



# Cost of AH product registration

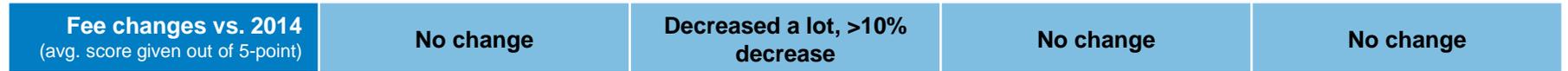
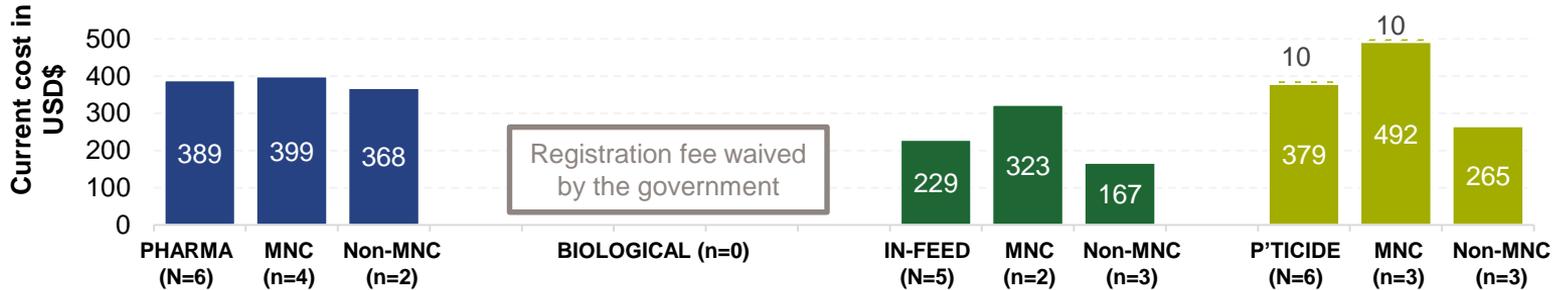
# The cost for this category of product for different species has not changed compared to 2014 with the exception of biologicals which has waived fees



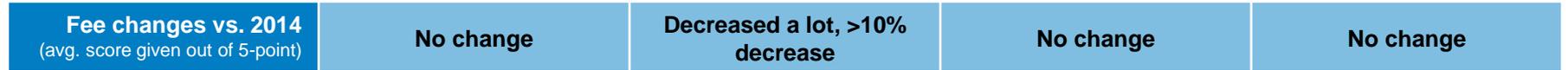
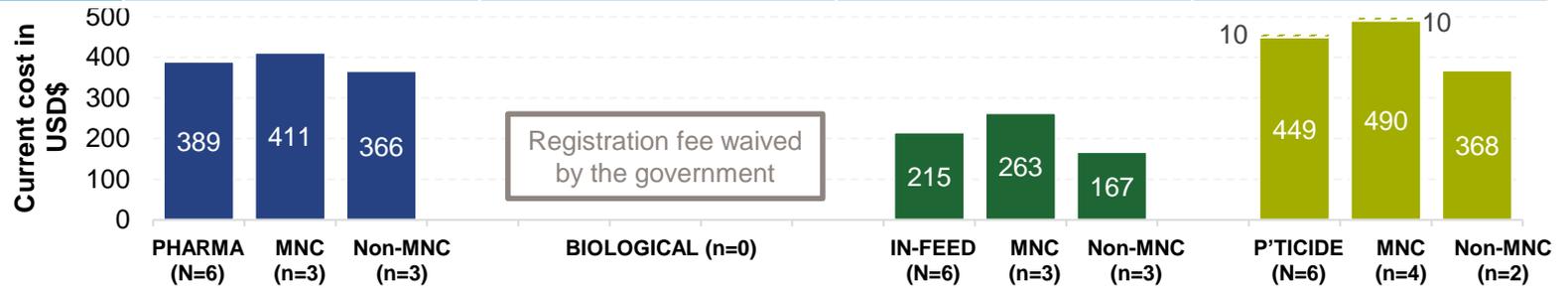
Data showed the average cost (in USD)



Companion animals



Production animals



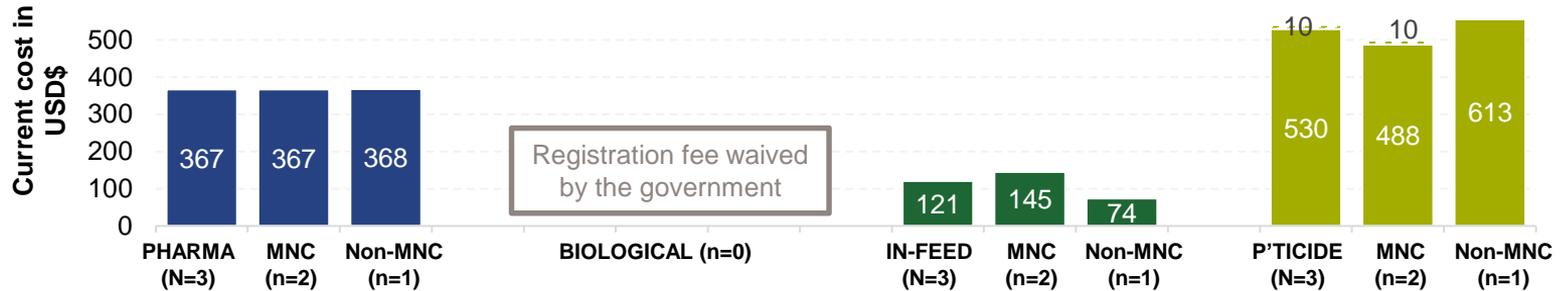
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# The cost for this category of product for aqua & others has not changed compared to 2014 with the exception of biologicals which has waived fees



Data showed the average cost (in USD)

■ ■ ■ ■ **Solid color, govt fees** Government fees for the submission of the application  
▨ ▨ ▨ ▨ **Line color, other fees** Other costs such as mandatory local trials, mandatory testing fees, import permit / import license etc. to allow approval.



Fee changes vs. 2014 (avg. score given out of 5-point)	PHARMA (N=3)	MNC (n=2)	Non-MNC (n=1)	BIOLOGICAL (n=0)	IN-FEED (N=3)	MNC (n=2)	Non-MNC (n=1)	P'TICIDE (N=3)	MNC (n=2)	Non-MNC (n=1)
	No change			Decreased a lot, >10% decrease	No change			No change		

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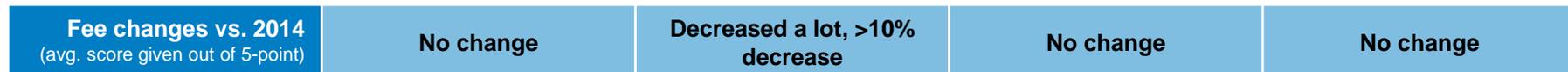
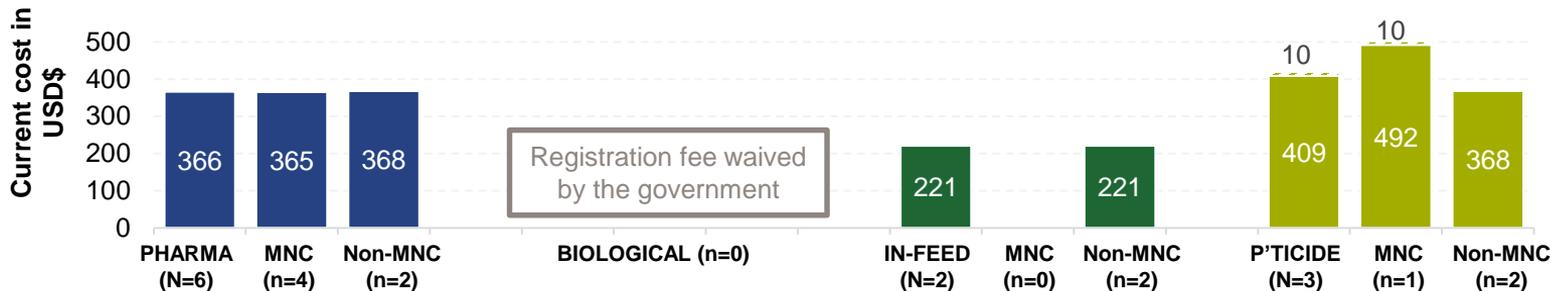
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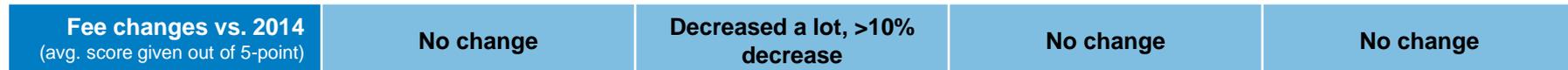
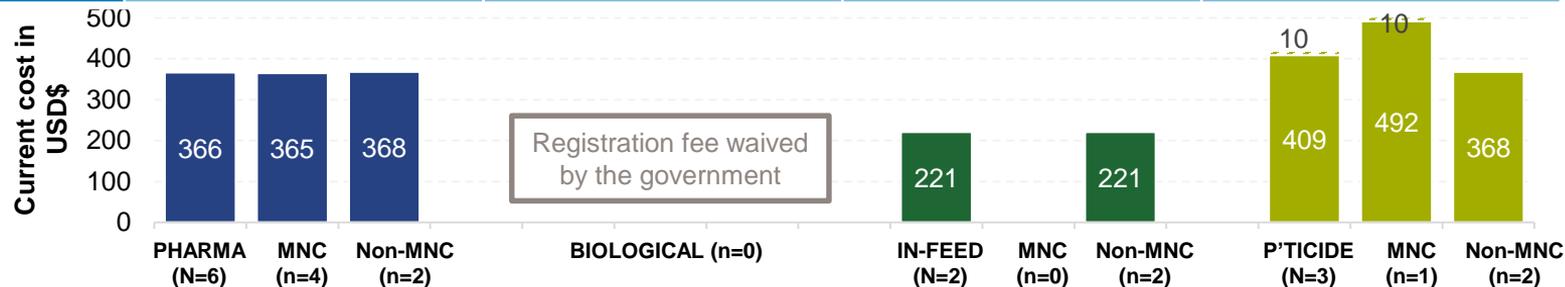
Data showed the average cost (in USD)

 **Solid color, govt fees** Government fees for the submission of the application  
 **Line color, other fees** Other costs such as mandatory local trials, mandatory testing fees, import permit / import license etc. to allow approval.

Companion animals



Production animals

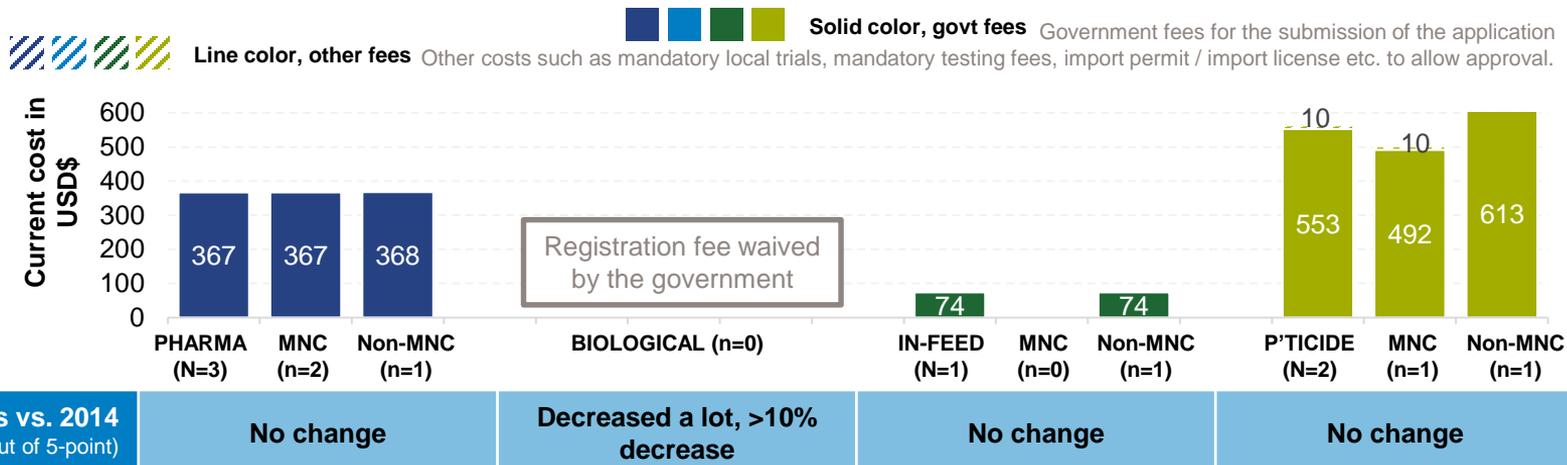


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# The cost for this category of product for aqua & others has not changed compared to 2014 with the exception of biologicals which has waived fees



Data showed the average cost (in USD)



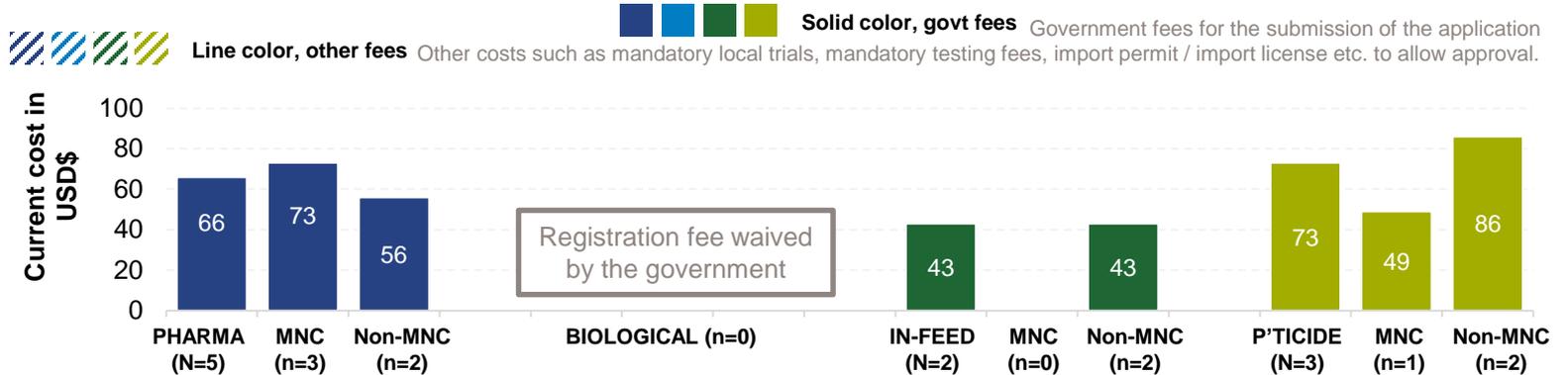
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# Pharmaceuticals and in-feed medications for companion animals had some slight decrease in cost since 2014



Data showed the average cost (in USD)

Companion animals



Fee changes vs. 2014 (avg. score given out of 5-point)	Decreased slightly, <10% decrease	Decreased a lot, >10% decrease	Decreased slightly, <10% decrease	No change
PHARMA (N=5), MNC (n=3), Non-MNC (n=2)	PHARMA (N=5), MNC (n=3), Non-MNC (n=2)	BIOLOGICAL (n=0)	IN-FEED (N=2), MNC (n=0), Non-MNC (n=2)	P'TICIDE (N=3), MNC (n=1), Non-MNC (n=2)

New regulations

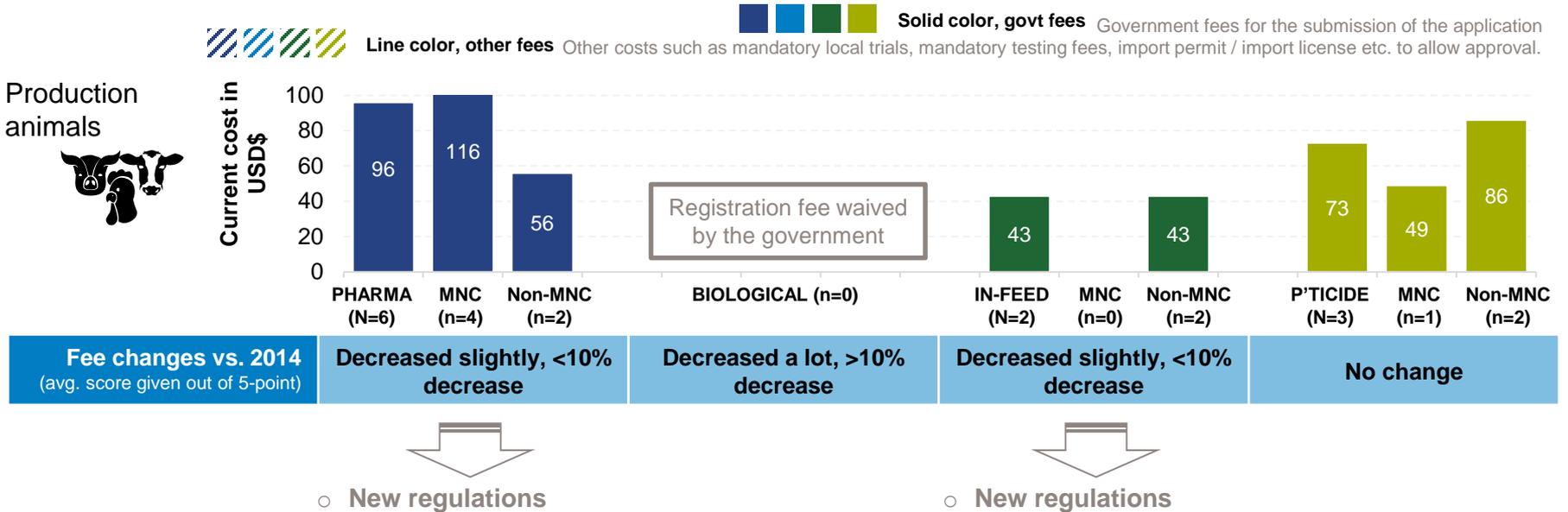
New regulations

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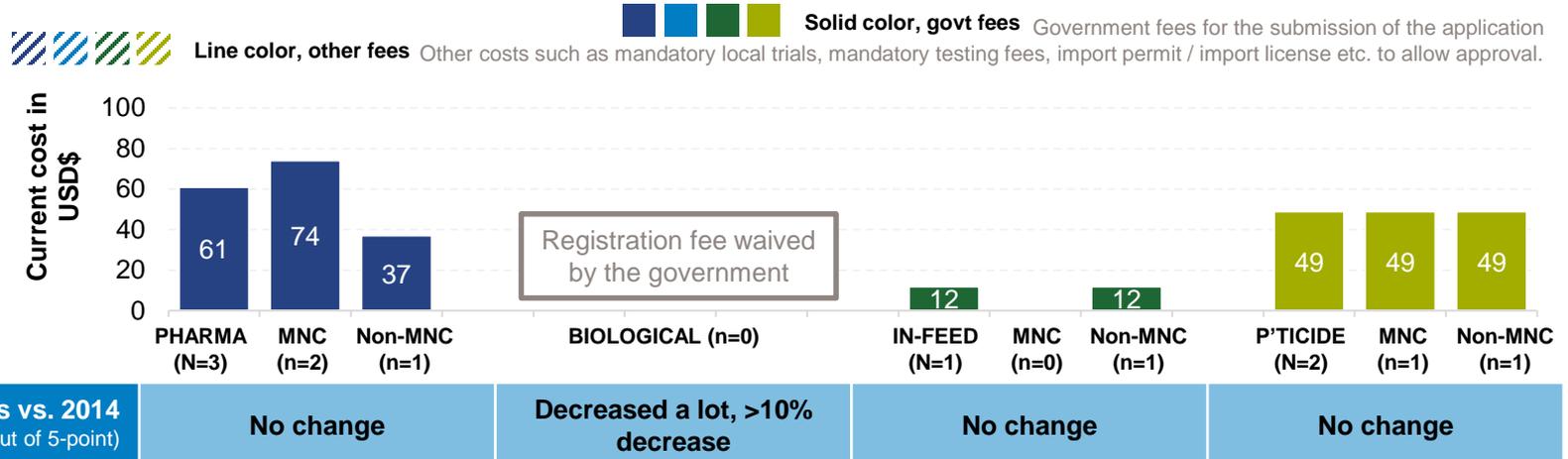


