products to market. Disease resistance regulations and on-site inspection of manufacturing facilities are considered challenges faced

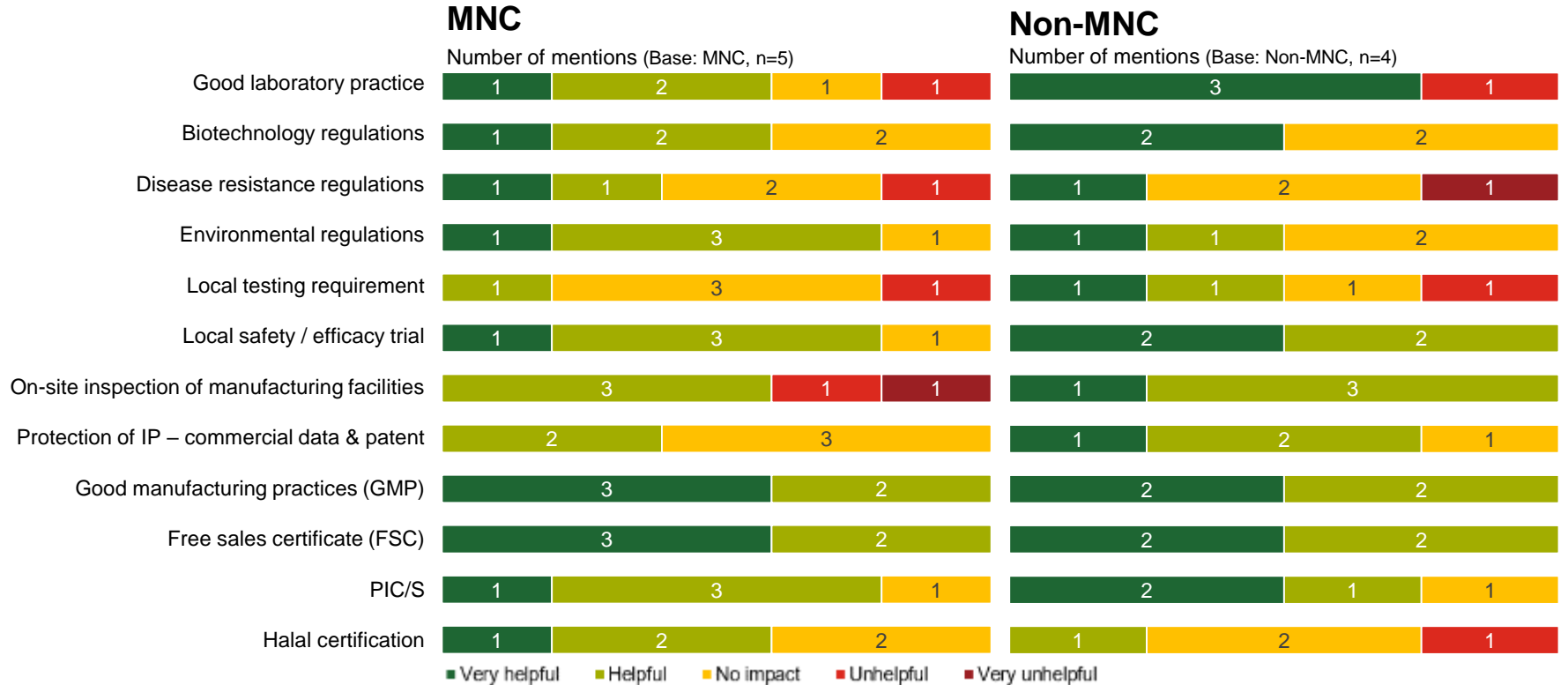


Base, N=9 (combined both MNC & Non-MNC)
Data shown no. of mentions



D3. 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 BRING NEW PRODUCT successfully and in a timely manner to your country/ASEAN?

MALAYSIA: Impact of govt. regulation on ability to bring new AH product successfully and timely manner to market
Expectedly, on-site inspection of manufacturing facilities are concerns for MNC companies.
Whilst non-MNC find disease resistance regulation to be more 'problematic'.

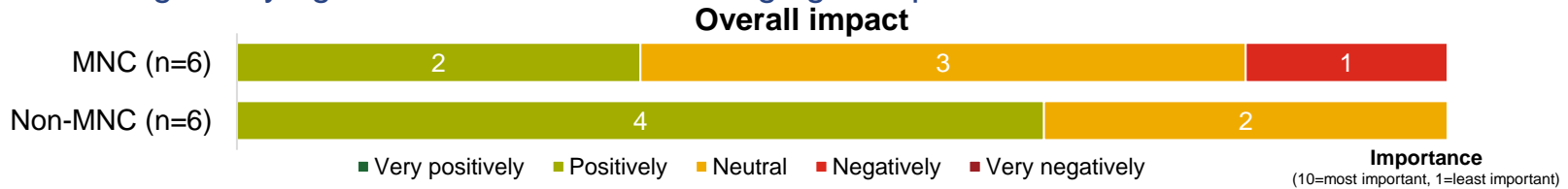


D3. Thinking about Government Regulations in your country/ASEAN, how would you assess the impact of each of the areas of regulation listed below on your ABILITY TO BRING NEW PRODUCT successfully and in a timely manner to your country/ASEAN?

Non-MNC considered current regulatory environment in Indonesia to have a more positive impact in bringing new products to market. MNC however considered inconsistency in implementation of regulation, local protectionism, lack of infrastructure for testing innovative products and lack of skilled staff in the regulatory agencies to deterrents in bringing new products to market



Base, N=12



Factors / challenges that are significant in preventing companies

bring NEW PRODUCTS

	Number of mentions (Base: MNC, n=6 ; Non-MNC, n=6)	MNC	Non-MNC
Inconsistency in implementation of regulation	6 (MNC: 6, Non-MNC: 2)	9.2	8.5
Local protectionism or other political interference (favoring local companies)	5 (MNC: 5, Non-MNC: 2)	7.4	10.0
Lack /poor infrastructure for testing of innovative products	5 (MNC: 5, Non-MNC: 2)	7.4	8.5
Unpredictable registration time	3 (MNC: 3, Non-MNC: 3)	7.3	7.7
Lack of skilled (animal health) staff in the regulatory agency	5 (MNC: 5, Non-MNC: 1)	8.2	10.0
Small size of market segment	1 (MNC: 1, Non-MNC: 2)	4.0	9.0
Pressure competitions (including parallel imports and generics)	2 (MNC: 2, Non-MNC: 0)	4.5	-
Negative consumer perceptions/attitudes	1 (MNC: 1, Non-MNC: 1)	5.0	10.0
Inadequate intellectual property protection (for patent or commercial data)	2 (MNC: 2, Non-MNC: 0)	5.5	-
Cost involved in registration not aligned to market opportunity	1 (MNC: 1, Non-MNC: 1)	2.0	8.0
Internal company organizational or culture barriers	1 (MNC: 1, Non-MNC: 0)	-	8.0
Regulation no longer fit the current situation	1 (MNC: 1, Non-MNC: 0)	10.0	-
Complicated registration process and requirement	1 (MNC: 1, Non-MNC: 0)	10.0	-

■ MNC
 ■ Non-MNC

D1. How does the regulatory environment in your country/ASEAN impact your ability to BRING NEW PRODUCT TO MARKET?