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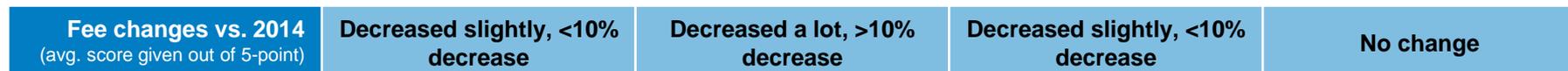
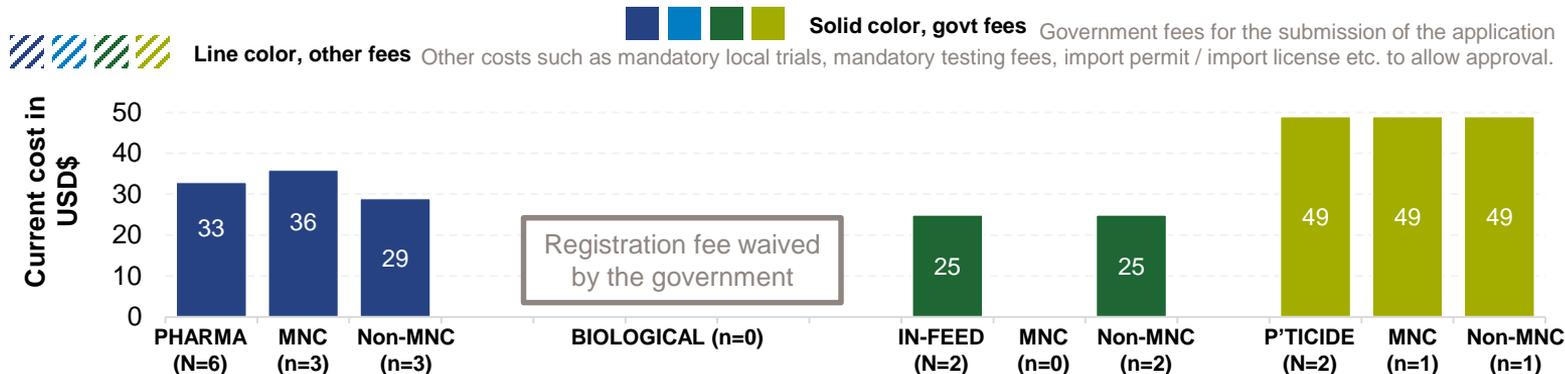
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# Pharmaceuticals and in-feed medications for companion animals had some slight decrease in cost since 2014



Data showed the average cost (in USD)

Companion animals



New regulations

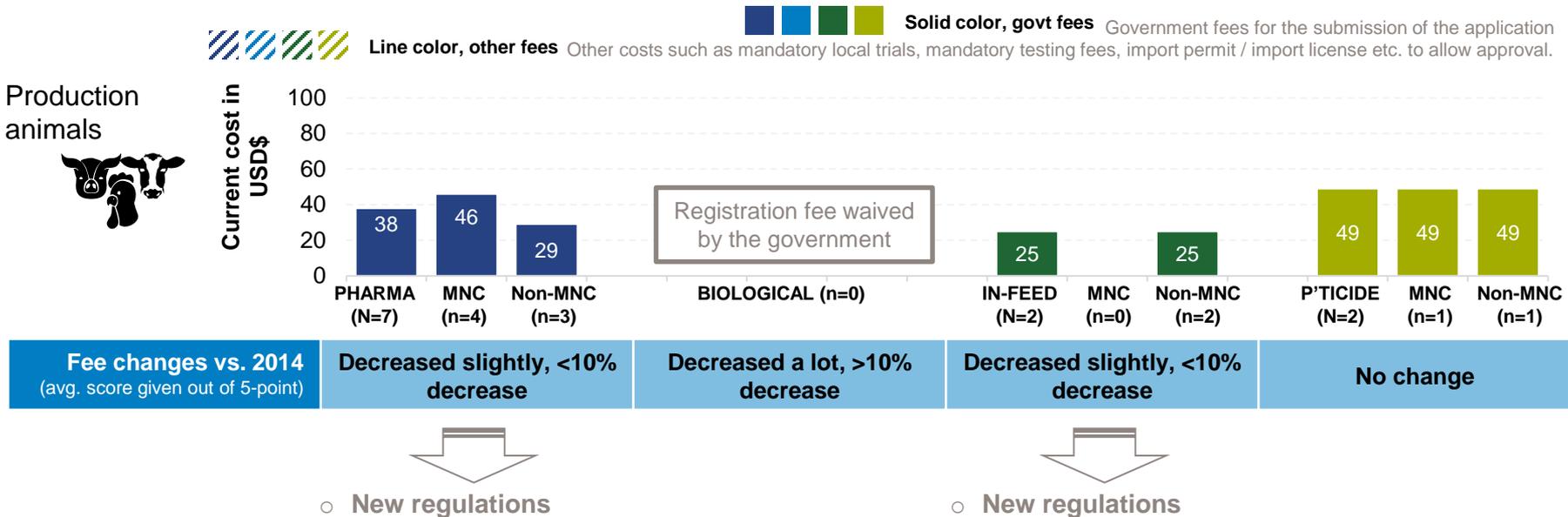
New regulations

B4a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B4b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B4c. What factors have caused the change?

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Data showed the average cost (in USD)

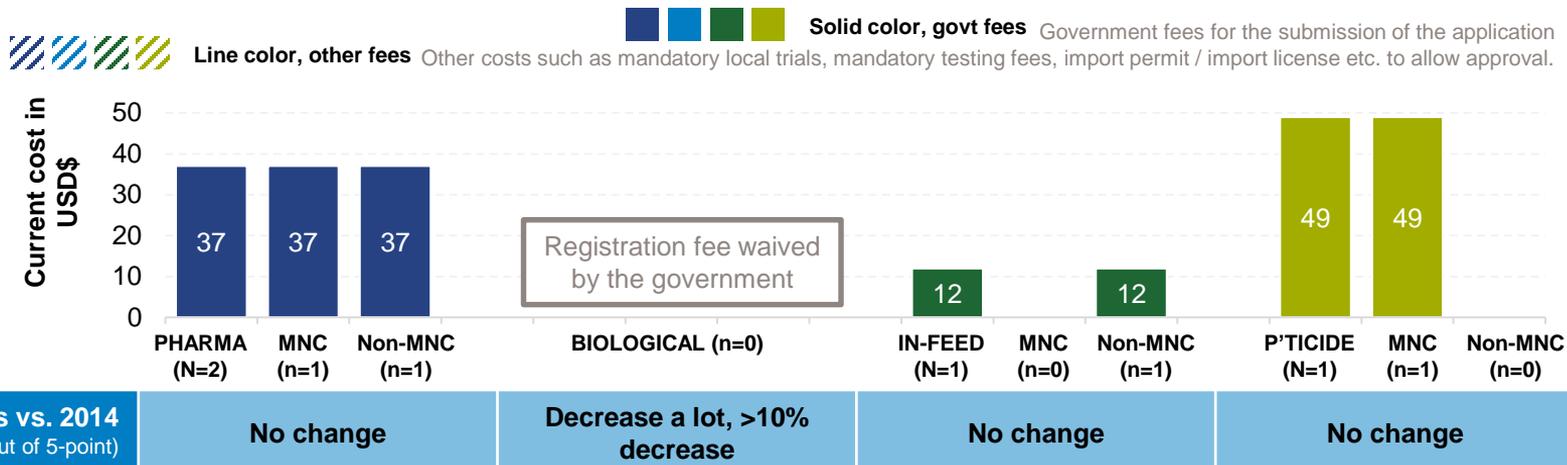


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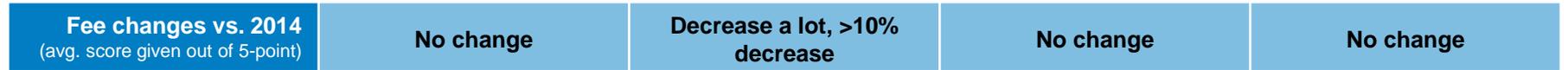
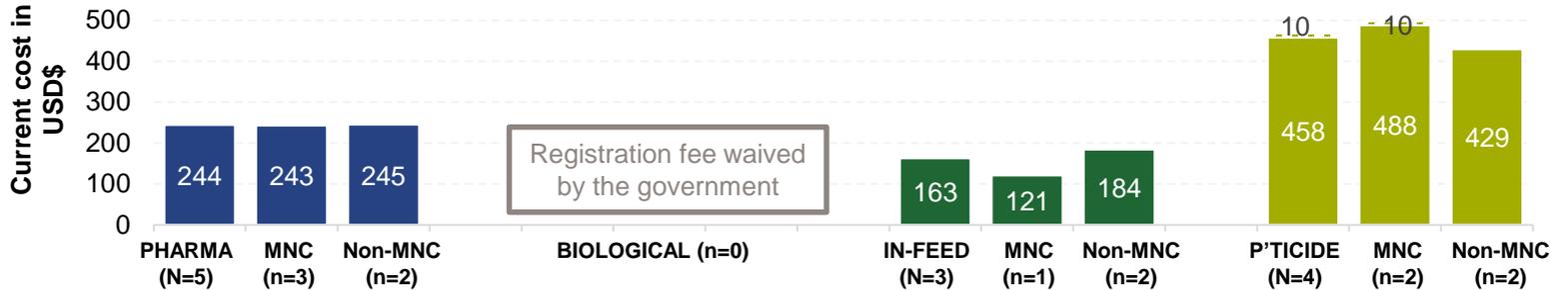
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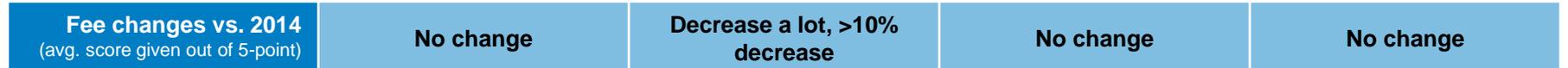
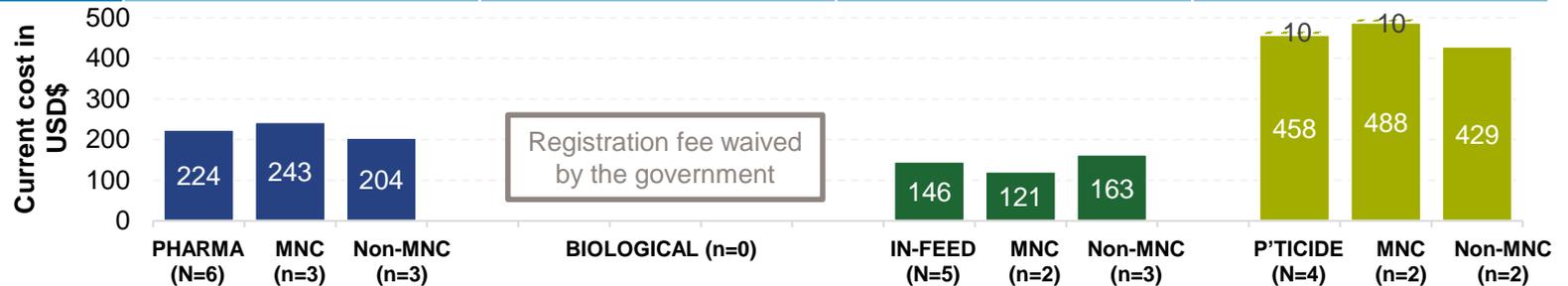
Data showed the average cost (in USD)

 **Solid color, govt fees** Government fees for the submission of the application  
 **Line color, other fees** Other costs such as mandatory local trials, mandatory testing fees, import permit / import license etc. to allow approval.

Companion animals



Production animals



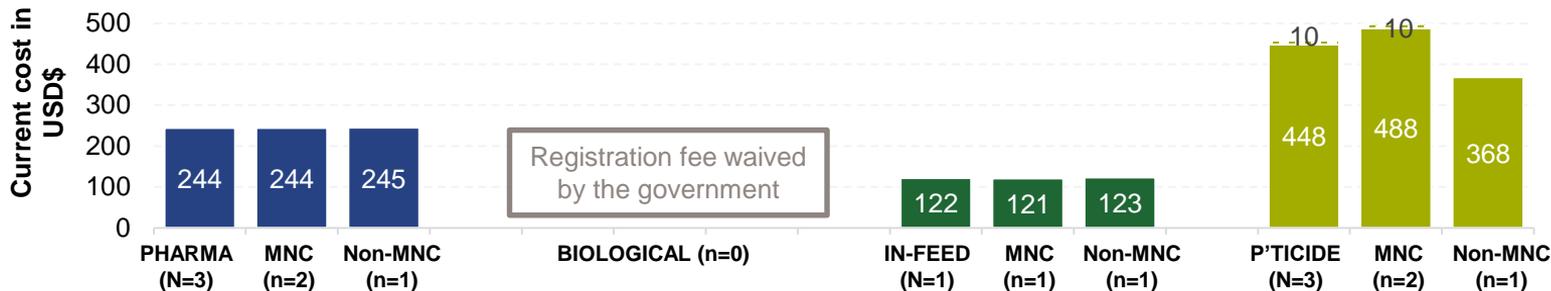
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# The cost for this category of product for aqua & others has not changed compared to 2014 with the exception of biologicals which has waived fees



Data showed the average cost (in USD)

▬ **Solid color, govt fees** Government fees for the submission of the application  
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Fee changes vs. 2014 (avg. score given out of 5-point)	PHARMA (N=3)	MNC (n=2)	Non-MNC (n=1)	BIOLOGICAL (n=0)	IN-FEED (N=1)	MNC (n=1)	Non-MNC (n=1)	P'TICIDE (N=3)	MNC (n=2)	Non-MNC (n=1)
	No change			Decrease a lot, >10% decrease	No change			No change		

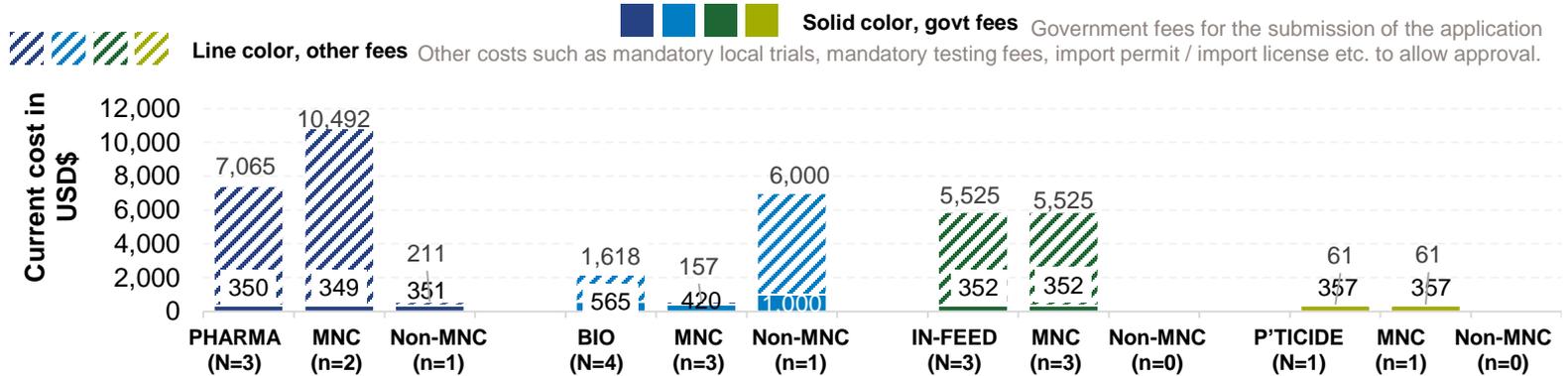
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# There is more than 10% increase in cost for all companion animal therapeutic types

Data showed the average cost (in USD)

Companion animals



Fee changes vs. 2014 (avg. score given out of 5-point)	Increased at lot, >10% increase			
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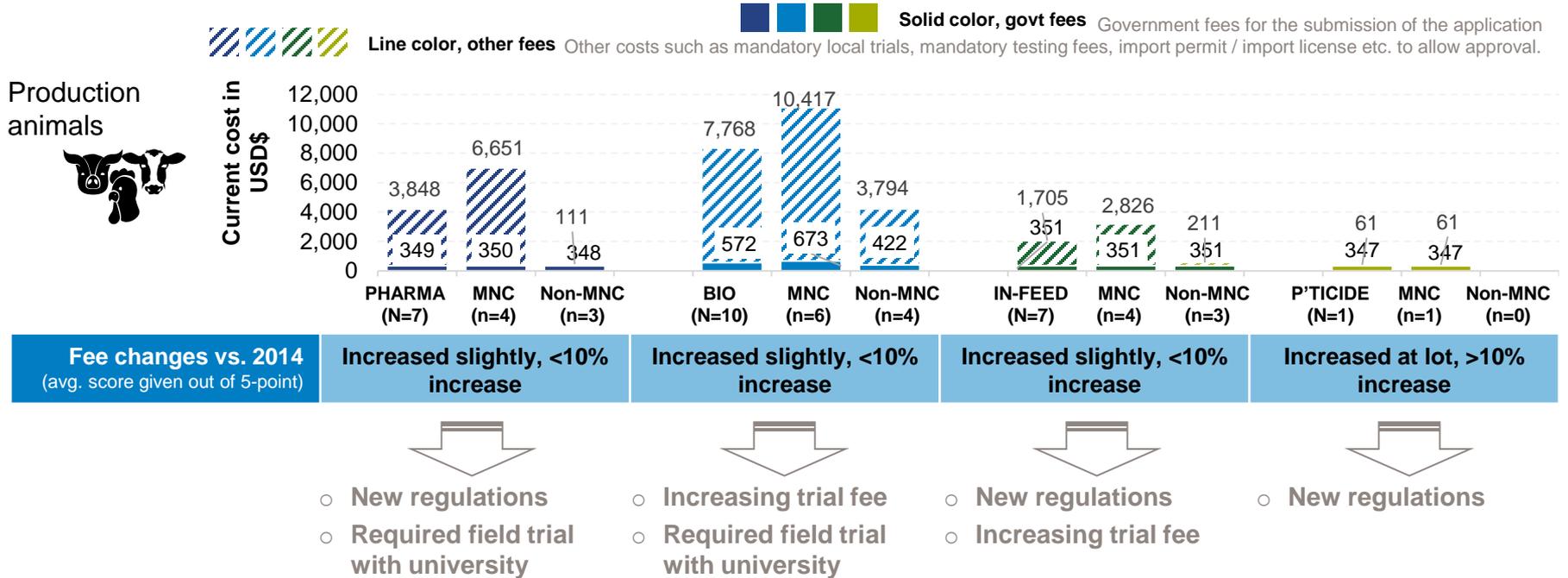
- New regulations
- Required field trial with university
- New regulations
- Required field trial with university
- New regulations
- Increasing trial fee
- New regulations

B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

# There is more than 10% increase in registration cost for most production animal therapeutic types



Data showed the average cost (in USD)

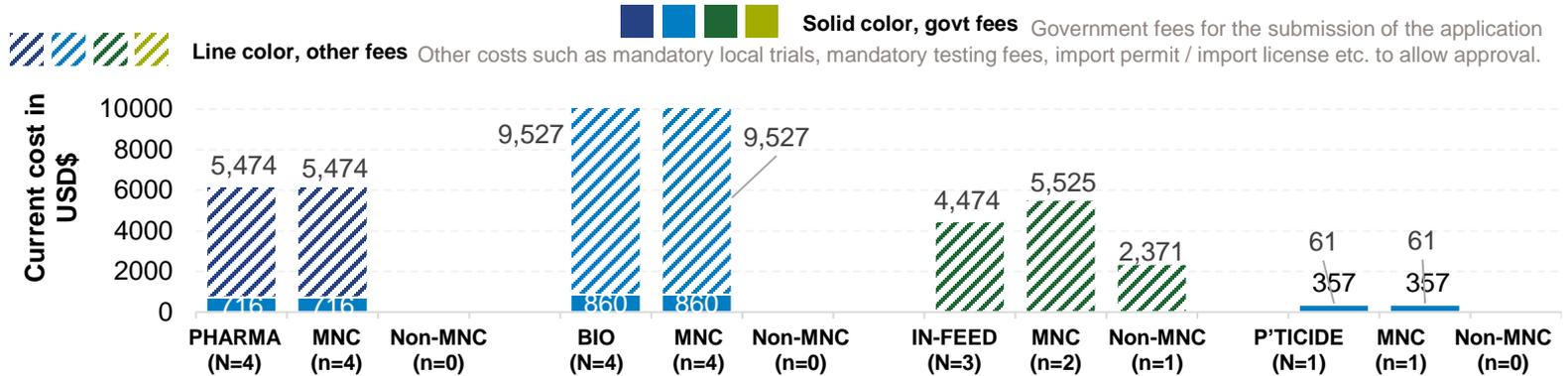


B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

# For aqua & others, there is no change in cost of registration except for pesticides



Data showed the average cost (in USD)



Fee changes vs. 2014 (avg. score given out of 5-point)	No change			No change			No change			Increased at lot, >10% increase		
	PHARMA (N=4)	MNC (n=4)	Non-MNC (n=0)	BIO (N=4)	MNC (n=4)	Non-MNC (n=0)	IN-FEED (N=3)	MNC (n=2)	Non-MNC (n=1)	P' TICIDE (N=1)	MNC (n=1)	Non-MNC (n=0)



○ New regulations

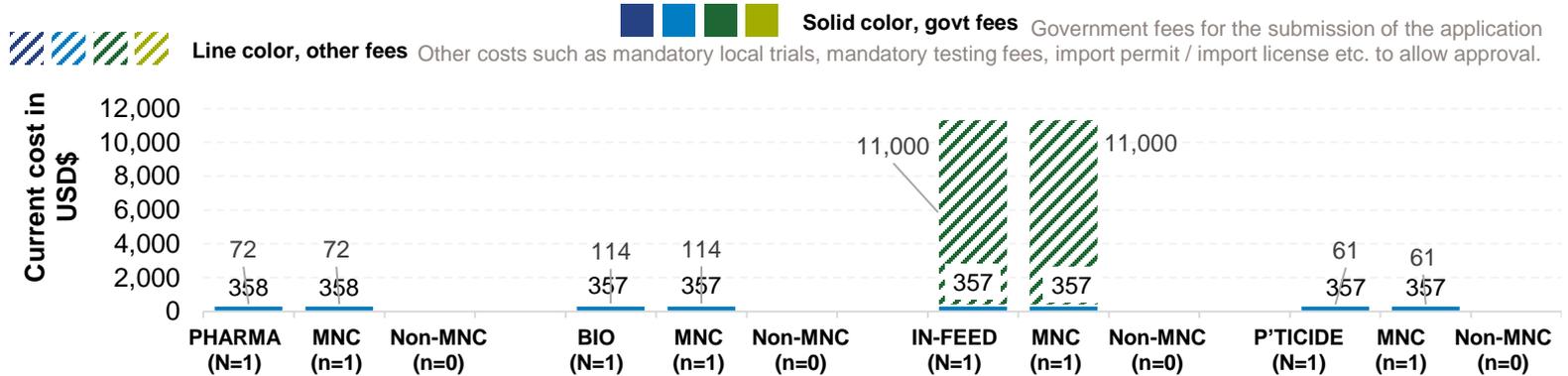
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# For companion animals, there is no change in cost of registration except for pesticides



Data showed the average cost (in USD)

Companion animals



Fee changes vs. 2014 (avg. score given out of 5-point)	Increased at lot, >10% increase	Increased at lot, >10% increase	Increased at lot, >10% increase	No change
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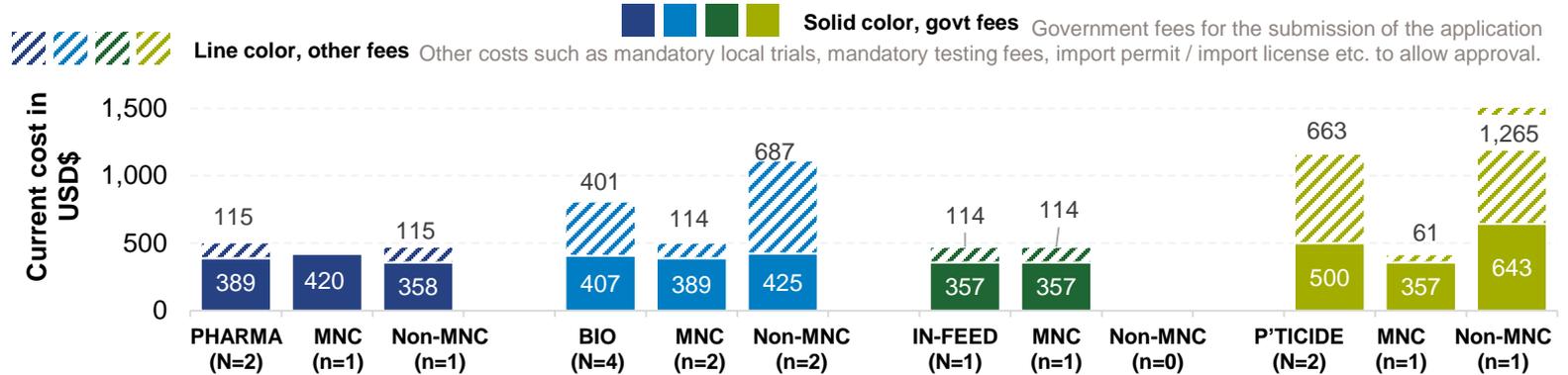
- New regulations – trial fee
- New regulations – trial fee
- New regulations – trial fee

B2a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B2b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B2c. What factors have caused the change?

# For production animals, there is increase in cost for all therapeutic types except for pharmaceuticals



Data showed the average cost (in USD)



Fee changes vs. 2014 (avg. score given out of 5-point)	No change			Increased slightly, <10% increase			Increased at lot, >10% increase			Increased at lot, >10% increase		

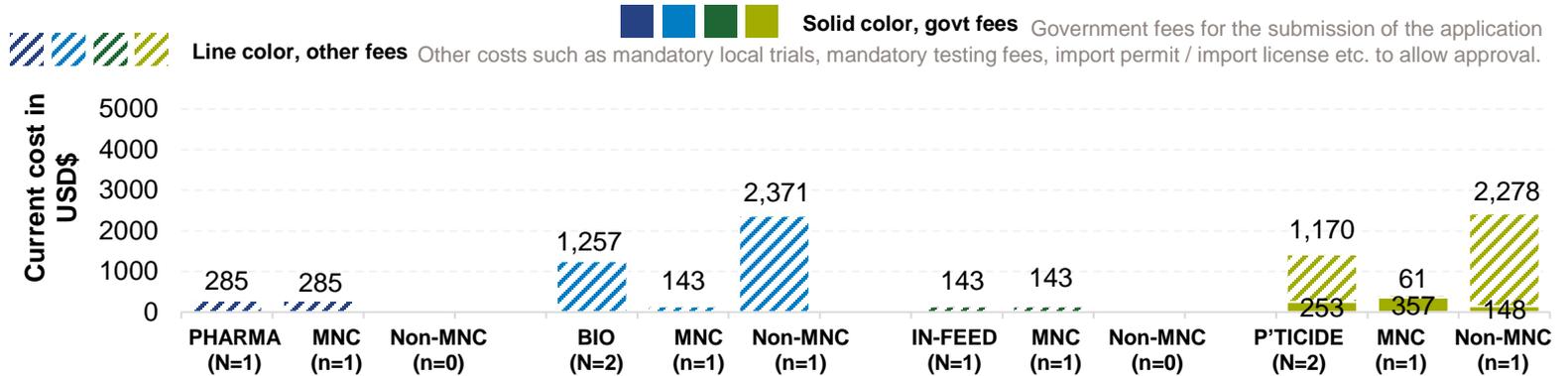
- New regulations – trial fee
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# For aqua & others, there is no change in cost of registration except for pesticides



Data showed the average cost (in USD)



Fee changes vs. 2014 (avg. score given out of 5-point)	PHARMA (N=1)	MNC (n=1)	Non-MNC (n=0)	BIO (N=2)	MNC (n=1)	Non-MNC (n=1)	IN-FEED (N=1)	MNC (n=1)	Non-MNC (n=0)	P'TICIDE (N=2)	MNC (n=1)	Non-MNC (n=1)
	No change			No change			No change			Increased at lot, >10% increase		



- New regulations – trial fee

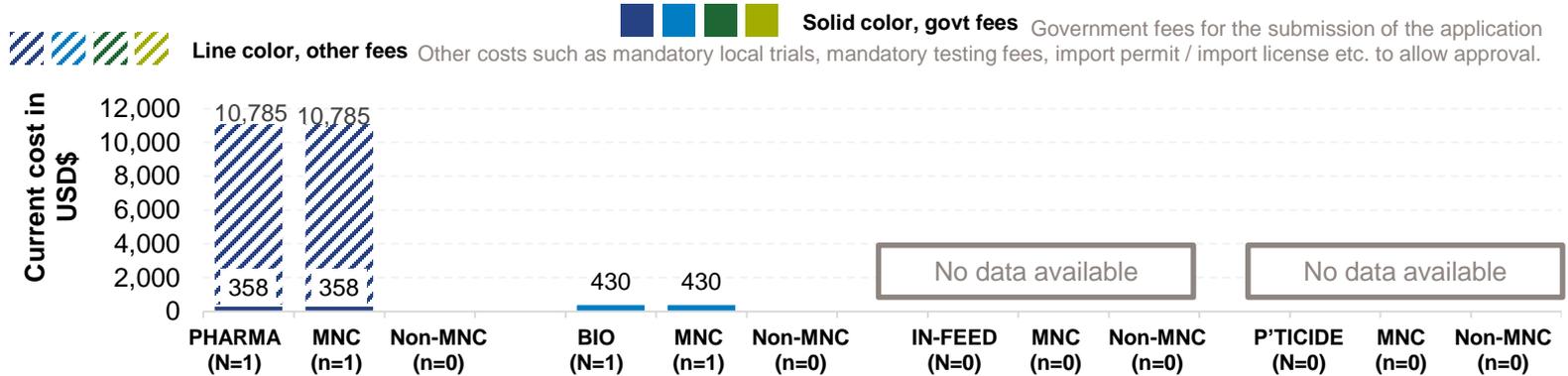
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# There is more than 10% increase in cost for companion animals pharmaceuticals and biologicals

Data showed the average cost (in USD)



Companion animals



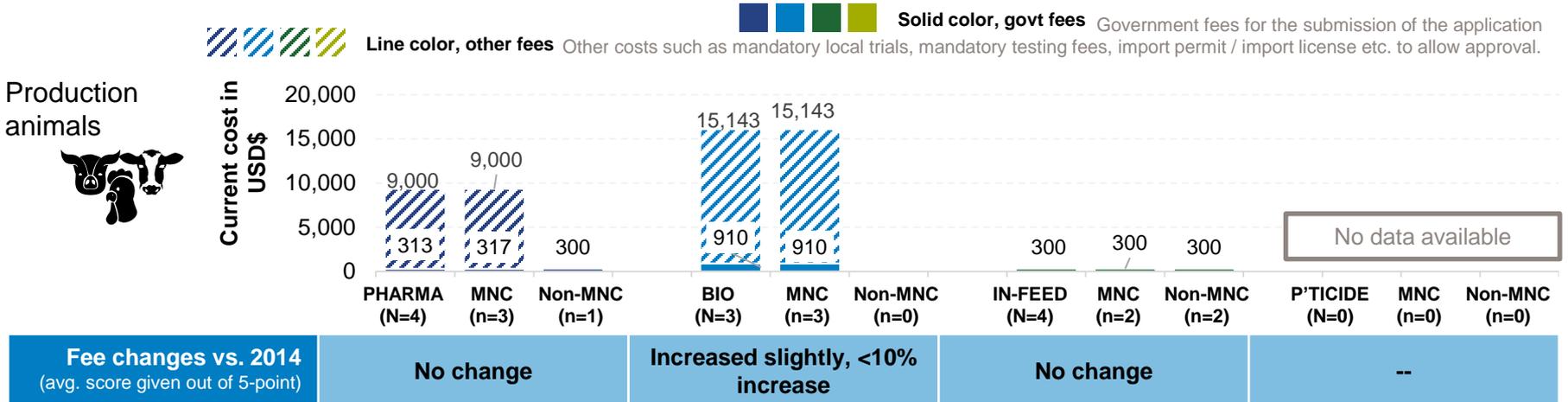
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	Increased at lot, >10% increase			Increased at lot, >10% increase			--			--		

- New regulations – field trial
- New regulations – field trial

B3a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B3b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B3c. What factors have caused the change?

# There is less than 10% increase in cost for production animals biologicals

Data showed the average cost (in USD)



- New regulations – field trial

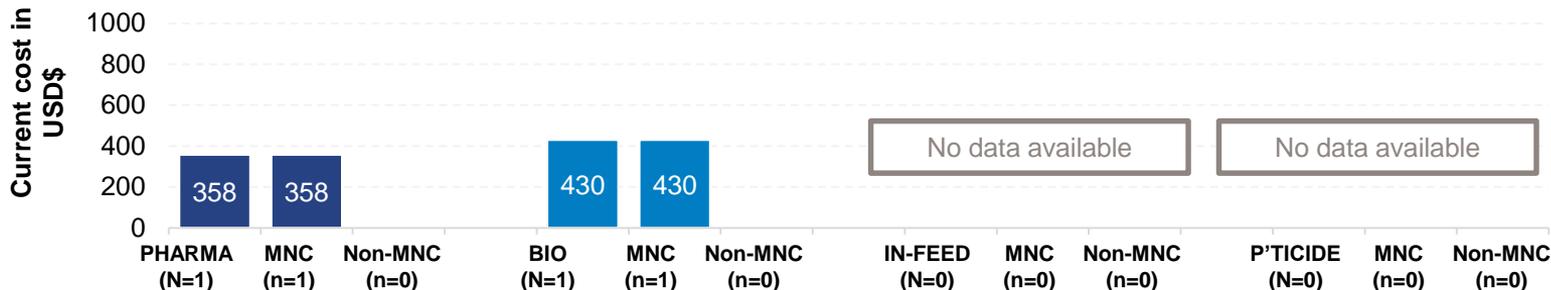
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# There is no change in cost for in-feed medications for companion and production animals

Data showed the average cost (in USD)

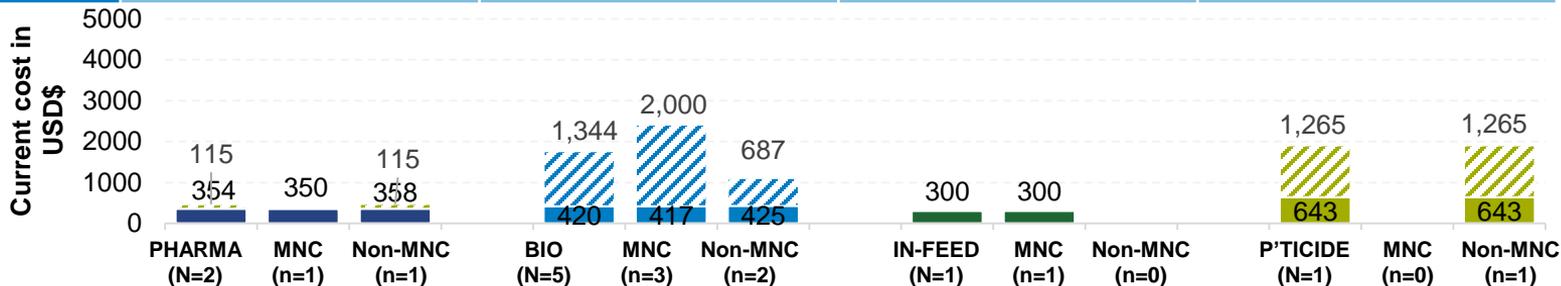


Companion animals



Fee changes vs. 2014 (avg. score given out of 5-point)	Increased slightly, <10% increase	Increased at lot, >10% increase	--	--
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Production animals



Fee changes vs. 2014 (avg. score given out of 5-point)	Increased slightly, <10% increase	Increased slightly, <10% increase	No change	No change
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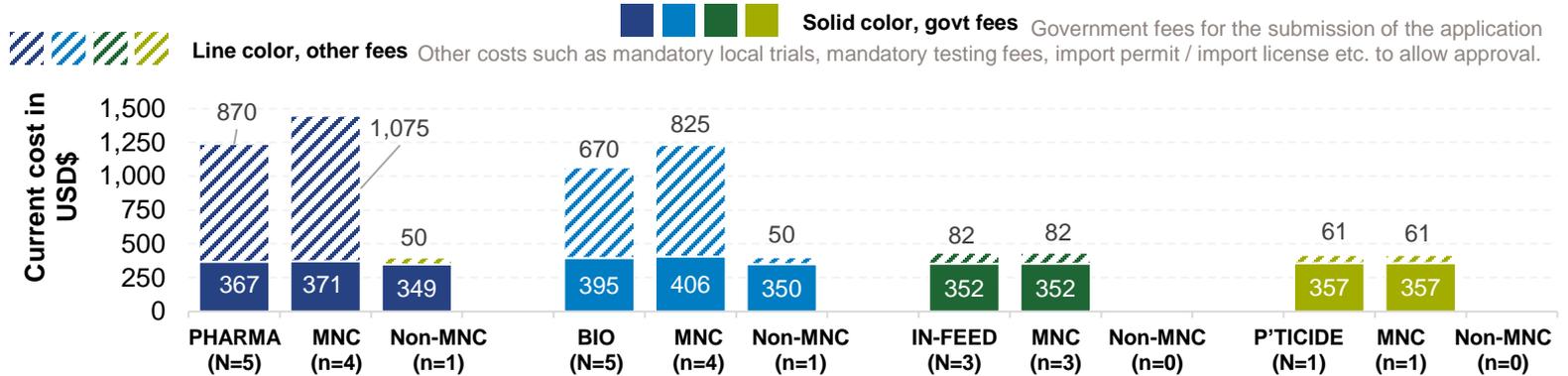
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# There is more than 10% increase in cost for all companion animal therapeutic types

Data showed the average cost (in USD)

Companion animals



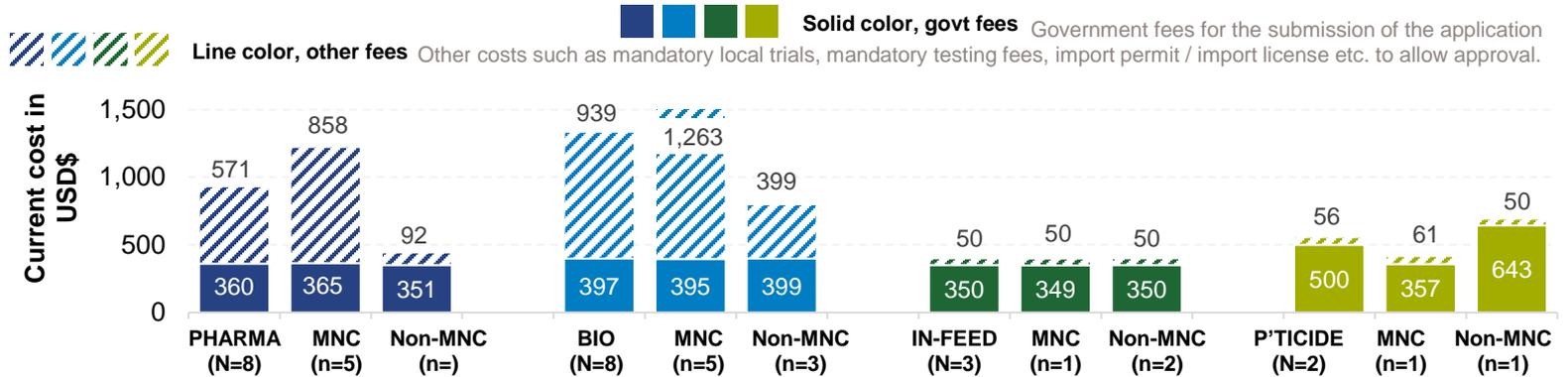
Fee changes vs. 2014 (avg. score given out of 5-point)	Increased at lot, >10% increase			
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- New regulations
- New requirement – trial fee

B5a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B5b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B5c. What factors have caused the change?