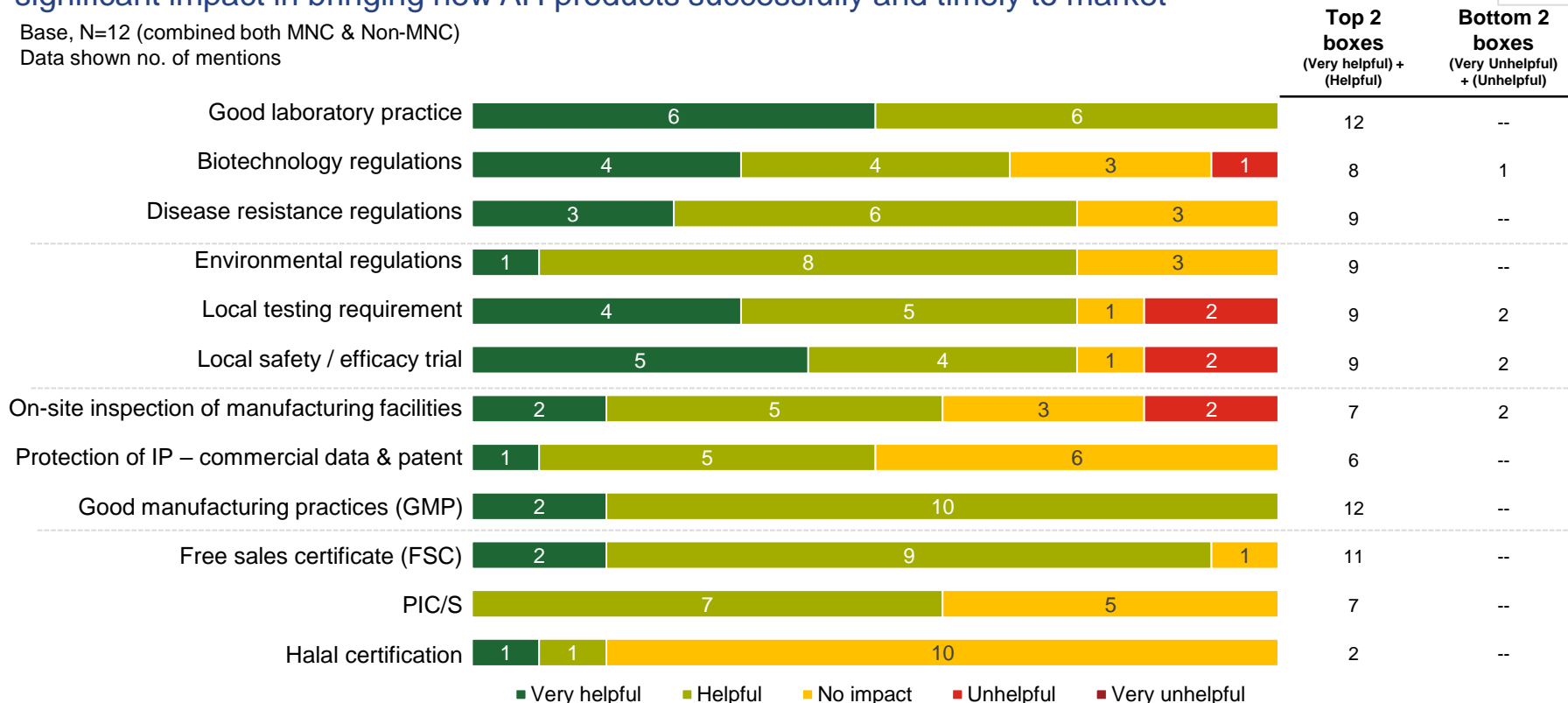
D2i Which of these, if any, are significant in preventing you to BRING NEW PRODUCT to your country/ASEAN?

INDONESIA: Impact of govt. regulation on ability to bring new AH product successfully and timely manner to market

Apart from local testing requirements, local safety/efficacy trial and on-site inspection of manufacturing facilities mentioned by a few managers, other areas of regulations do not have significant impact in bringing new AH products successfully and timely to market

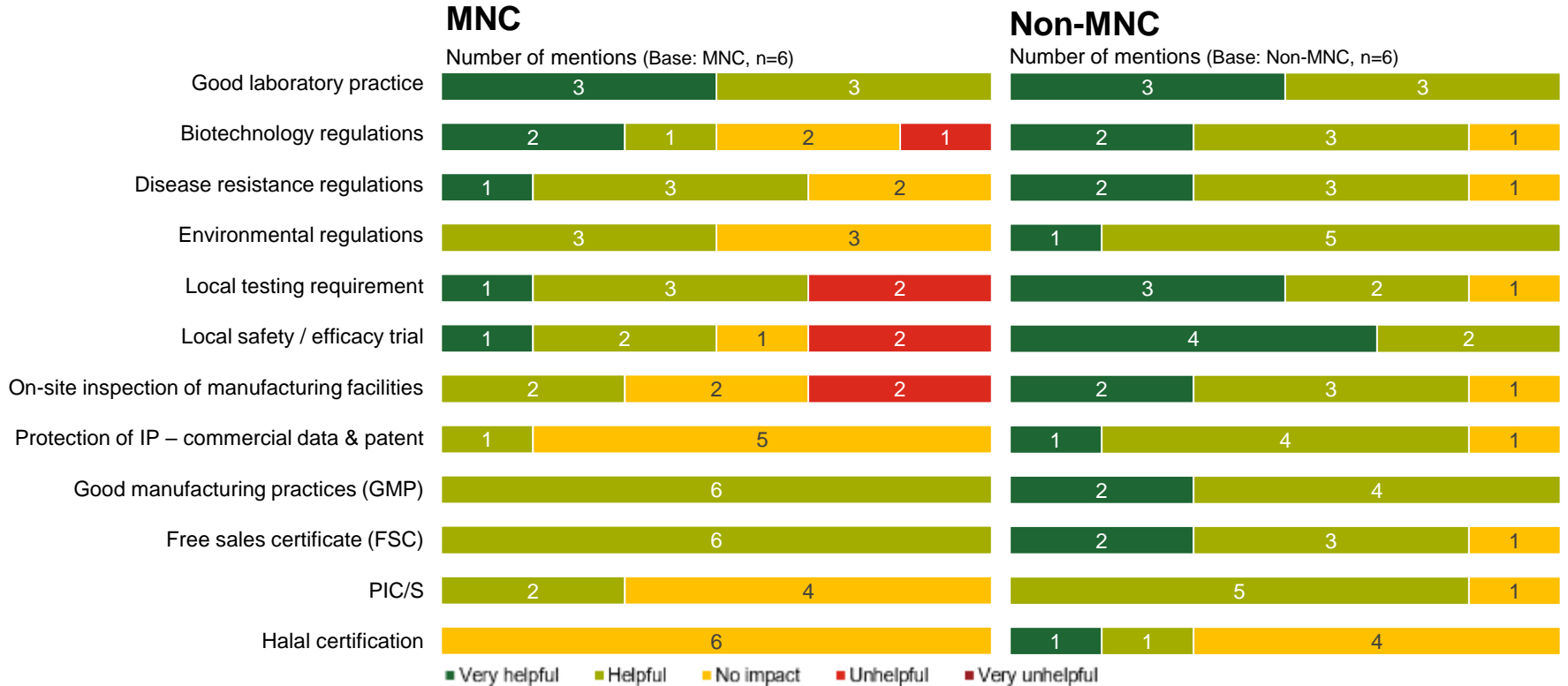


Base, N=12 (combined both MNC & Non-MNC)
Data shown no. of mentions



D3. 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 BRING NEW PRODUCT successfully and in a timely manner to your country/ASEAN?

No unexpected, non-MNC find different areas of regulation to be helpful in bringing new products to market successfully and timely manner (with the exception of Halal certification).

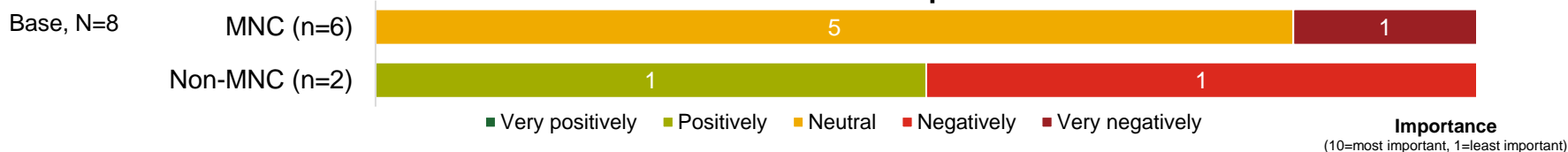


THAILAND: Impact of regulatory environment in bringing new AH animal health product

By and large, regulatory managers felt that current regulatory environment in Thailand are neither positive or negative in bringing new AH products to market. Few complaints are related to unpredictable registration timeline and lack of skilled (animal health) staff in regulatory agencies.



Overall impact



Factors / challenges that are significant in preventing companies bring NEW PRODUCTS

Factor / Challenge	Number of mentions (Base: MNC, n=6 ; Non-MNC, n=2)		MNC	Non-MNC
Unpredictable registration time	3	2	8.0	9.5
Lack of skilled (animal health) staff in the regulatory agency	3	2	8.7	9.5
Inconsistency in implementation of regulation	2	2	9.0	7.0
Pressure competitions (including parallel imports and generics)	3	1	8.0	6.0
Small size of market segment	3	1	7.3	5.0
Cost involved in registration not aligned to market opportunity	2	1	7.0	8.0
Local protectionism or other political interference (favoring local companies)	2	0	7.5	--
Lack /poor infrastructure for testing of innovative products	1	1	4.0	8.0
Negative consumer perceptions/attitudes	2	0	9.0	--
Unattainable standard (human standard registration)	2	0	10.0	--
Inadequate intellectual property protection (for patent or commercial data)	1	0	7.0	--
Internal company organizational or culture barriers	1	0	7.0	--

Legend: ■ MNC ■ Non-MNC

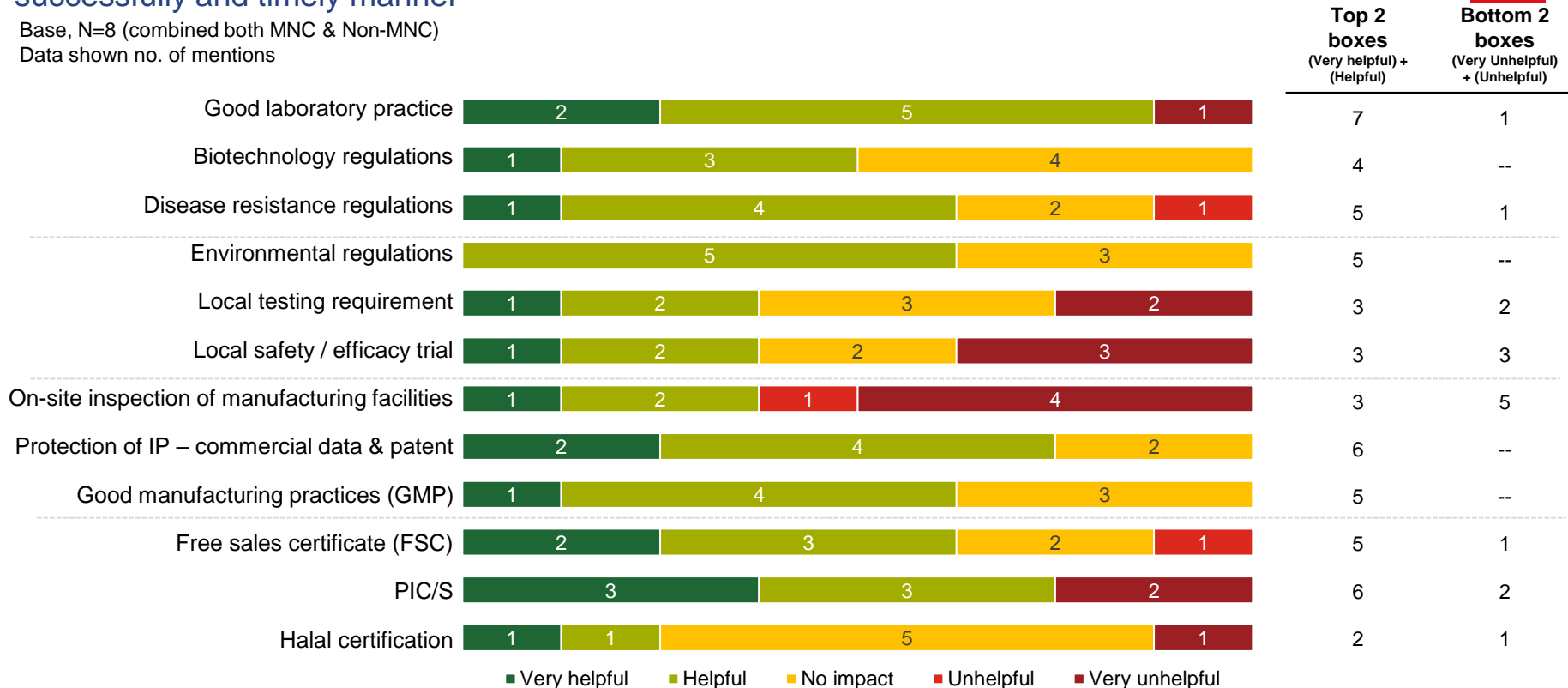
D1. How does the regulatory environment in your country/ASEAN impact your ability to BRING NEW PRODUCT TO MARKET? D2. Which of these, if any, are significant in preventing you to BRING NEW PRODUCT to your country/ASEAN?

THAILAND: Impact of govt. regulation on ability to bring new AH product successfully and timely manner to market

safety/efficacy trial requirement and on-site inspection of manufacturing facilities in the regulation for AH products are the pain-points experienced in bringing new products to market successfully and timely manner