# There is increase in cost for all production animal therapeutic types

Data showed the average cost (in USD)



Fee changes vs. 2014 (avg. score given out of 5-point)	Increased slightly, <10% increase	Increased at lot, >10% increase	Increased slightly, <10% increase	Increased at lot, >10% increase
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- New regulations
- New requirement – trial fee
- Inflation



- New regulations
- New requirement – trial fee
- Inflation



- New regulations



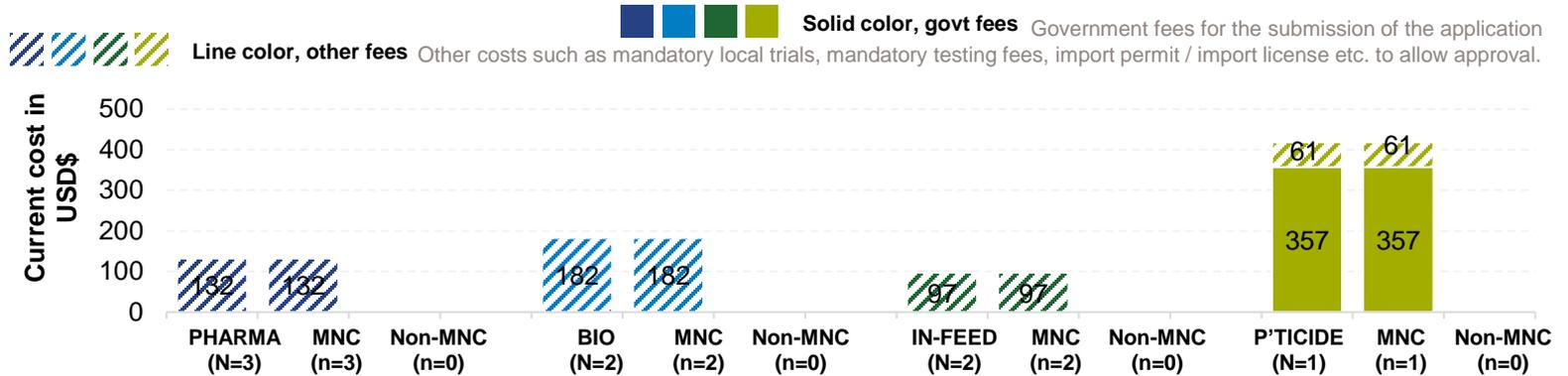
- New regulations

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# There is no change in cost for aqua & others pharmaceuticals



Data showed the average cost (in USD)



Fee changes vs. 2014 (avg. score given out of 5-point)	No change			Increased slightly, <10% increase			Increased slightly, <10% increase			Increased at lot, >10% increase		



- New requirement – field trial
- New requirement – Product quality testing fee



- New requirement – field trial
- New requirement – Product quality testing fee



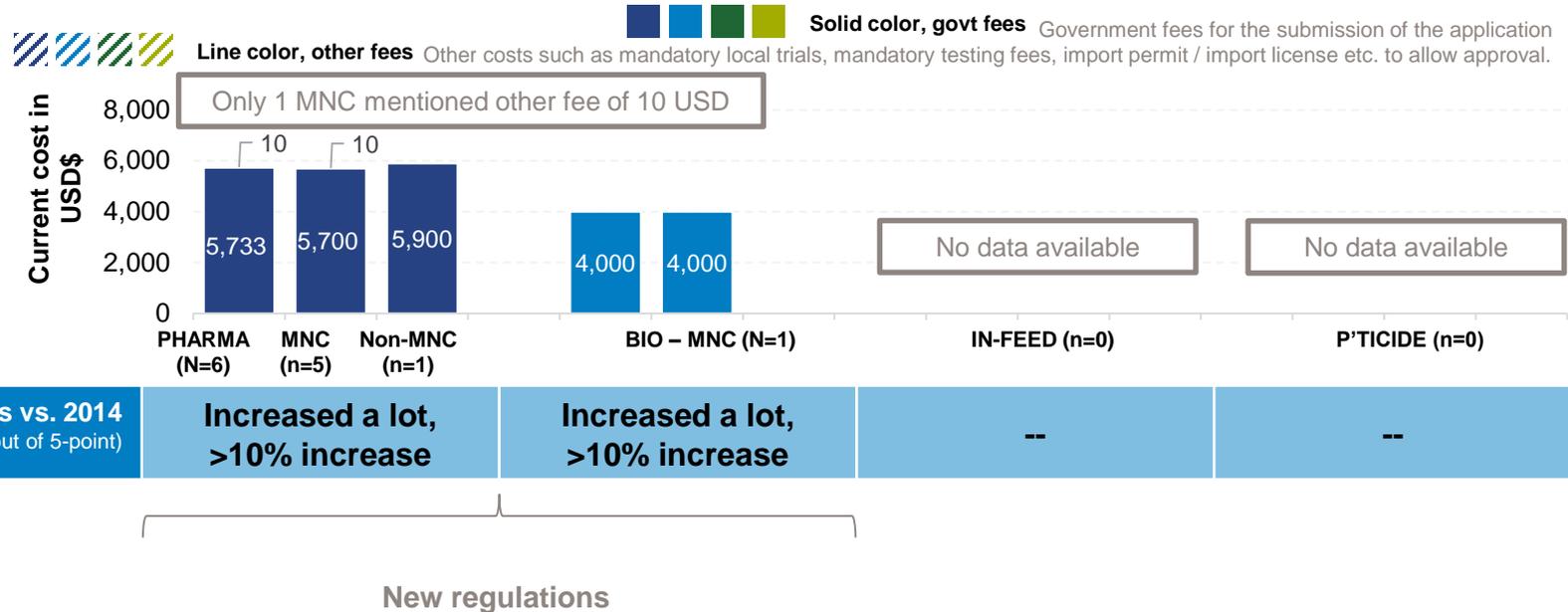
- New regulations

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# Both pharmaceuticals and biologicals AH products in Thailand experienced an increase in government cost

Data showed the average cost (in USD)

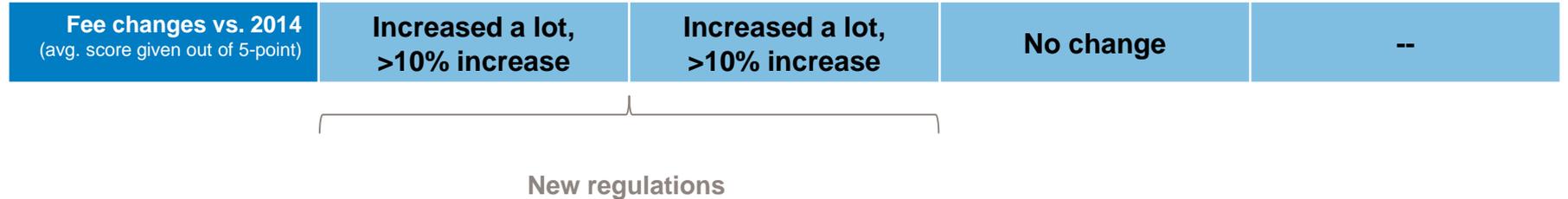
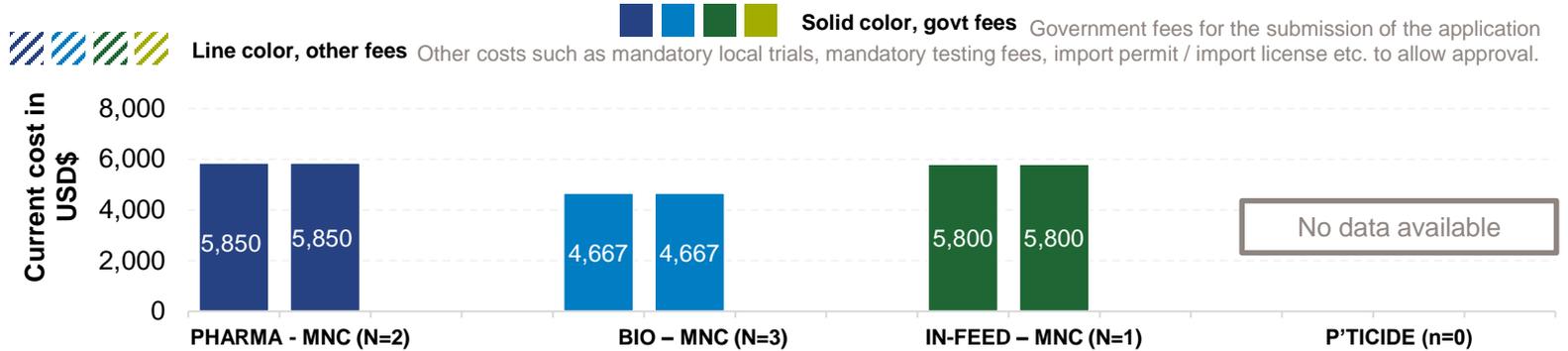
Companion animals



B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

# In-feed medications AH products in Thailand did not have change in government cost

Data showed the average cost (in USD)



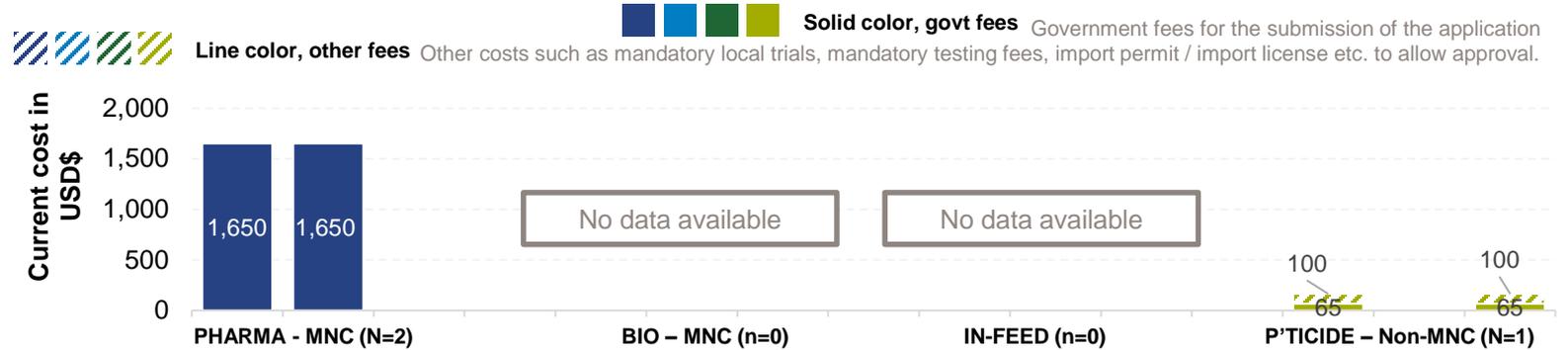
B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

# The government fees for pharmaceuticals and pesticides have increased with the new regulations in place in Thailand



Data showed the average cost (in USD)

Companion animals

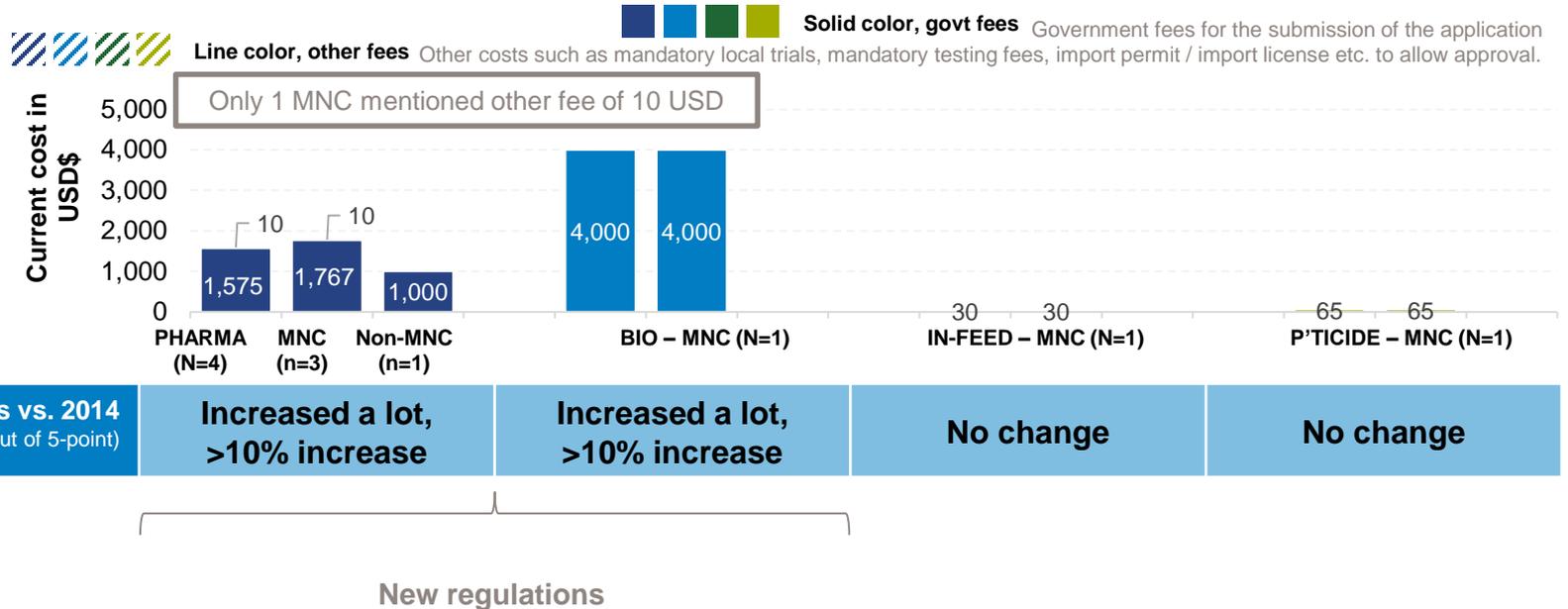


B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

# The governments fees for pharmaceuticals and biologicals have increased **kynetec** with the new regulations in place in Thailand



Data showed the average cost (in USD)



B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

# Pesticide AH products do not have changes in fee since 2014

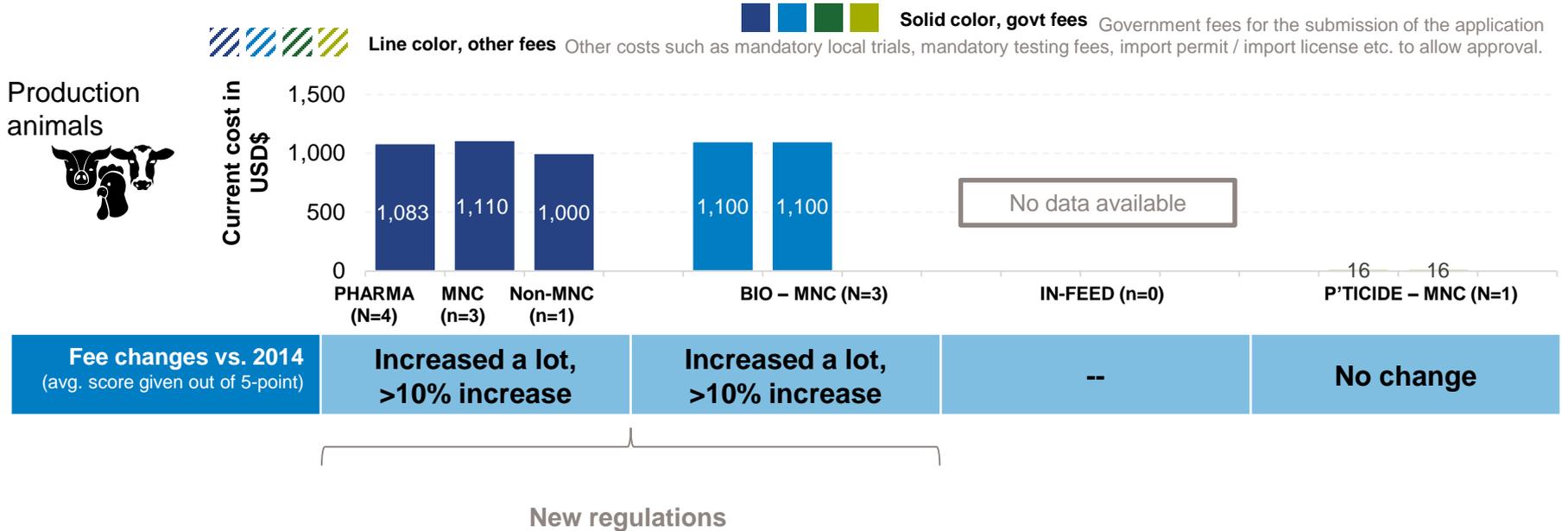
Data showed the average cost (in USD)



B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

# Both pharmaceuticals and biologicals products for production animals increased in fees since 2014

Data showed the average cost (in USD)



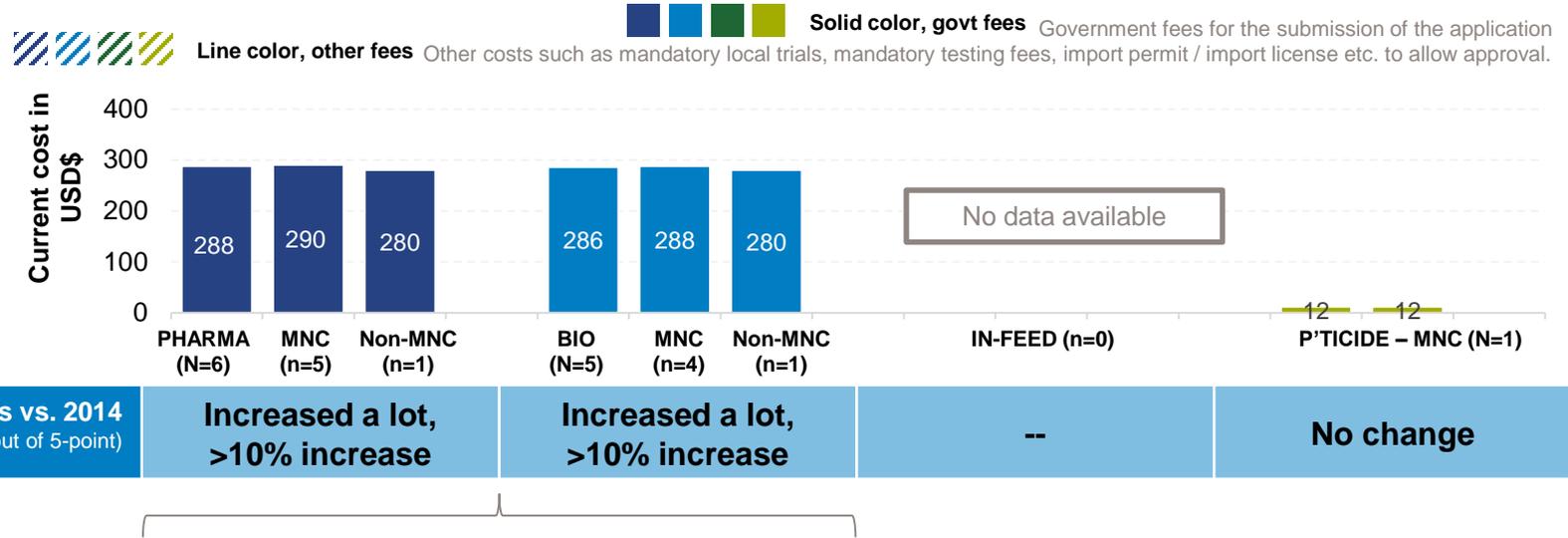
B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

# For companion animals, the government fees for pharmaceuticals and biologicals products increased more than 10%



Data showed the average cost (in USD)

Companion animals



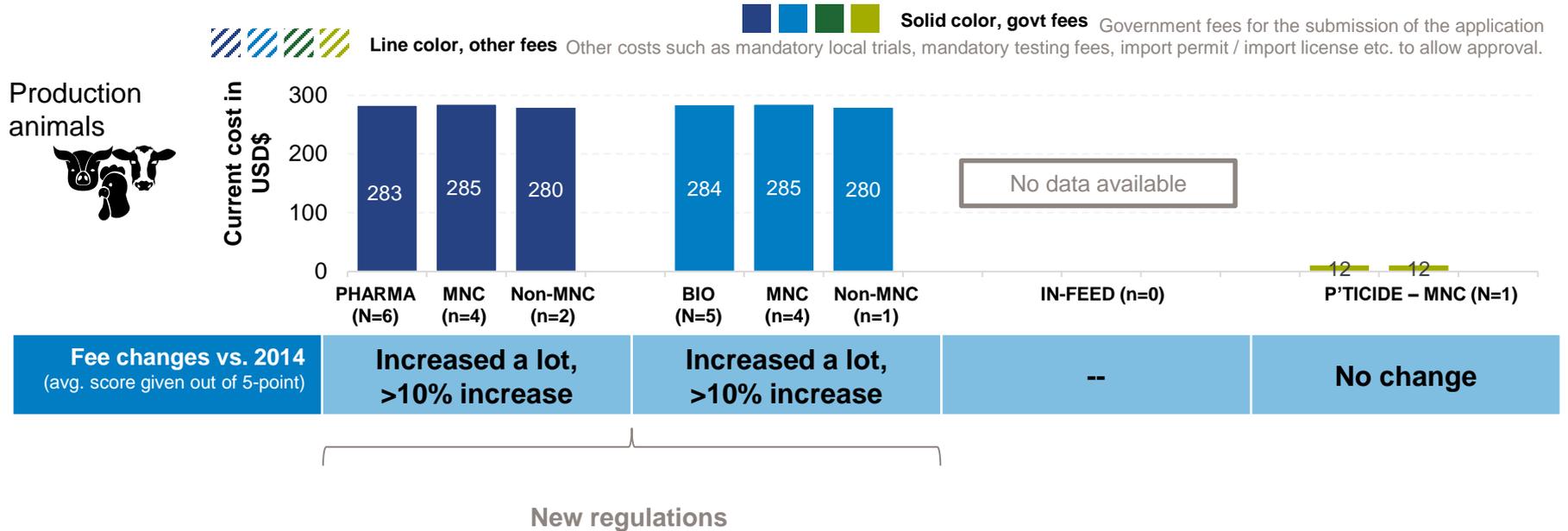
New regulations

B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

# For production animals, the government fees for pesticide products have not increased since 2014



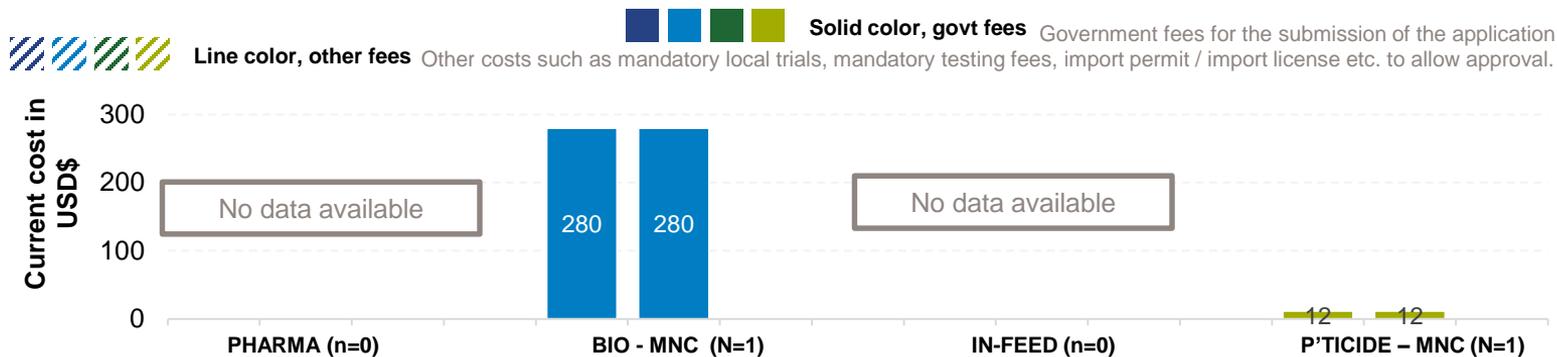
Data showed the average cost (in USD)