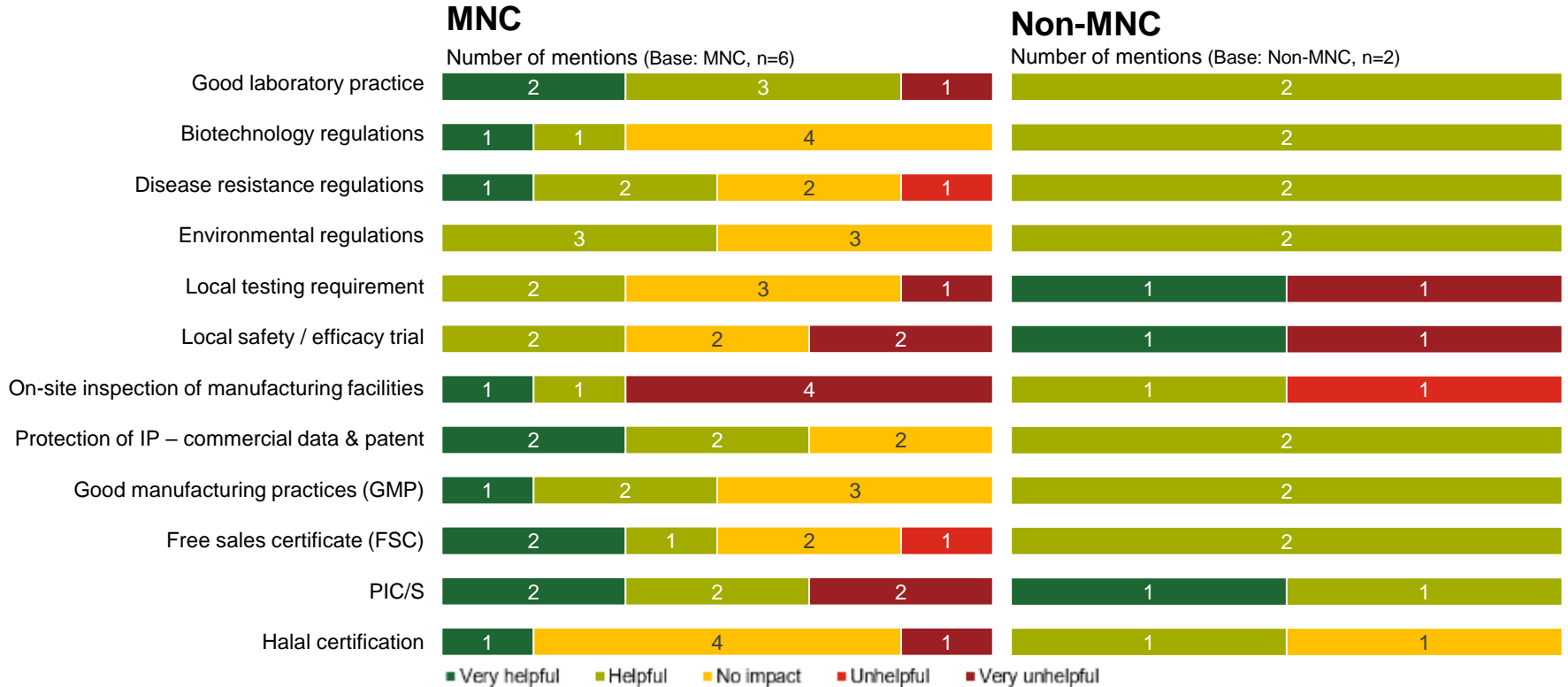


Base, N=8 (combined both MNC & Non-MNC)
Data shown no. of mentions



D3. 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 BRING NEW PRODUCT successfully and in a timely manner to your country/ASEAN?

For some MNC and non-MNC companies, PIC/S requirement remains to be a concern with respect to bringing new AH products to market.



D3. 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 BRING NEW PRODUCT successfully and in a timely manner to your country/ASEAN?

THAILAND: Supportive verbatims from qualitative phase interviews & follow-up call backs during quantitative stage with MNCs

Why some managers considered GMP, FSC and PIC/S to be helpful in bringing new AH product successfully and timely manner to market?

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

Good manufacturing practices (GMP)



- It is a positive when the companies tried to register EU products. But it can be problematic for companies that want to registered US or other non-PIC/S compliance AH products.



Have not faced many difficulties. Mainly been internal factors. – MNC



I gave 5 rating means GMP is needed for a pharmaceutical company and it is a first assessment to consider a quality and safety of products. – MNC

Free sales certificate (FSC)



- There is no major issue with the FSC for both local and MNC companies on generic product. FSC is easy to apply – just need to request the paper from the origin...and generally easy to obtain.



No, we don't have the problem. I think it will be a problem when the product is brand new that was not registered anywhere else yet. –MNC



From my experience, I don't have any problem, because, we have regional team support – MNC



Can use this FSC as replacement / 2nd option for GMP certificate. – MNC

PIC/S



- For PIC/S compliance manufacturer plants, the burden is relatively minimal as requirements / documentations needed are lesser. All agreed that the high standard of PIC/S GMP ensures (good) product's quality.



The Director tries to compromise. Recently they told usokay they can accept the WHO GMP standard but they accept it to be equal to PICS certified by other authority. – MNC



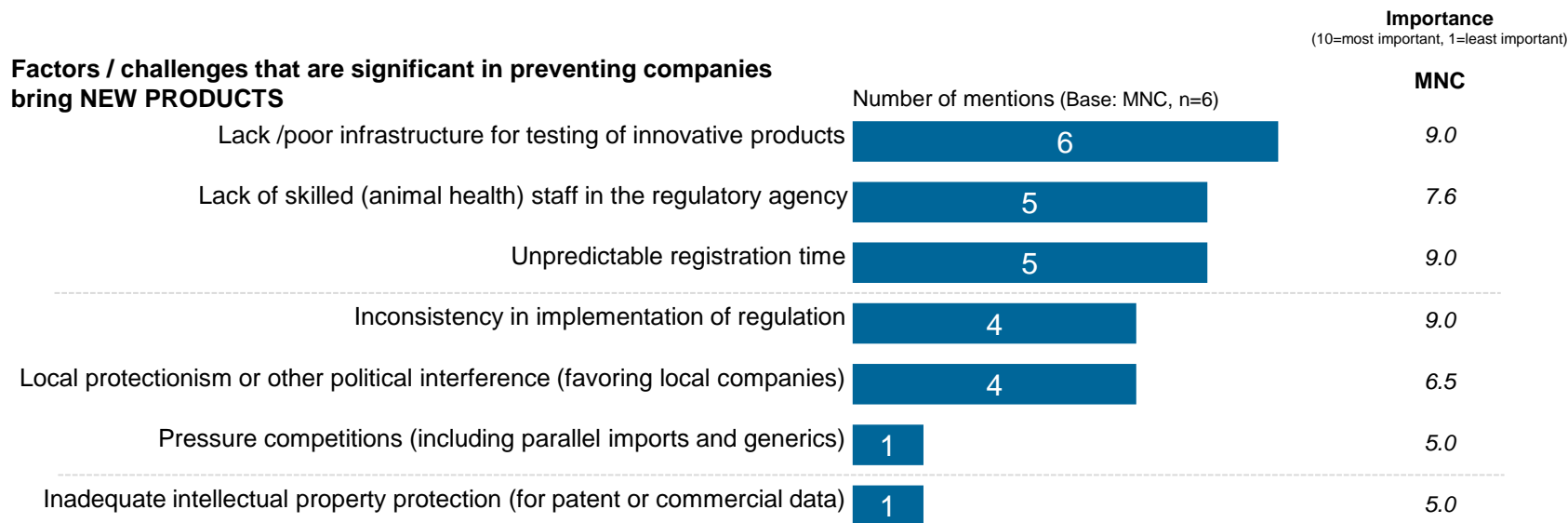
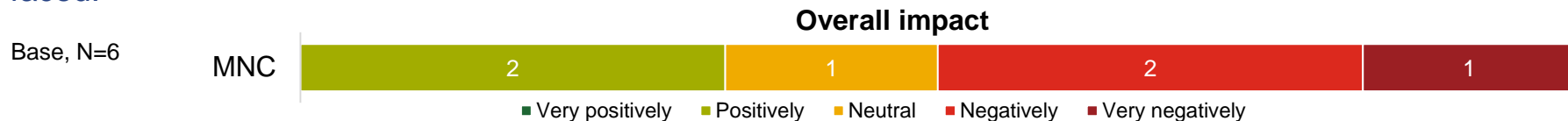
Thai FDA is recognize PIC/S standard, if a manufacturer have certified PIC/S standard, it is very easy and very welcome from Thai FDA. The required document just only 4 items, the approval timeframe is just 1-2 months. – MNC



At the beginning time of GMP regulation implemented, the practice and requirement for submission from the Thai FDA is uncertain. Now, the Thai FDA have clear standard practice and requirement already, so it helps us a lot to understand what they want. As the result, that the submission in PIC/s category is easier than the other category (PIC/s certified and Non-PIC/s). - MNC

■ Very helpful
 ■ Helpful
 ■ No impact
 ■ Unhelpful
 ■ Very unhelpful

Half of AH companies claimed that the current regulatory environment have negative impact to bringing new AH products to market. Lack of infrastructure for testing of innovative products, lack of skilled staff in regulatory agencies and unpredictable registration time are the main challenges faced.