B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

# For aqua and others, only biological products have more than 10% increase in fees

Data showed the average cost (in USD)



Fee changes vs. 2014 (avg. score given out of 5-point)	PHARMA (n=0)	BIO - MNC (N=1)	IN-FEED (n=0)	P'TICIDE - MNC (N=1)
	--	Increased a lot, >10% increase	--	No change

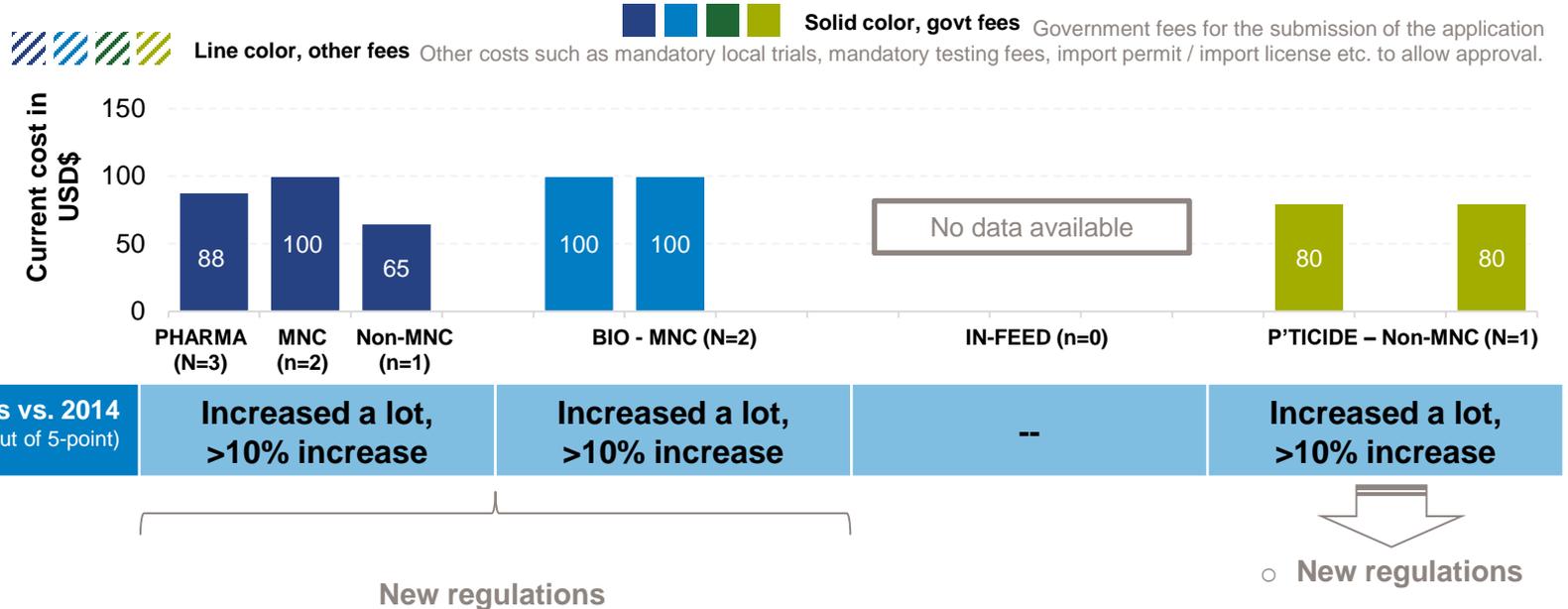
  
 New regulations

B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

# Most of the therapeutic classes experienced a sharp increase in the government fees

Data showed the average cost (in USD)

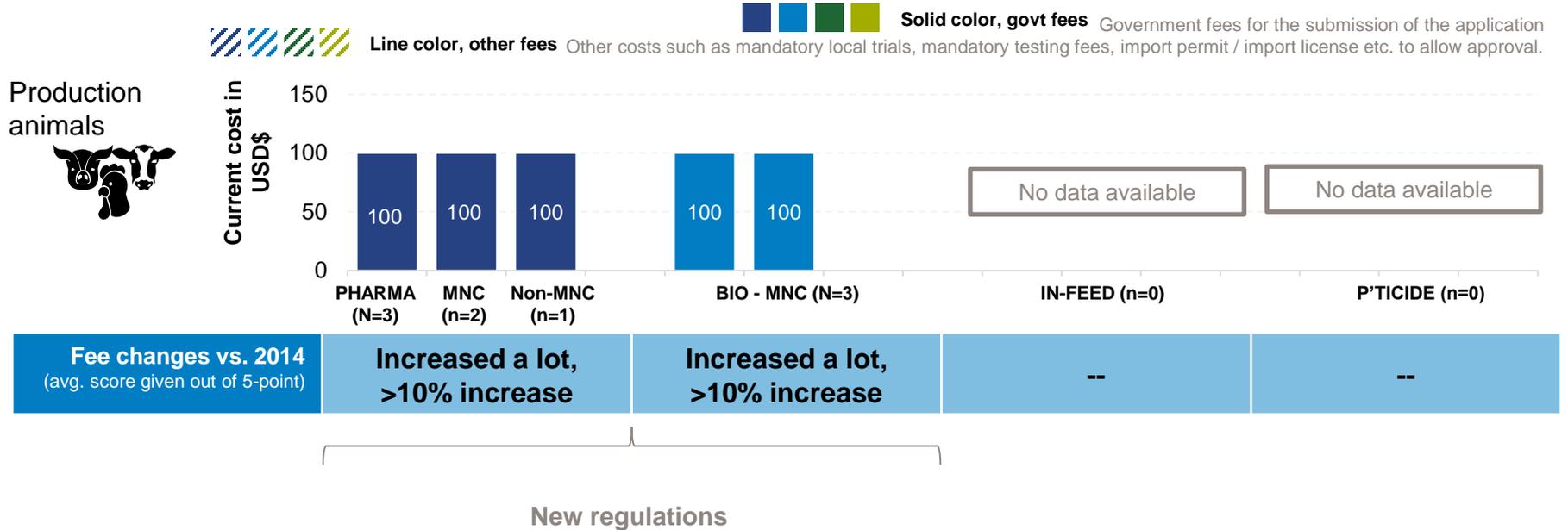
Companion animals



B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

# Pharmaceuticals and biologicals in production animal experienced a sharp increase in the government fees

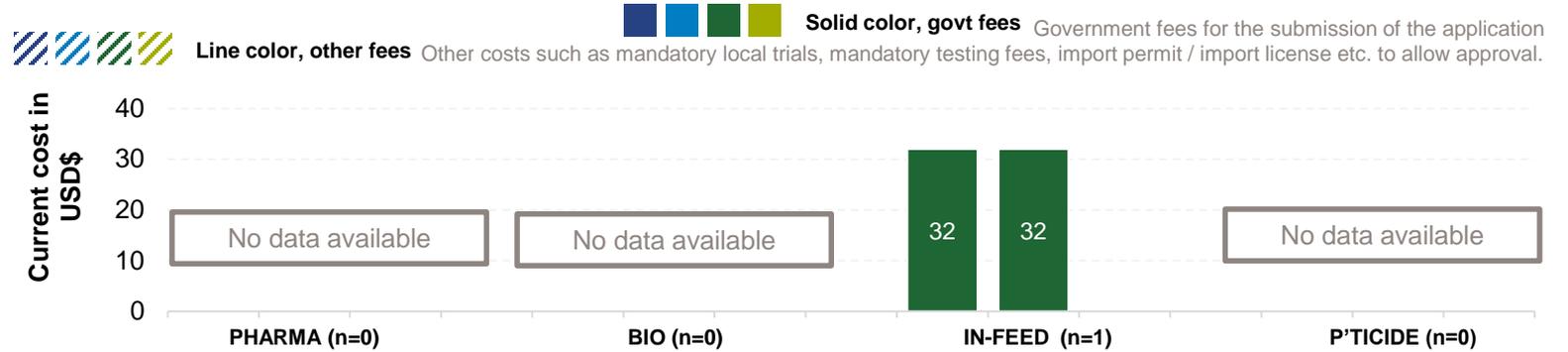
Data showed the average cost (in USD)



B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

# In-feed medication for aqua & others has no change in the government fees

Data showed the average cost (in USD)



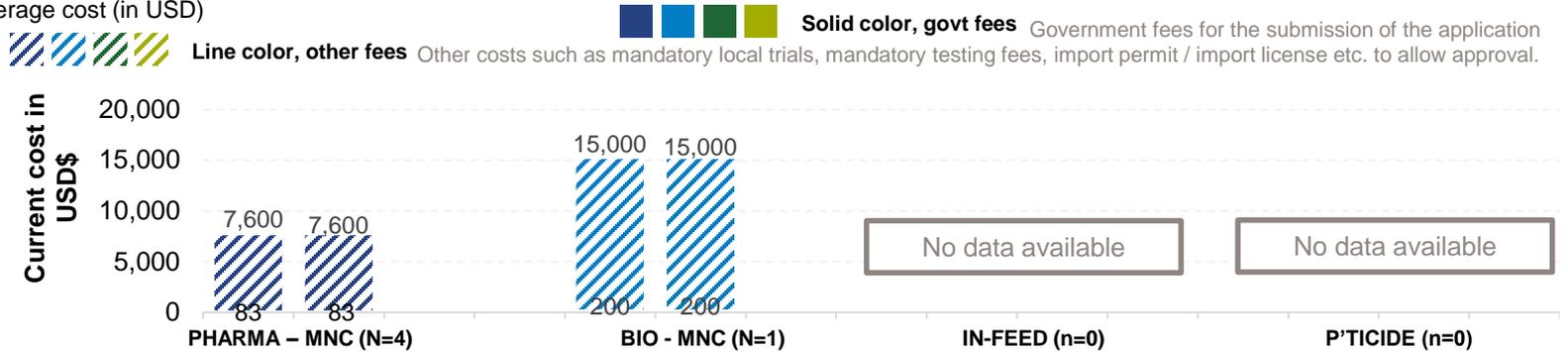
Fee changes vs. 2014 (avg. score given out of 5-point)	PHARMA (n=0)	BIO (n=0)	IN-FEED (n=1)	P'TICIDE (n=0)
	--	--	<b>No Change</b>	--

B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

# For companion animals, the registration fee for biological products increased more than 10%, which is much more than pharmaceutical products

Data showed the average cost (in USD)

Companion animals



Fee changes vs. 2014 (avg. score given out of 5-point)	Increased slightly, <10% increase	Increased a lot, >10% increase	--	--

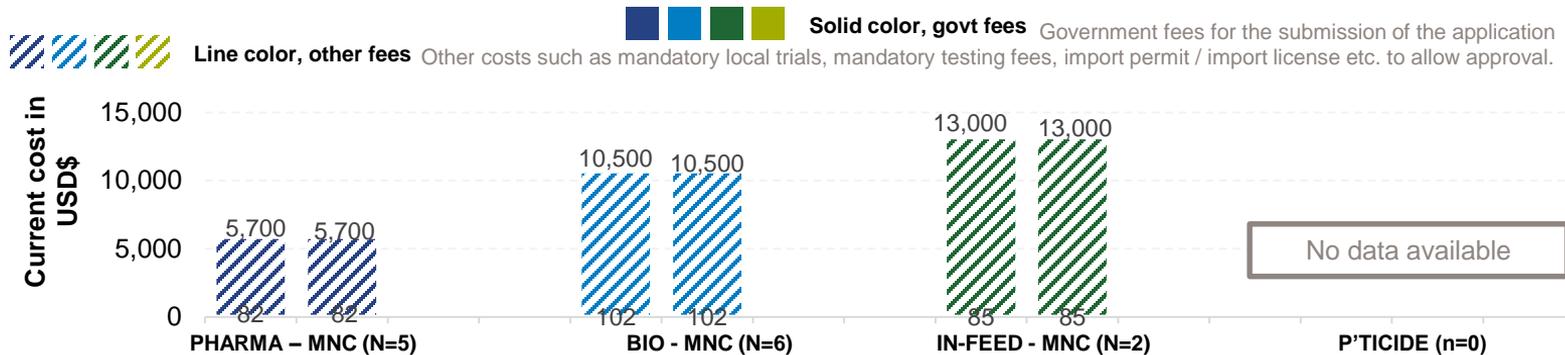
- Increased material cost for local trial
- New regulations
- Live animal for local trial
- Increased local trial fee
- Increased quality testing fee

B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

# For production animals, the registration fee for biologicals and in-feed medications increased more than 10%, much more than pharmaceuticals



Data showed the average cost (in USD)



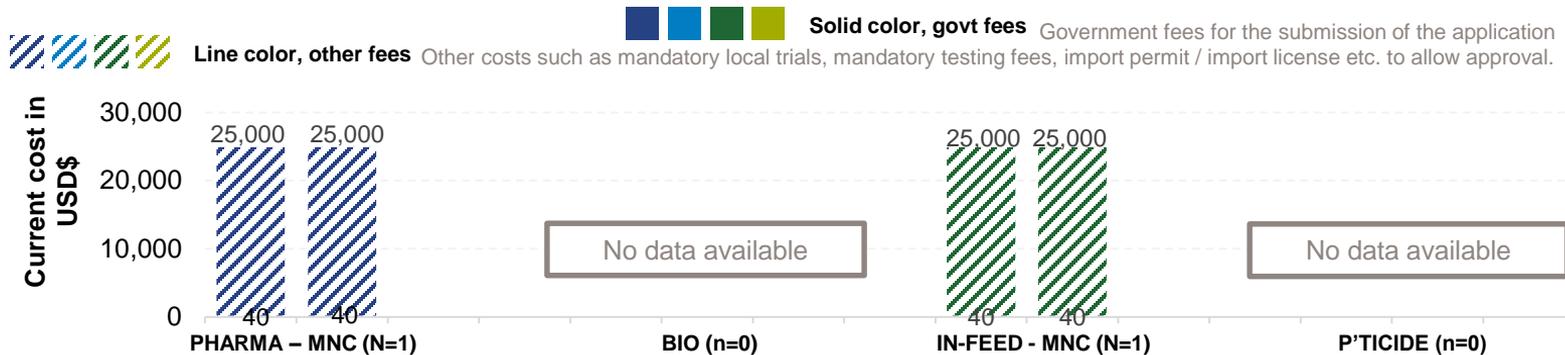
Fee changes vs. 2014 (avg. score given out of 5-point)	Increased slightly, <10% increase	Increased a lot, >10% increase	Increased a lot, >10% increase	--
	<ul style="list-style-type: none"> <li>○ Increased material cost for local trial</li> <li>○ Increased quality testing fee</li> </ul>	<ul style="list-style-type: none"> <li>○ Increased material/live animal/labor/utility cost for local trial</li> <li>○ Increased trial fee/requirement</li> <li>○ Limited CROs</li> </ul>	<ul style="list-style-type: none"> <li>○ Increased material/live animal cost for local trial</li> <li>○ Increased trial requirement</li> </ul>	

B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

# For aqua & others, the registration fee for in-feed medication products increased more than 10%, much more than pharmaceuticals



Data showed the average cost (in USD)



Fee changes vs. 2014 (avg. score given out of 5-point)	Increased slightly, <10% increase	--	Increased a lot, >10% increase	--
---	--------------------------------------	----	-----------------------------------	----

○ Increased material cost for local trial

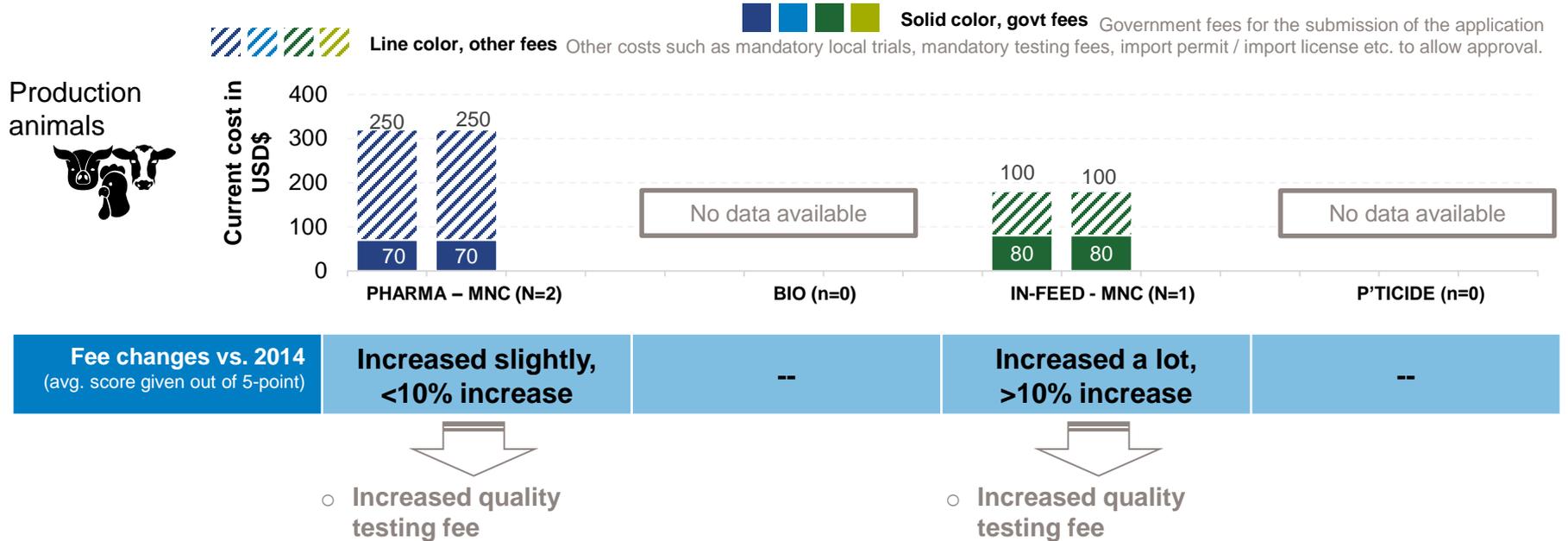
○ Increased material cost for local trial

B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

# The fees of in-feed medication products in production animals increased more than 10% whereas pharmaceuticals increased less than 10% in fees



Data showed the average cost (in USD)

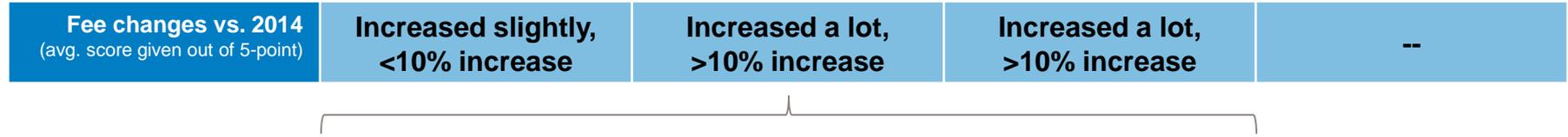
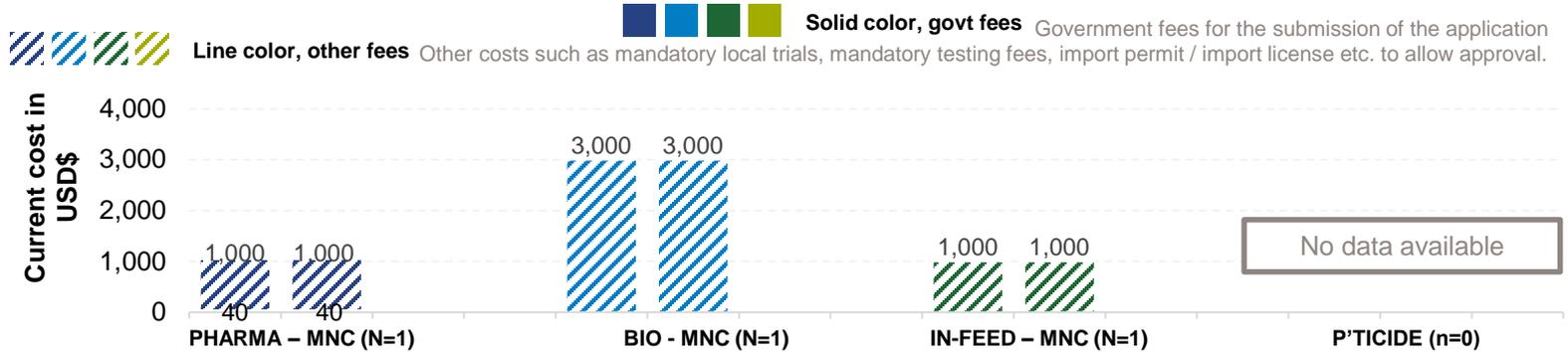


B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

# Most of the AH products have increase for other fees such as quality testing fees

Data showed the average cost (in USD)

Companion animals



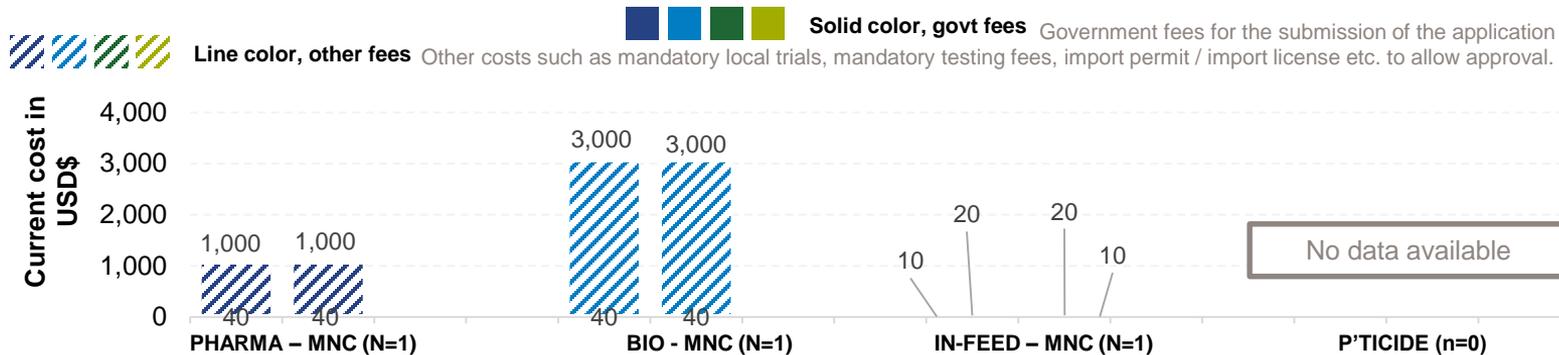
Increased quality testing fee

B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?