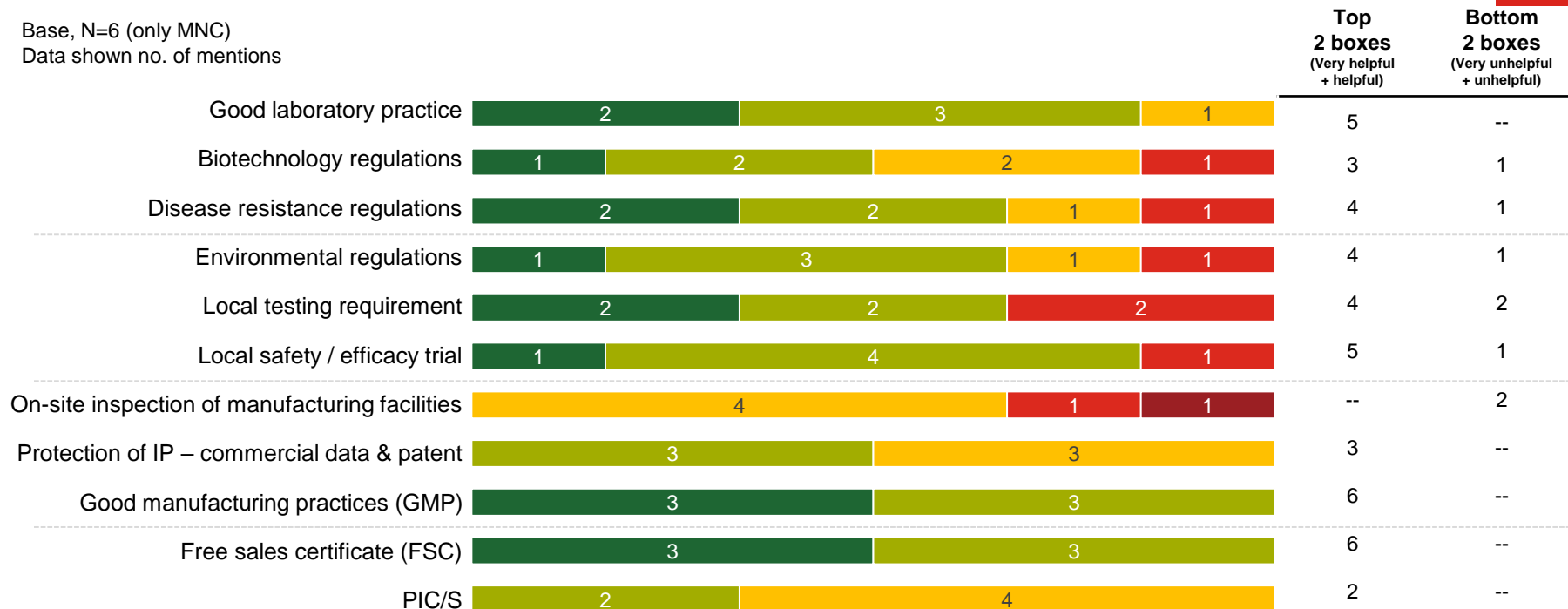
D1. How does the regulatory environment in your country/ASEAN impact your ability to BRING NEW PRODUCT TO MARKET? D2. Which of these, if any, are significant in preventing you to BRING NEW PRODUCT to your country/ASEAN?

VIETNAM: Impact of govt. regulation on ability to bring new AH product successfully and timely manner to market

On-site inspection of manufacturing facilities and local testing requirements are the main issues experienced in trying to bring new AH products successfully and timely manner to market.



Base, N=6 (only MNC)
Data shown no. of mentions

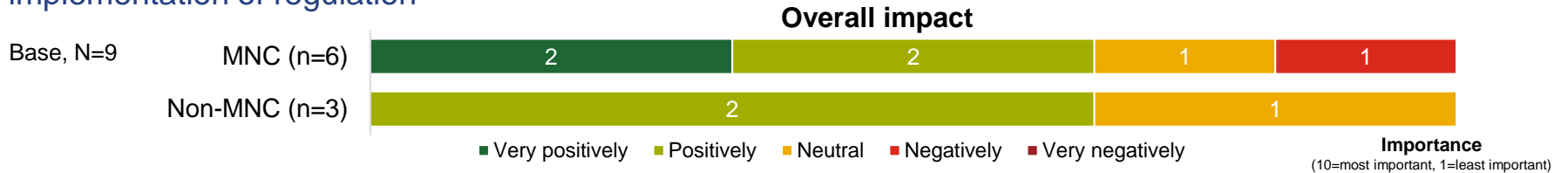


Note: Halal certification requirements is excluded in the report as it is not application to this country

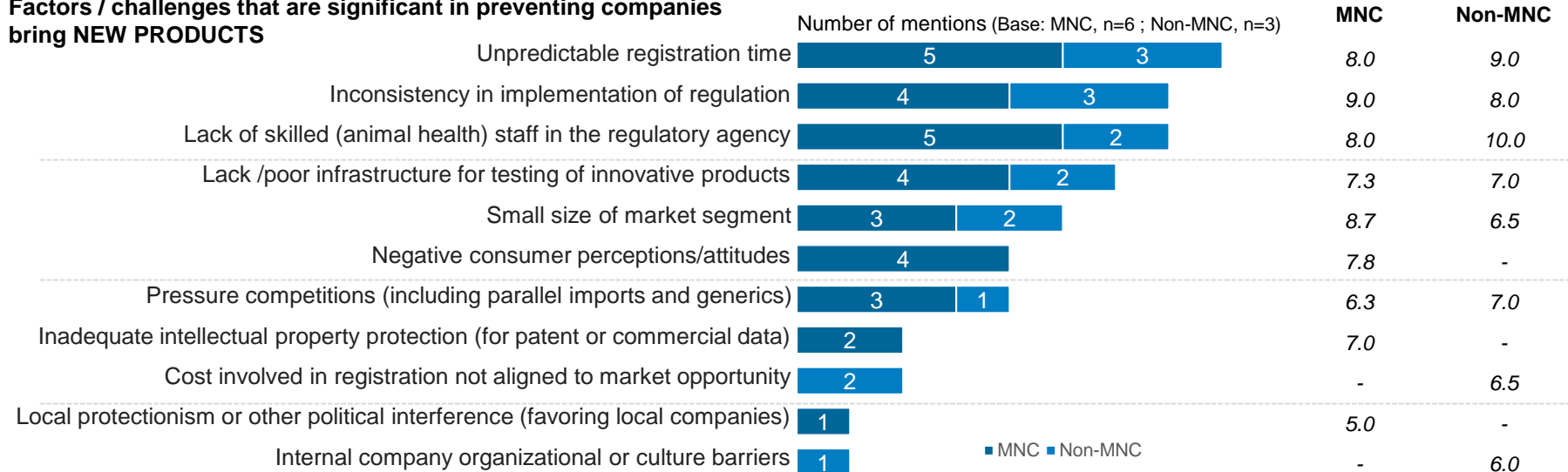
■ Very helpful
 ■ Helpful
 ■ No impact
 ■ Unhelpful
 ■ Very unhelpful

D3. 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 BRING NEW PRODUCT successfully and in a timely manner to your country/ASEAN?