# Only in-feed medications do not have an increase for other fees such as quality testing fee

Data showed the average cost (in USD)



Fee changes vs. 2014 (avg. score given out of 5-point)	Increased slightly, <10% increase	Increased slightly, <10% increase	No Change	--
	Increased quality testing fee			

B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

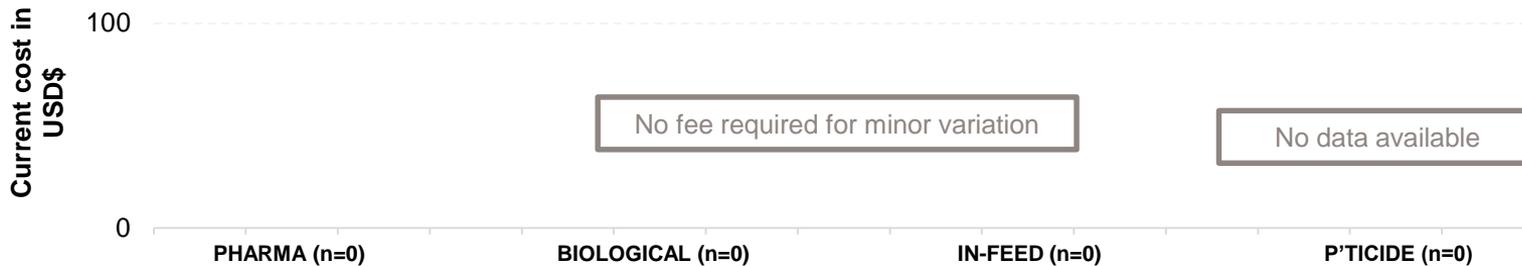


# There is no stated fixed fees required for minor variation across all therapeutic classes and species

Data showed the average cost (in USD)

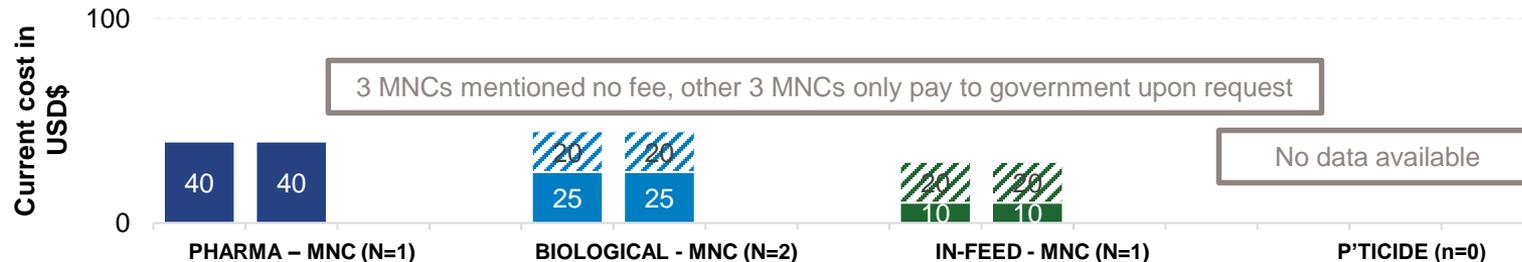


Companion animals



Fee changes vs. 2014 (avg. score given out of 5-point)	PHARMA (n=0)	BIOLOGICAL (n=0)	IN-FEED (n=0)	P'TICIDE (n=0)
	No change	No change	--	--

Production animals



Fee changes vs. 2014 (avg. score given out of 5-point)	PHARMA - MNC (N=1)	BIOLOGICAL - MNC (N=2)	IN-FEED - MNC (N=1)	P'TICIDE (n=0)
	No change	No change	No change	No change

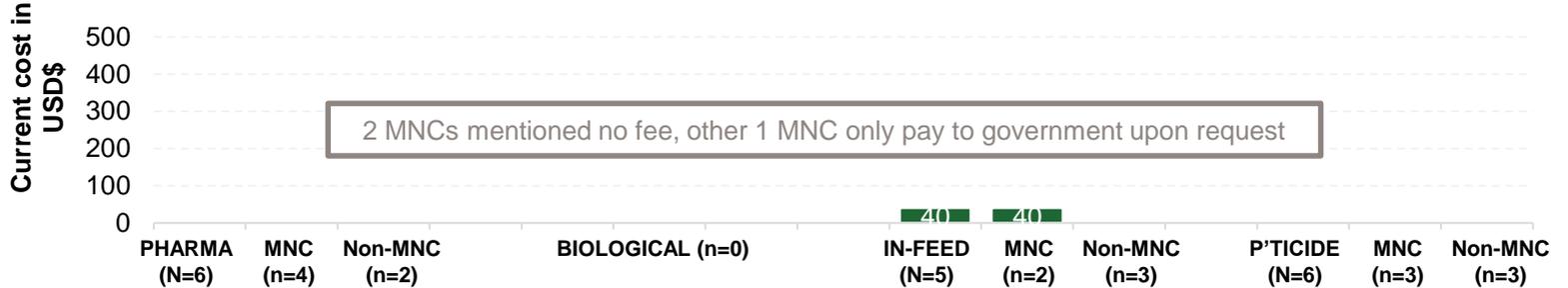
B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your (cost of registration of.....in your country)/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

# There is no stated fixed fees required for minor variation across all therapeutic classes in aqua & others

Data showed the average cost (in USD)


**Solid color, govt fees** Government fees for the submission of the application  
**Line color, other fees** Other costs such as mandatory local trials, mandatory testing fees, import permit / import license etc. to allow approval.

Aqua & others 



Fee changes vs. 2014 (avg. score given out of 5-point)	PHARMA (N=6)	MNC (n=4)	Non-MNC (n=2)	BIOLOGICAL (n=0)	IN-FEED (N=5)	MNC (n=2)	Non-MNC (n=3)	P'TICIDE (N=6)	MNC (n=3)	Non-MNC (n=3)
	No change			No change		No change			--	

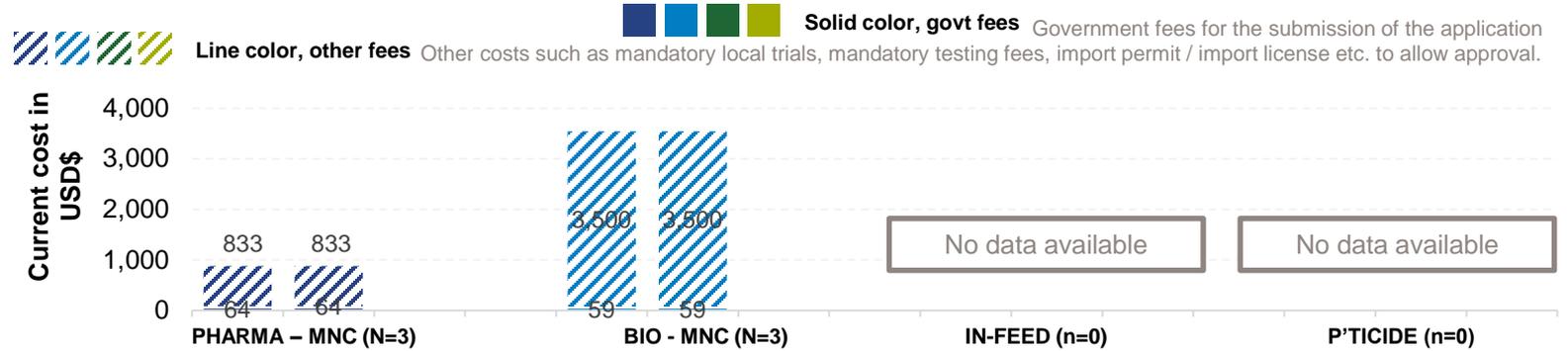
B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

# For companion animals, biological products experienced a higher increase **kynetec** in fees since 2014 compared to pharmaceutical products



Data showed the average cost (in USD)

Companion animals

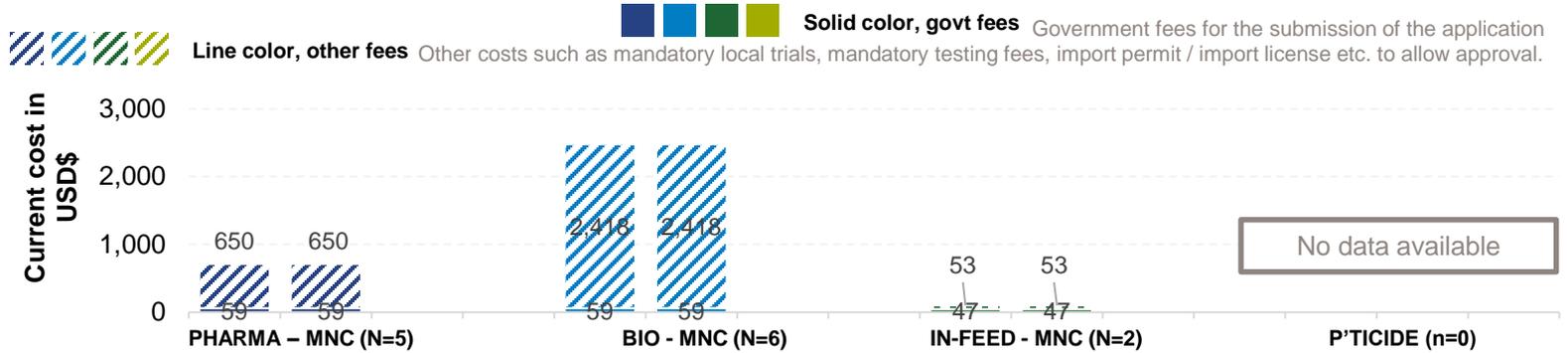


B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

# For production animals, all the therapeutic classes except for pesticides experienced a slight increased in fees since 2014



Data showed the average cost (in USD)

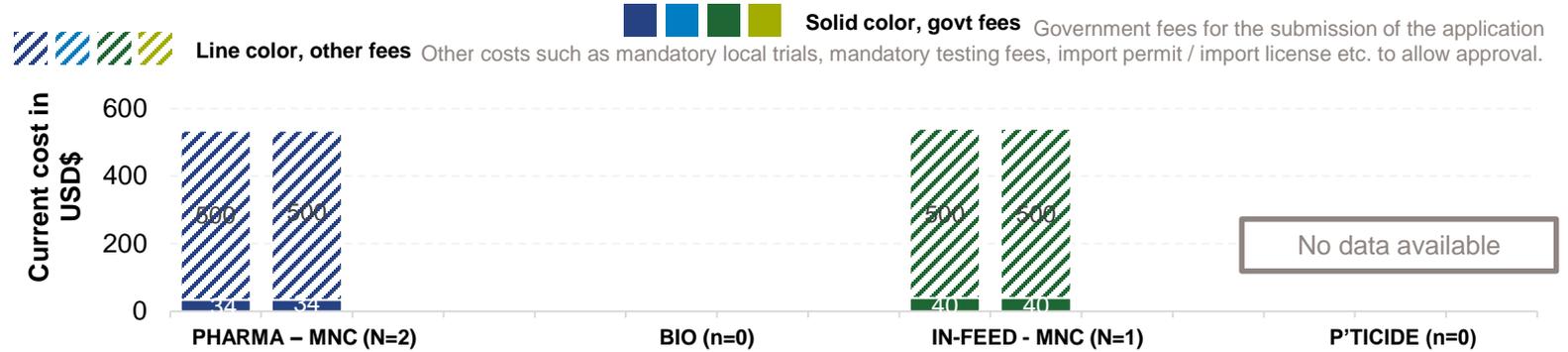


Fee changes vs. 2014 (avg. score given out of 5-point)	Increased slightly, <10% increase	Increased slightly, <10% increase	Increased slightly, <10% increase	--
	<ul style="list-style-type: none"> <li>○ Increased quality testing fee</li> </ul>	<ul style="list-style-type: none"> <li>○ Increased quality testing fee</li> <li>○ Increased local trial fee</li> </ul>	<ul style="list-style-type: none"> <li>○ Increased quality testing fee</li> </ul>	

B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

# For aqua & others, the fees of both pharmaceuticals and in-feed medication products remain stagnant since 2014

Data showed the average cost (in USD)



Fee changes vs. 2014 (avg. score given out of 5-point)	PHARMA - MNC (N=2)	BIO (n=0)	IN-FEED - MNC (N=1)	P'TICIDE (n=0)
	No change	--	No change	--

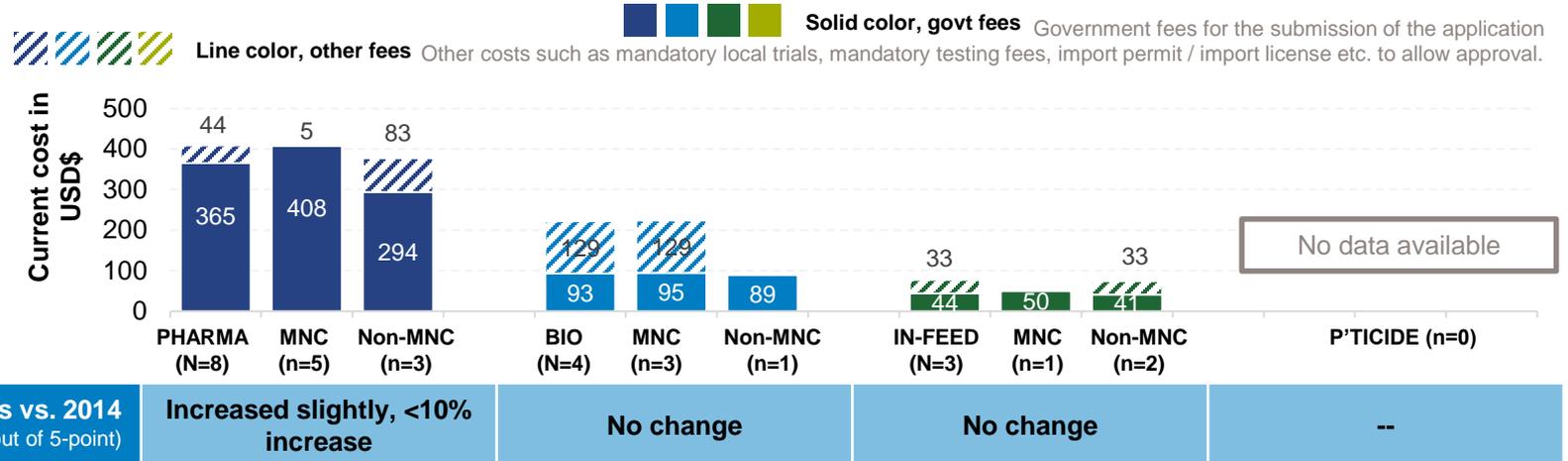
B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

# In Philippines, there is only a slight increase in the registration fees of pharmaceutical products for companion animals



Data showed the average cost (in USD)

Companion animals

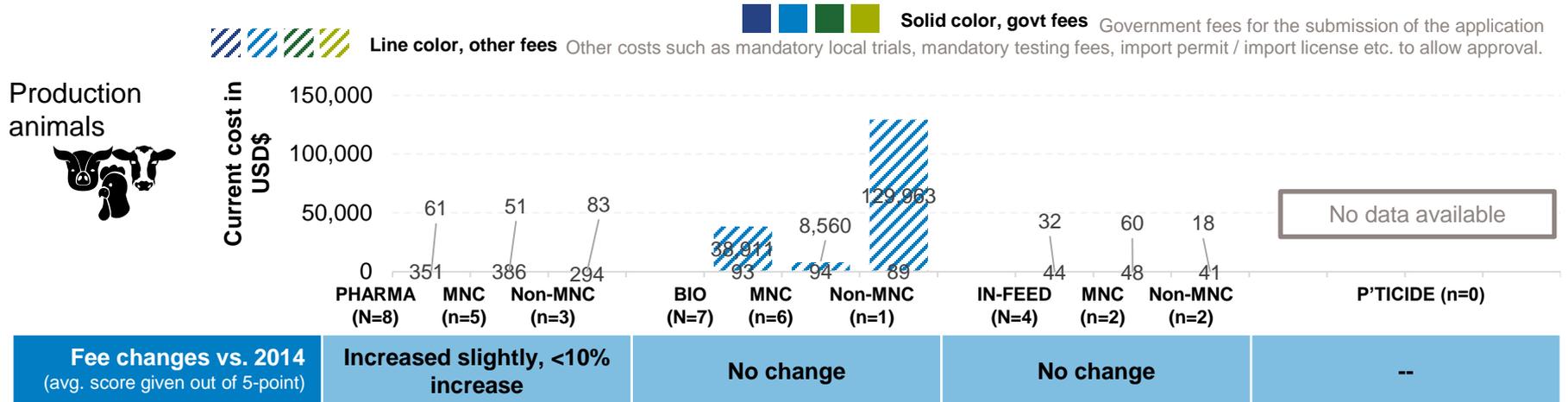


- Monitor Release Registration Validity is extended

B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

# In Philippines, there is only a slight increase in the registration fees of pharmaceutical products for production animals

Data showed the average cost (in USD)

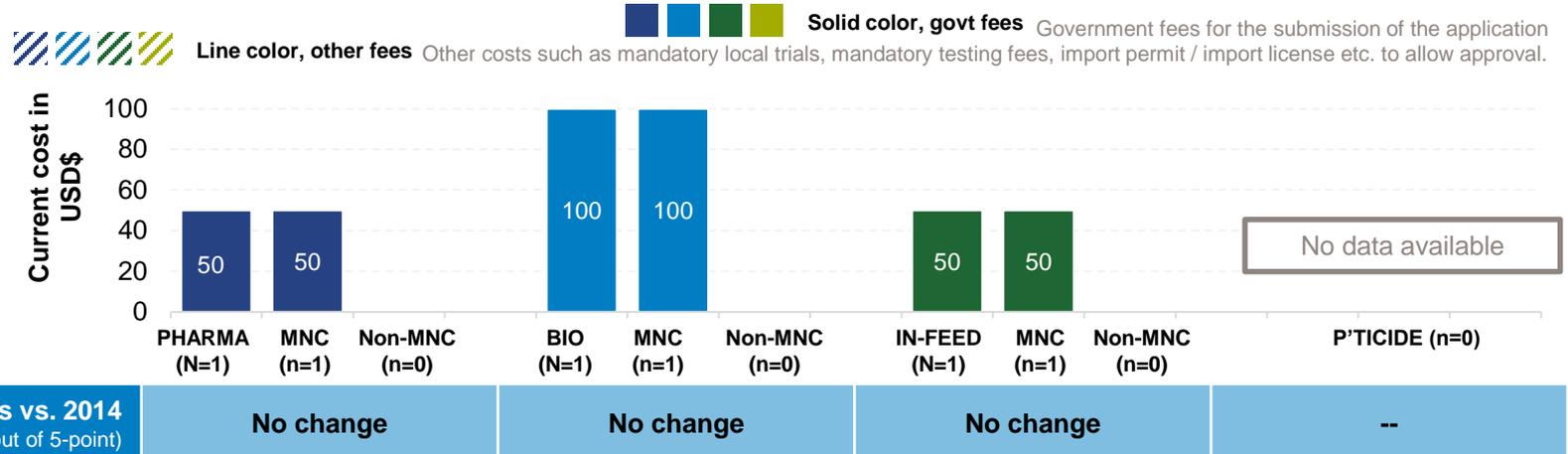


- Monitor Release Registration Validity is extended

B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

# In Philippines, almost all the therapeutic classes remain no change in fees for aqua & others

Data showed the average cost (in USD)