Most MNC and non-MNC regulatory managers find the regulatory environment in Philippines to be conducive to bringing new AH products to market. There are however still challenges faced – unpredictable registration time, lack of skilled staff and inconsistency in implementation of regulation



Factors / challenges that are significant in preventing companies bring NEW PRODUCTS

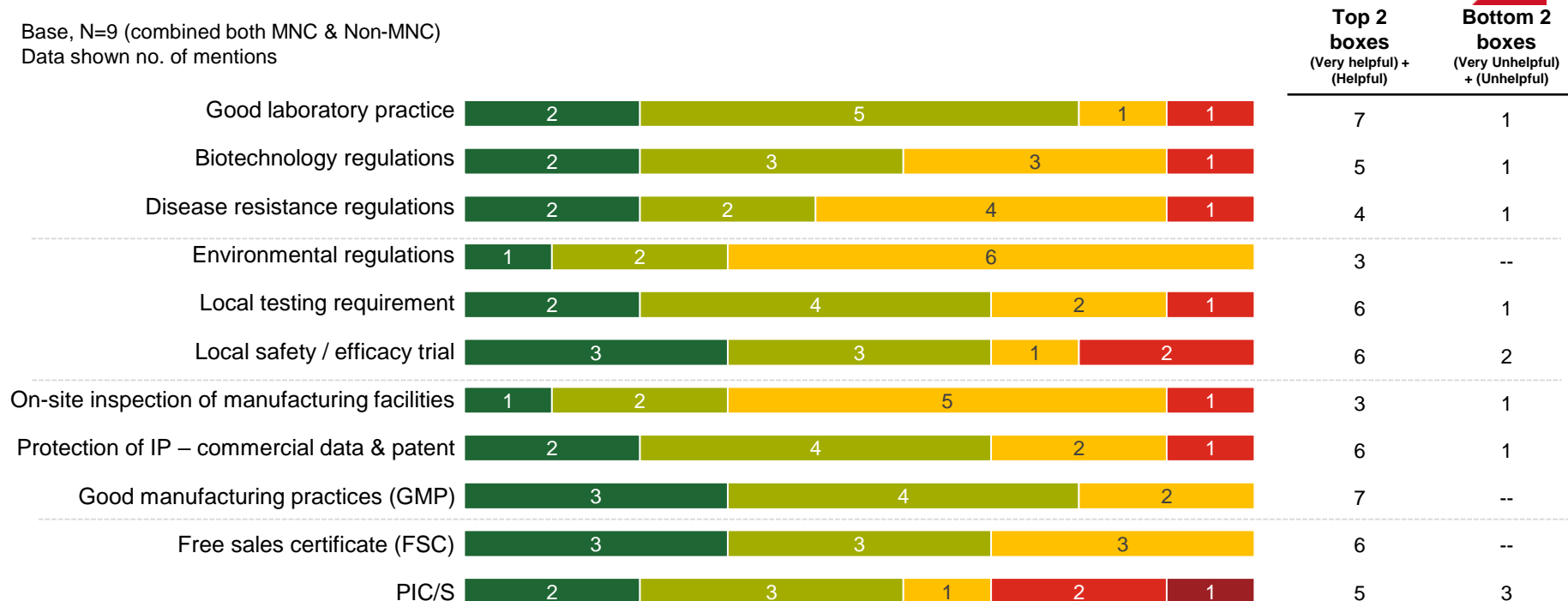


PHILIPPINES: Impact of govt. regulation on ability to bring new AH product successfully and timely manner to market

Expectedly, PIC/S requirements will have (difficult) impact in bringing new products to market successfully and timely manner in the Philippines



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

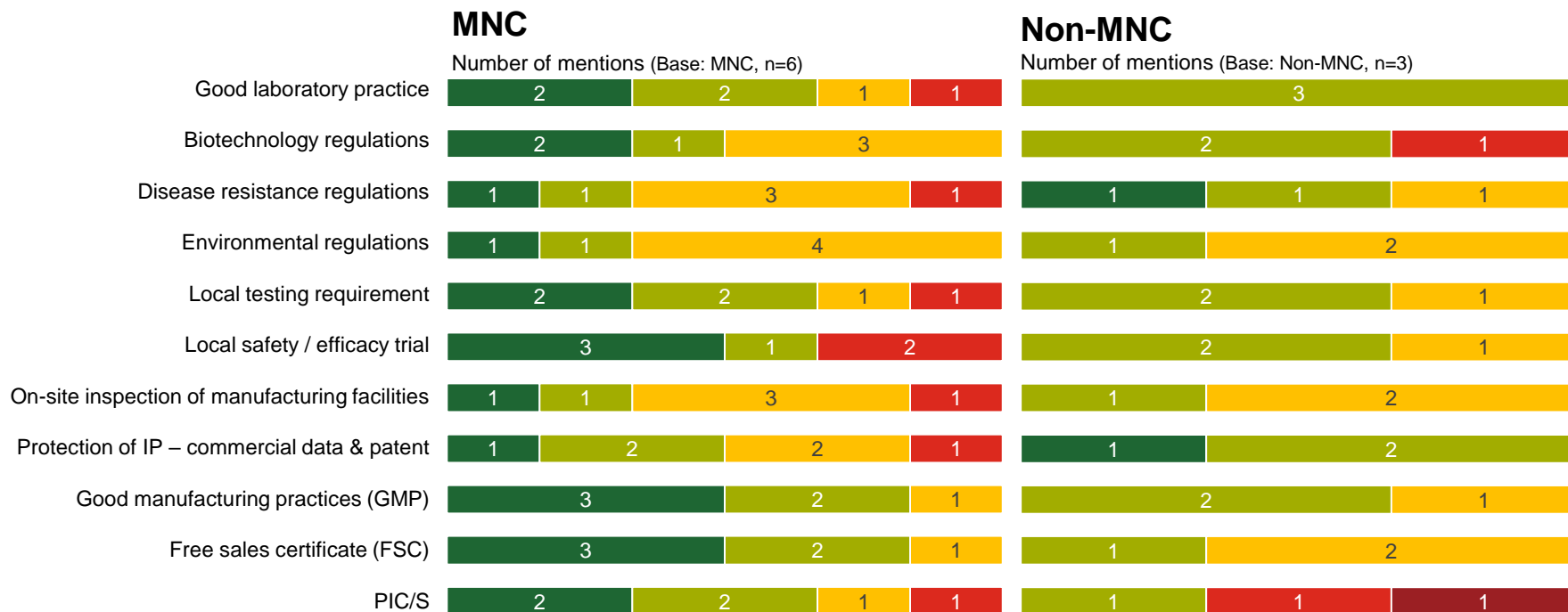


Note: Halal certification requirements is excluded in the report as it is not application to this country

■ Very helpful
 ■ Helpful
 ■ No impact
 ■ Unhelpful
 ■ Very unhelpful

D3. 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 BRING NEW PRODUCT successfully and in a timely manner to your country/ASEAN?

PIC/S requirement is more concerning to non-MNC, whilst local safety/efficacy trials post to be more problematic to MNC companies in bringing new AH product successfully and timely manner

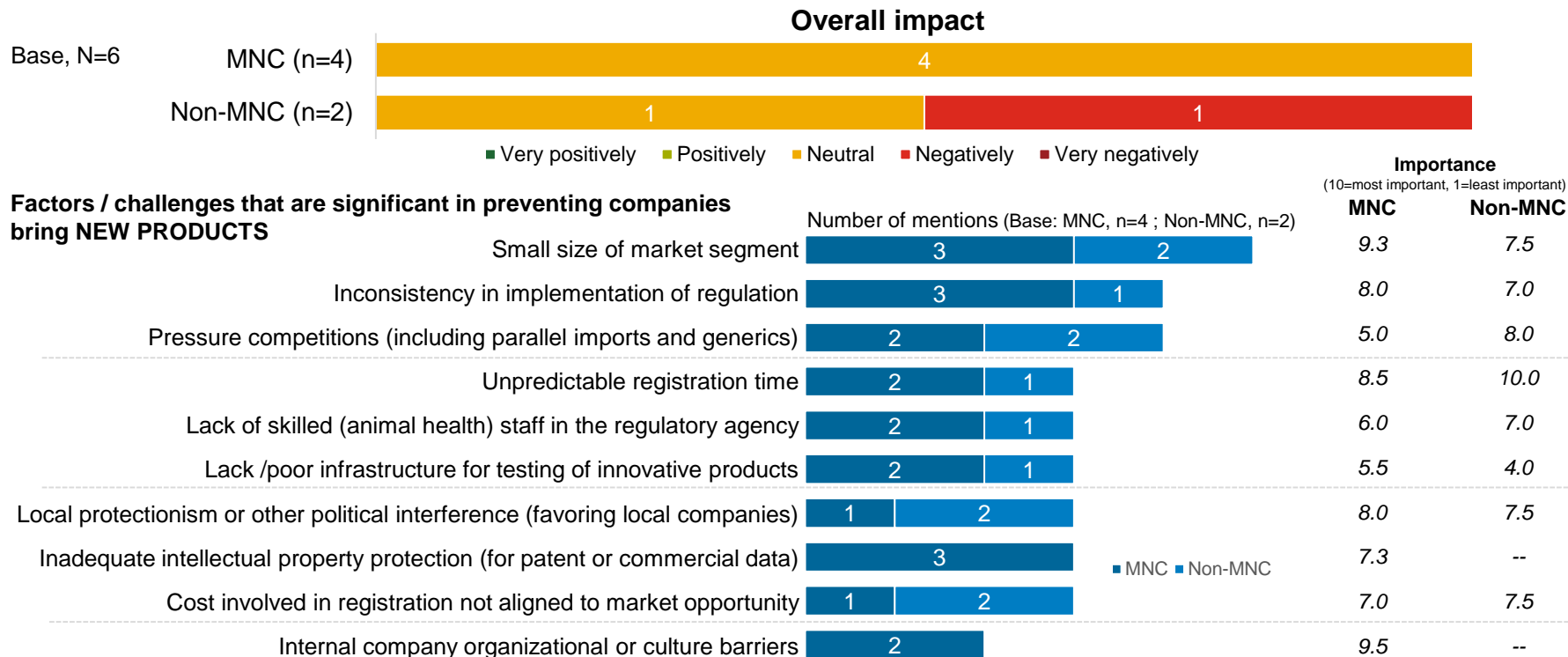


Note: Halal certification requirements is excluded in the report as it is not application to this country

■ Very helpful ■ Helpful ■ No impact ■ Unhelpful ■ Very unhelpful

D3. 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 BRING NEW PRODUCT successfully and in a timely manner to your country/ASEAN?

As most MNC sell in Myanmar through distributors, they tend to be neutral in their assessment on impact of regulatory environment in bringing new AH products to market. The concern to these MNC companies are small market size and inconsistency in implementation of regulation. 1 in 2 non-MNC said the current regulatory environment has negative impact.

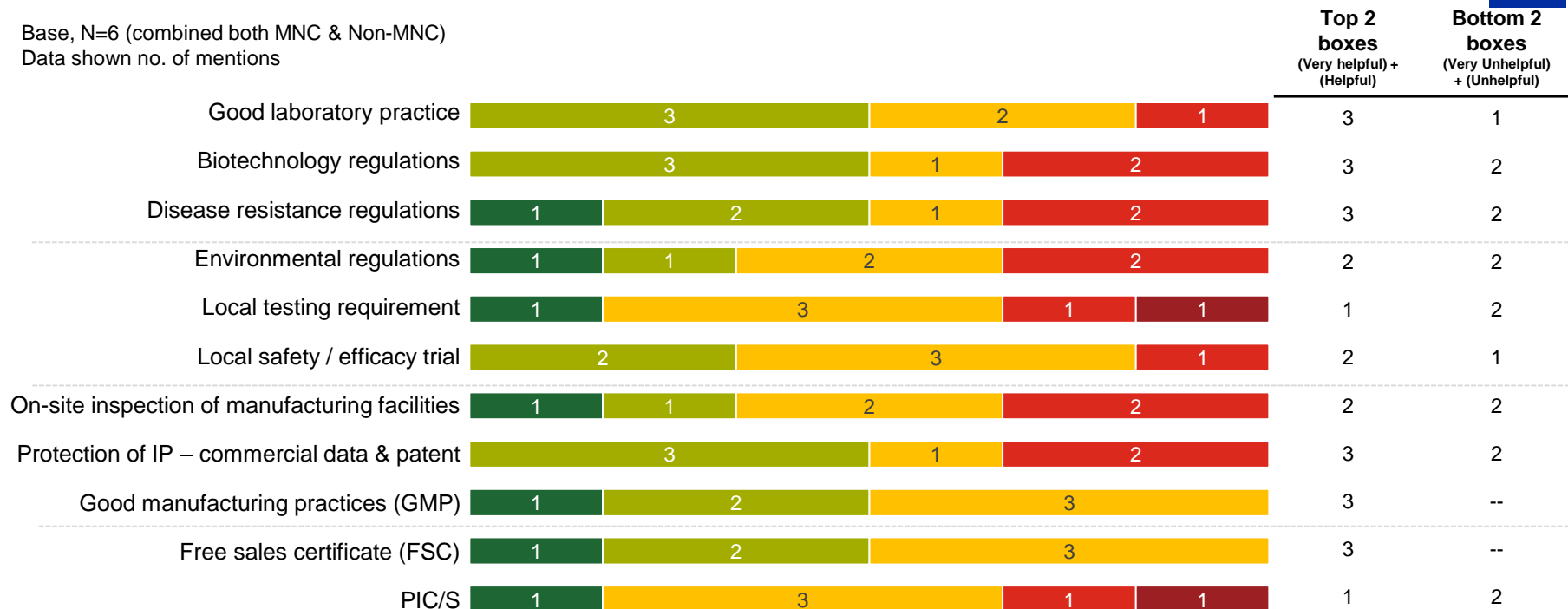


D1. How does the regulatory environment in your country/ASEAN impact your ability to BRING NEW PRODUCT TO MARKET? D2. Which of these, if any, are significant in preventing you to BRING NEW PRODUCT to your country/ASEAN?

CAMBODIA: Impact of govt. regulation on ability to bring new AH product successfully and timely manner to market
 Local testing requirements is not helpful in bringing AH products successfully and timely manner.