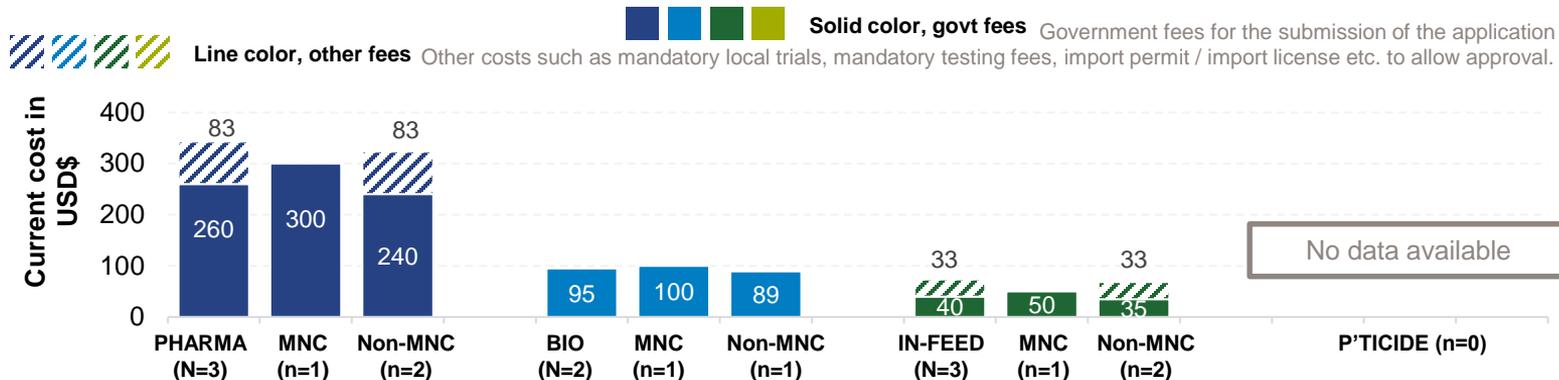
B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

# For generic AH product registration in companion animals, only the fees of **kynetec** pharmaceuticals increased slightly - less than 10% since 2014



Data showed the average cost (in USD)

Companion animals



Fee changes vs. 2014 (avg. score given out of 5-point)	PHARMA (N=3)	MNC (n=1)	Non-MNC (n=2)	BIO (N=2)	MNC (n=1)	Non-MNC (n=1)	IN-FEED (N=3)	MNC (n=1)	Non-MNC (n=2)	P'TICIDE (n=0)
	Increased slightly, <10% increase	Increased slightly, <10% increase	Increased slightly, <10% increase	No change	No change	No change	No change	No change	No change	--



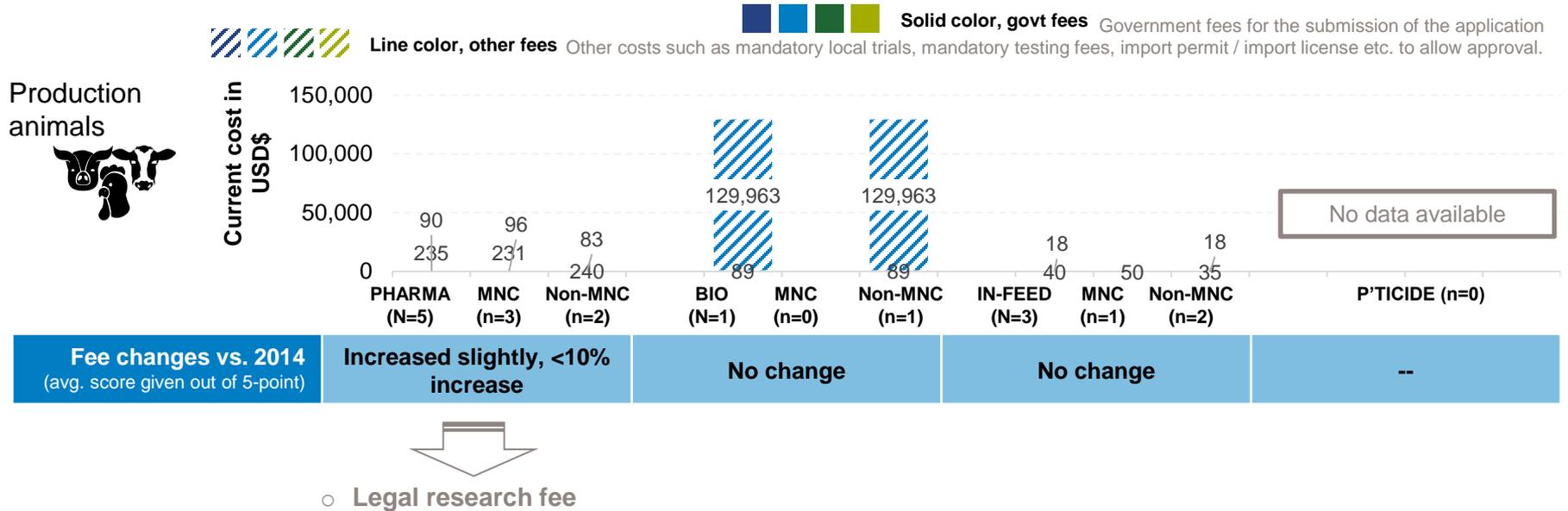
○ Legal research fee

B2a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B2b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B2c. What factors have caused the change?

# For generic AH product registration in production animals, the fees of biologicals and in-feed medications remain the same since 2014



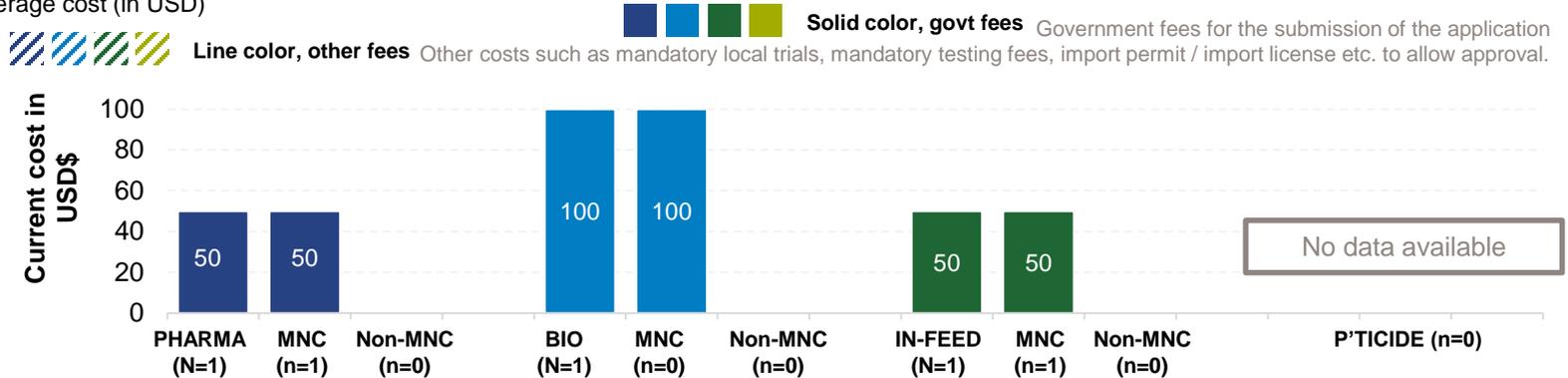
Data showed the average cost (in USD)



B2a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B2b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B2c. What factors have caused the change?

# For generic AH product registration in production animals, the fees of all the therapeutic classes except for pesticide remain stagnant compared to 2014

Data showed the average cost (in USD)



Fee changes vs. 2014 (avg. score given out of 5-point)	PHARMA			BIO			IN-FEED			P'TICIDE (n=0)
	No change			No change			No change			--

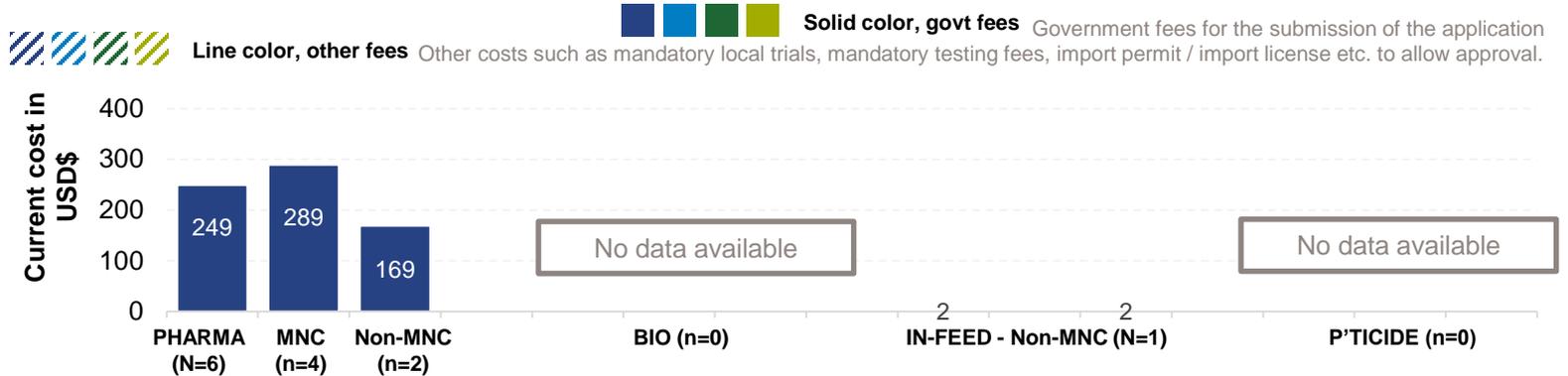
B2a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B2b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B2c. What factors have caused the change?



# There is less than 10% increase in the fees for major variation in companion animal's pharmaceuticals

Data showed the average cost (in USD)

Companion animals



Fee changes vs. 2014 (avg. score given out of 5-point)	PHARMA (N=6)	MNC (n=4)	Non-MNC (n=2)	BIO (n=0)	IN-FEED - Non-MNC (N=1)	P'TICIDE (n=0)
	Increased slightly, <10% increase	Increased slightly, <10% increase	Increased slightly, <10% increase	--	No change	--



- ASEAN variation guideline
- Legal research fee

B3a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B3b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B3c. What factors have caused the change?

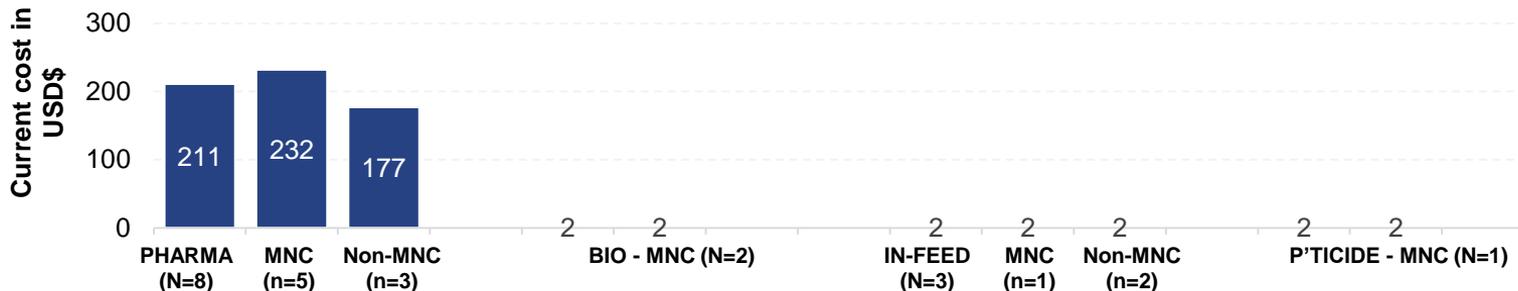


# There is no change in the fees for major variation in both production animals and aqua & others AH products

Data showed the average cost (in USD)

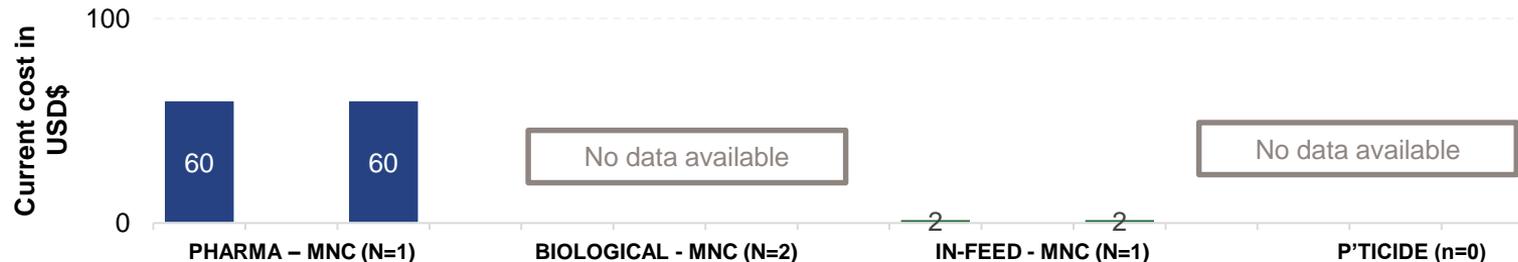
 **Solid color, govt fees** Government fees for the submission of the application  
 **Line color, other fees** Other costs such as mandatory local trials, mandatory testing fees, import permit / import license etc. to allow approval.

Production animals



Fee changes vs. 2014 (avg. score given out of 5-point)	No change		No change		No change		No change	
---	-----------	--	-----------	--	-----------	--	-----------	--

Aqua & others



Fee changes vs. 2014 (avg. score given out of 5-point)	No change	--	No change	--
---	-----------	----	-----------	----

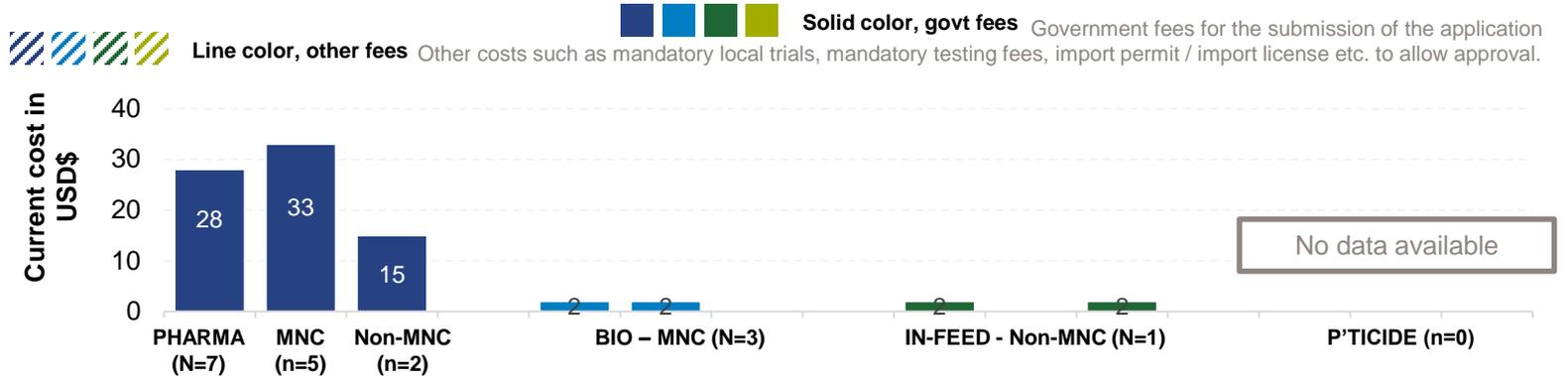
B3a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B3b: Which of the following statement best indicates how your (cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B3c. What factors have caused the change?

# The cost for this category of product for different species has not changed **kynetec** compared to 2014 except for companion animal's pharmaceuticals



Data showed the average cost (in USD)

Companion animals



Fee changes vs. 2014 (avg. score given out of 5-point)	Increased slightly, <10% increase	No change	No change	--



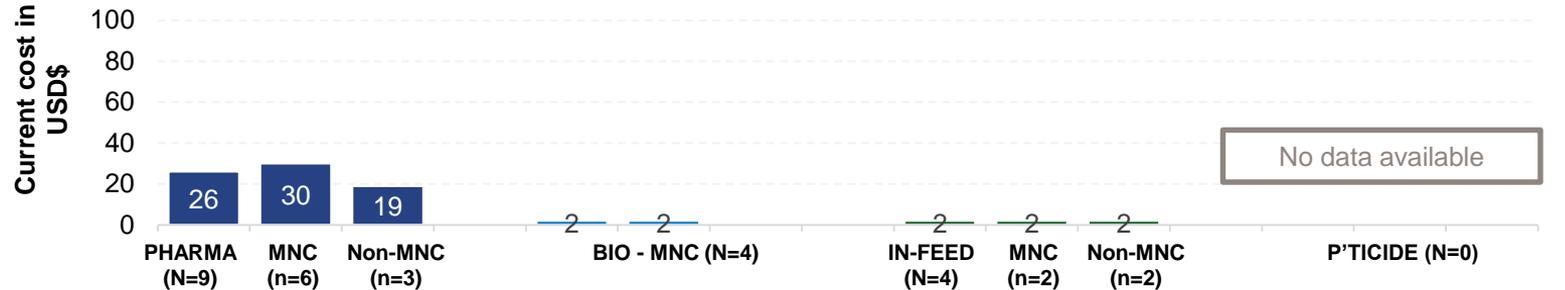
- ASEAN variation guideline
- Legal research fee

B4a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B4b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B4c. What factors have caused the change?

# The cost for this category of product for different species has not changed compared to 2014



Data showed the average cost (in USD)



Fee changes vs. 2014 (avg. score given out of 5-point)	PHARMA (N=9)	MNC (n=6)	Non-MNC (n=3)	BIO - MNC (N=4)	IN-FEED (N=4)	MNC (n=2)	Non-MNC (n=2)	P'TICIDE (N=0)
	No change	No change	No change	No change	No change	No change	No change	--



Fee changes vs. 2014 (avg. score given out of 5-point)	PHARMA - Non-MNC (N=1)	BIOLOGICAL (N=0)	IN-FEED - (N=0)	P'TICIDE (N=0)
	No change	--	--	--

B4a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B4b: Which of the following statement best indicates how your (cost of registration of.....in your country)/ASEAN in the categories given below has changed since 2014? B4c. What factors have caused the change?

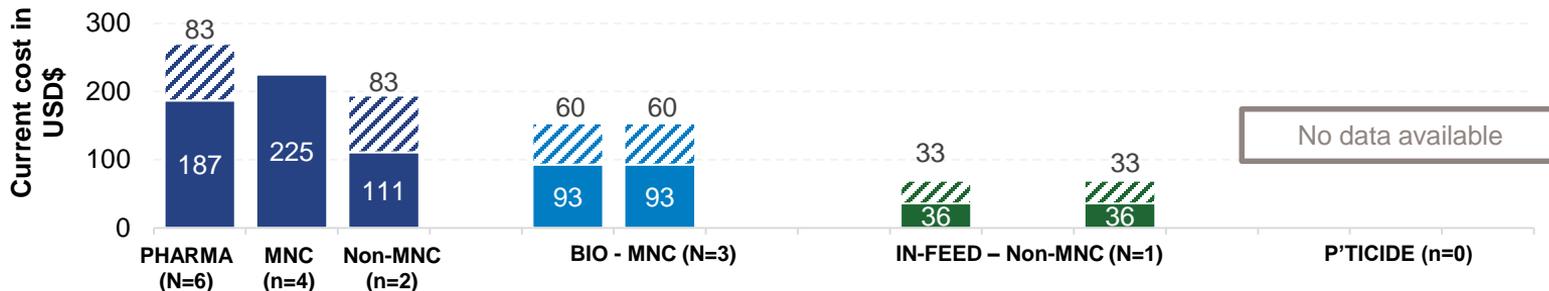
# The renewal cost for all the therapeutic classes across different species have not changed since 2014



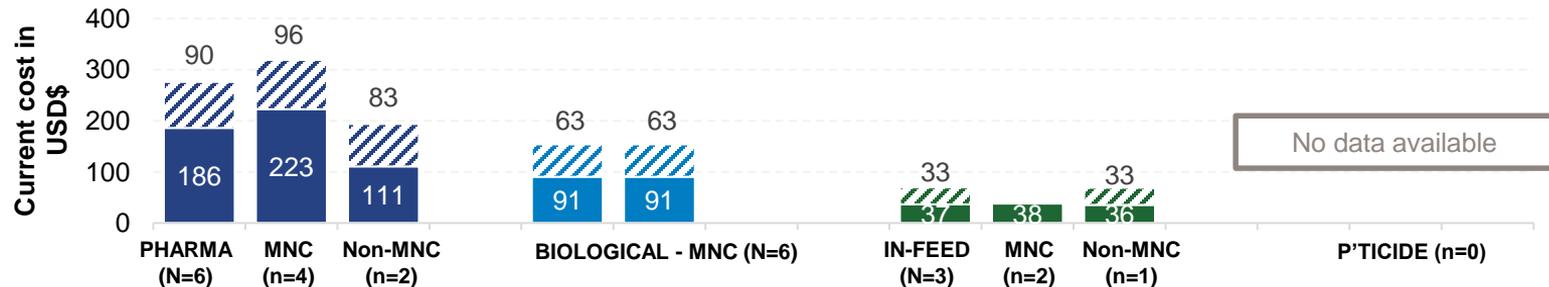
Data showed the average cost (in USD)



Companion animals



Production animals



B5a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B5b: Which of the following statement best indicates how your (cost of registration of.....in your country)/ASEAN in the categories given below has changed since 2014? B5c. What factors have caused the change?