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

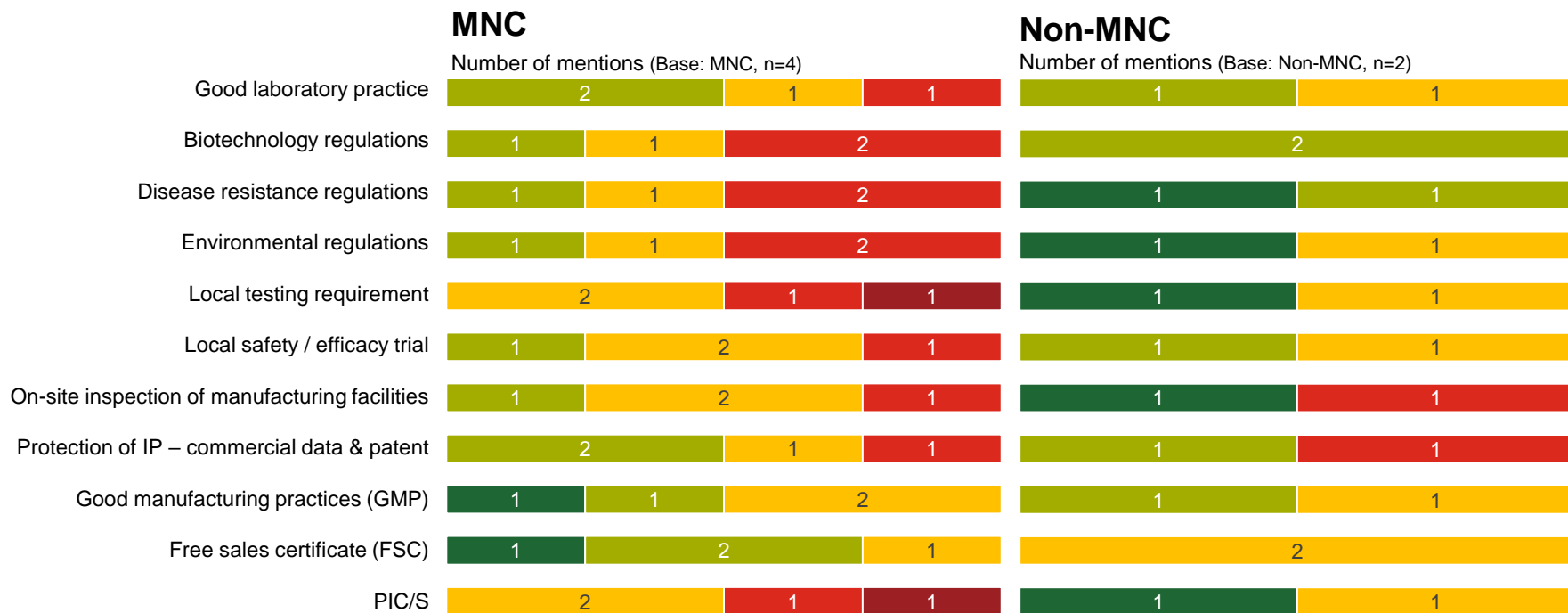


Note: Halal certification requirements is excluded in the report as it is not application to this country

■ Very helpful
 ■ Helpful
 ■ No impact
 ■ Unhelpful
 ■ Very unhelpful

D3. 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 BRING NEW PRODUCT successfully and in a timely manner to your country/ASEAN?

PIC/S is considered one area of regulation that could potentially be challenging in bringing new AH products to market, in addition to local testing requirements...feedbacks for MNC companies.

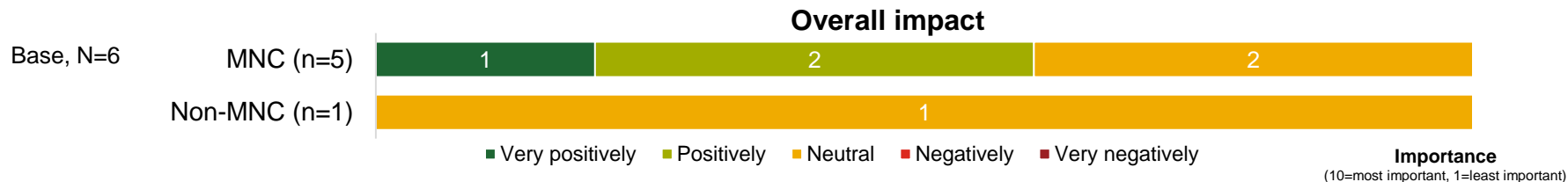


Note: Halal certification requirements is excluded in the report as it is not application to this country

■ Very helpful ■ Helpful ■ No impact ■ Unhelpful ■ Very unhelpful

D3. 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 BRING NEW PRODUCT successfully and in a timely manner to your country/ASEAN?

MNC companies generally agreed that regulatory environment in Myanmar are positive or at least neutral to their ability to bring new products to market. The only limitation in the market size – small, hence not always viable in bringing new product(s) to this marketplace



Factors / challenges that are significant in preventing companies bring NEW PRODUCTS

	Number of mentions (Base: MNC, n=5 ; Non-MNC, n=1)	MNC	Non-MNC
Small size of market segment	4 (MNC) 1 (Non-MNC)	9.8	10.0
Inadequate intellectual property protection (for patent or commercial data)	2	7.0	--
Negative consumer perceptions/attitudes	1 (MNC) 1 (Non-MNC)	8.0	9.0
Lack /poor infrastructure for testing of innovative products	2	5.0	--
Inconsistency in implementation of regulation	2	6.5	--
Pressure competitions (including parallel imports and generics)	2	8.5	--
Local protectionism or other political interference (favoring local companies)	2	9.0	--
Unpredictable registration time	1 (MNC)	7.0	--
Internal company organizational or culture barriers	1 (MNC)	10.0	--
Cost involved in registration not aligned to market opportunity	1 (MNC)	3.0	--

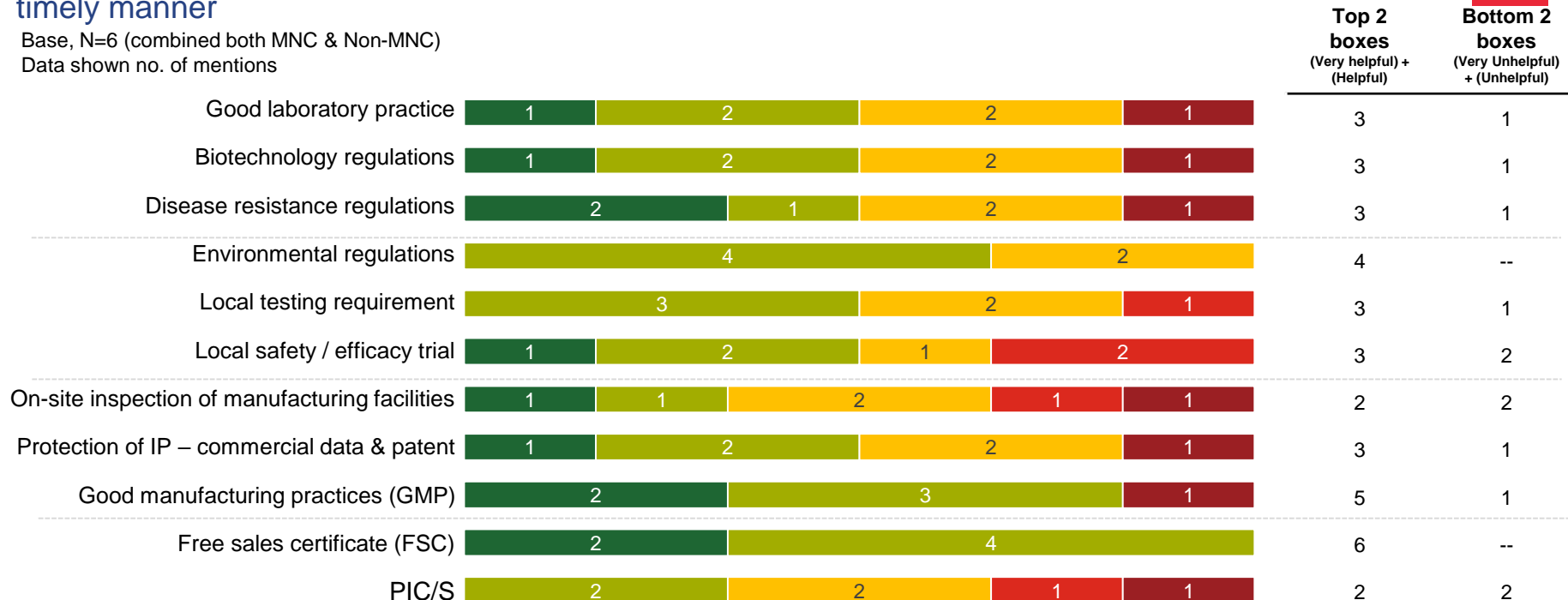
D1. How does the regulatory environment in your country/ASEAN impact your ability to BRING NEW PRODUCT TO MARKET? D2. Which of these, if any, are significant in preventing you to BRING NEW PRODUCT to your country/ASEAN?

MYANMAR: Impact of govt. regulation on ability to bring new AH product successfully and timely manner to market

Local safety/efficacy trials, on-site inspection of manufacturing facilities and PIC/S are the areas in the current regulation that limit the ability to bring new products successfully and timely manner

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

Data shown no. of mentions



Note: Halal certification requirements is excluded in the report as it is not application to this country

■ Very helpful
 ■ Helpful
 ■ No impact
 ■ Unhelpful
 ■ Very unhelpful

D3. 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 BRING NEW PRODUCT successfully and in a timely manner to your country/ASEAN?