# The renewal cost for all the therapeutic classes across different species have not changed since 2014



Data showed the average cost (in USD)

 **Solid color, govt fees** Government fees for the submission of the application  
 **Line color, other fees** Other costs such as mandatory local trials, mandatory testing fees, import permit / import license etc. to allow approval.

Aqua & others 



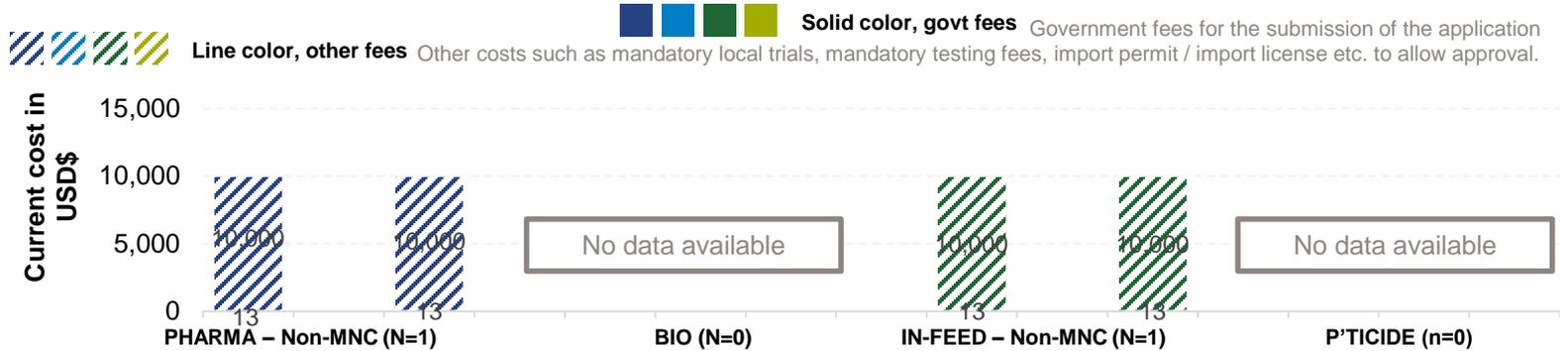
Fee changes vs. 2014 (avg. score given out of 5-point)	PHARMA (N=0)	BIOLOGICAL (n=0)	IN-FEED (N=1)	MNC (n=1)	Non-MNC (n=0)	P'TICIDE (n=0)
	No change	--	No change	No change	No change	--

B5a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B5b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B5c. What factors have caused the change?

# The registration fees for both pharmaceuticals and in-feed medications decreased slightly due to close rapport with officials



Data showed the average cost (in USD)



Fee changes vs. 2014 (avg. score given out of 5-point)	Decreased slightly, <10% decrease	--	Decreased slightly, <10% decrease	--
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Relationship with officials

Relationship with officials

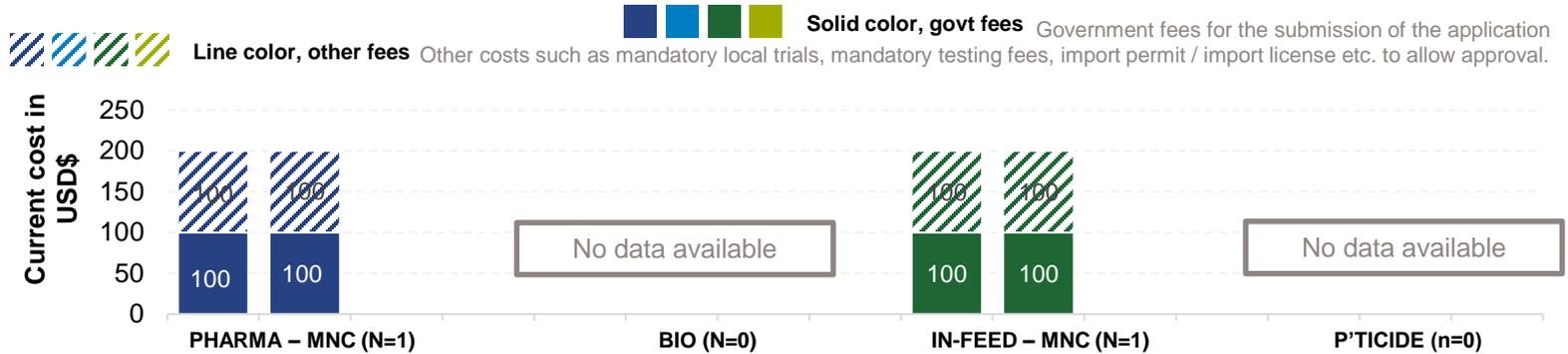
B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

# There is no change of cost for generic registration in pharmaceuticals and **kynetec** in-feed medication products compared to 2014



Data showed the average cost (in USD)

Companion animals



Fee changes vs. 2014 (avg. score given out of 5-point)	PHARMA – MNC (N=1)	BIO (N=0)	IN-FEED – MNC (N=1)	P'TICIDE (n=0)
	No change	--	No change	--

B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

# The cost to register generic products for all the therapeutic classes in production animals decreased slightly compared to 2014

Data showed the average cost (in USD)



B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

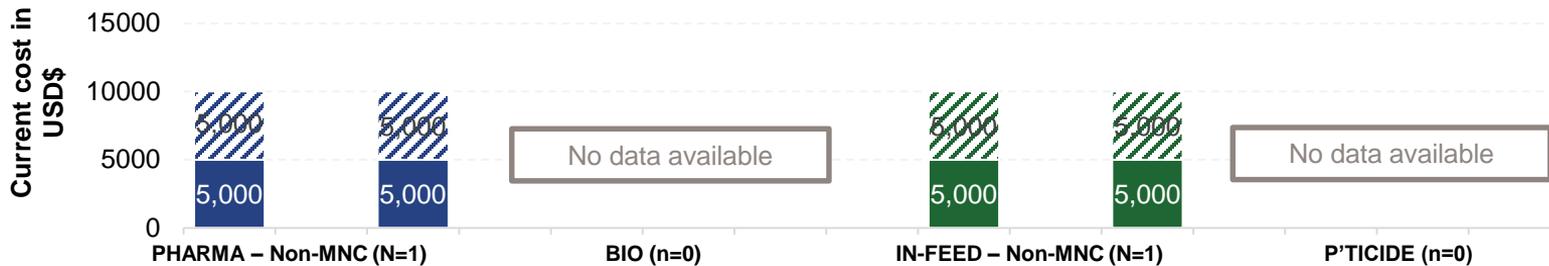
# The cost for major variation remains the same for all therapeutic classes across different species compared to 2014



Data showed the average cost (in USD)

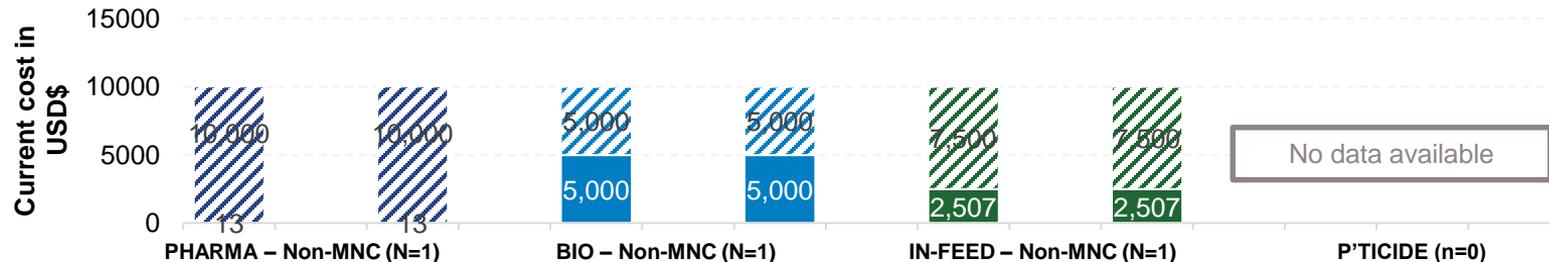


Companion animals



Fee changes vs. 2014 (avg. score given out of 5-point)	PHARMA – Non-MNC (N=1)	BIO (n=0)	IN-FEED – Non-MNC (N=1)	P'TICIDE (n=0)
No change	No change	--	No change	--

Production animals



Fee changes vs. 2014 (avg. score given out of 5-point)	PHARMA – Non-MNC (N=1)	BIO – Non-MNC (N=1)	IN-FEED – Non-MNC (N=1)	P'TICIDE (n=0)
No change	No change	No change	No change	--

B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your (cost of registration of.....in your country)/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

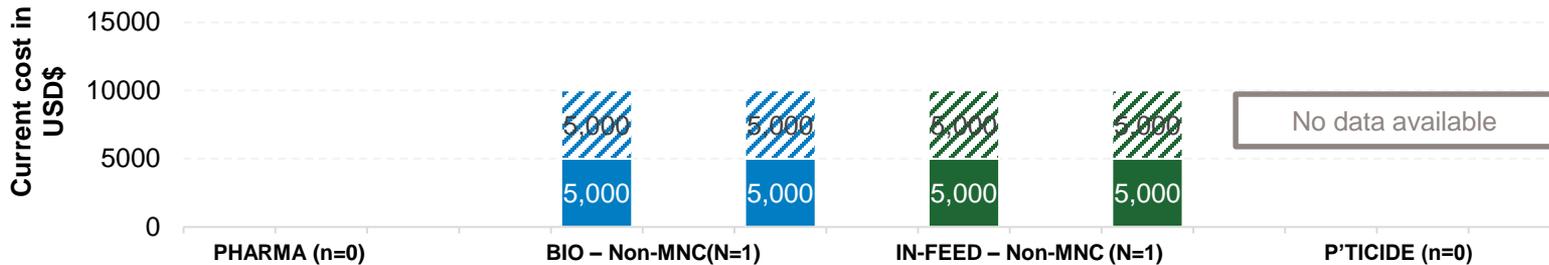
# The cost for major variation remains the same for all therapeutic classes across different species compared to 2014



Data showed the average cost (in USD)



Aqua & others



Fee changes vs. 2014 (avg. score given out of 5-point)	PHARMA (n=0)	BIO - Non-MNC (N=1)	IN-FEED - Non-MNC (N=1)	P'TICIDE (n=0)
	--	No change	No change	--

B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

(cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?)

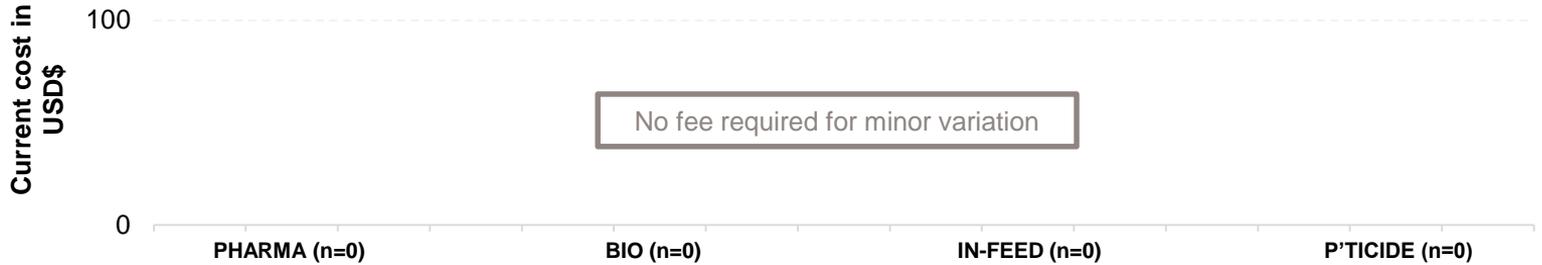


# There is no fees required for minor variation of all the products across different species

Data showed the average cost (in USD)

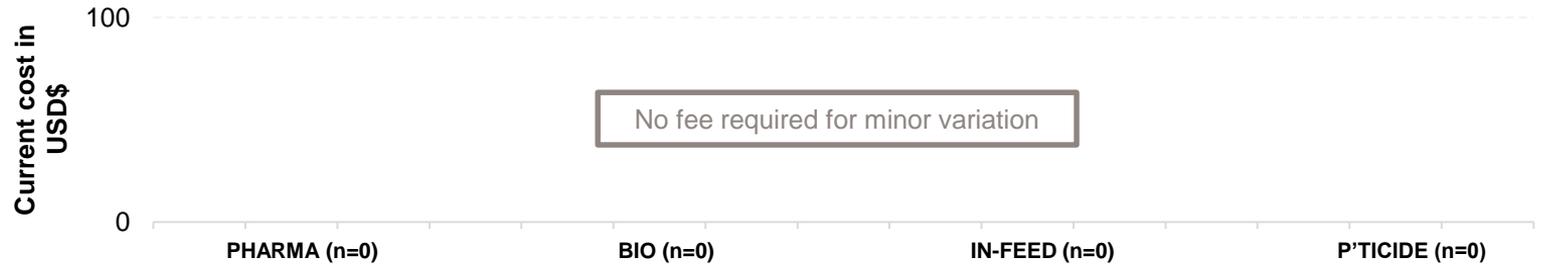


Companion animals



<b>Fee changes vs. 2014</b> (avg. score given out of 5-point)	<b>No change</b>	<b>No change</b>	<b>No change</b>	<b>No change</b>
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Production animals



<b>Fee changes vs. 2014</b> (avg. score given out of 5-point)	<b>No change</b>	<b>No change</b>	<b>No change</b>	<b>No change</b>
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B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your (cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

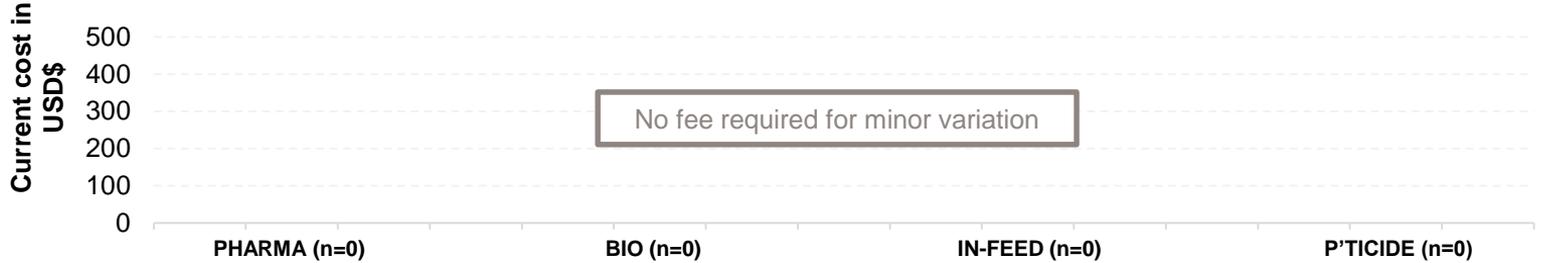


# There is no fees required for minor variation of all the products across different species

Data showed the average cost (in USD)

 **Solid color, govt fees** Government fees for the submission of the application  
 **Line color, other fees** Other costs such as mandatory local trials, mandatory testing fees, import permit / import license etc. to allow approval.

Aqua & others

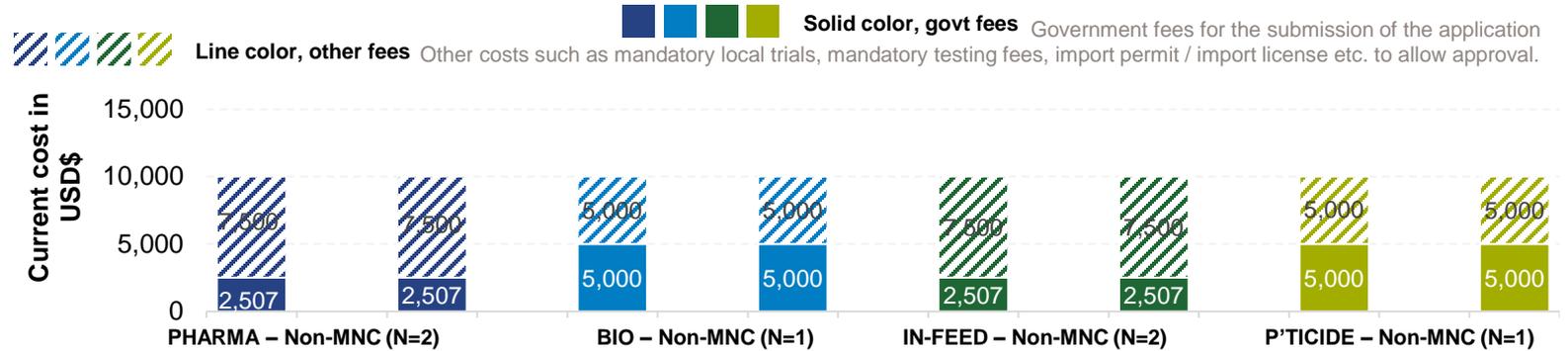
Fee changes vs. 2014 (avg. score given out of 5-point)	PHARMA (n=0)	BIO (n=0)	IN-FEED (n=0)	P'TICIDE (n=0)
	No change	No change	No change	No change

B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

# The renewal fees for production animals remain no change for all the AH products



Data showed the average cost (in USD)



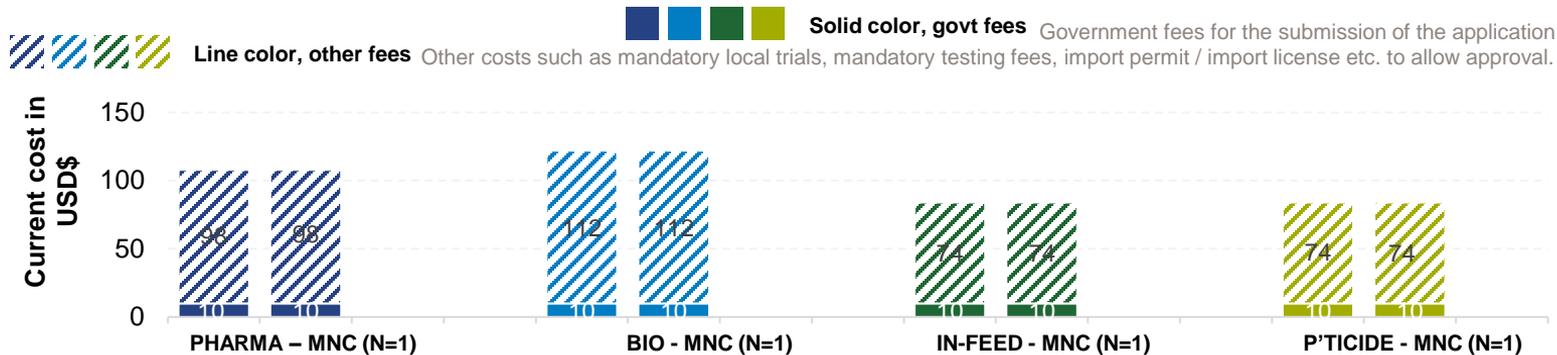
Fee changes vs. 2014 (avg. score given out of 5-point)	PHARMA – Non-MNC (N=2)	BIO – Non-MNC (N=1)	IN-FEED – Non-MNC (N=2)	P'TICIDE – Non-MNC (N=1)
<b>No change</b>	<b>No change</b>	<b>No change</b>	<b>No change</b>	<b>No change</b>

B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

# All the registration fees of AH products for production animals increased less than 10% compared to 2014



Data showed the average cost (in USD)



Fee changes vs. 2014 (avg. score given out of 5-point)	Increased slightly, <10% increase	Increased slightly, <10% increase	Increased slightly, <10% increase	Increased slightly, <10% increase
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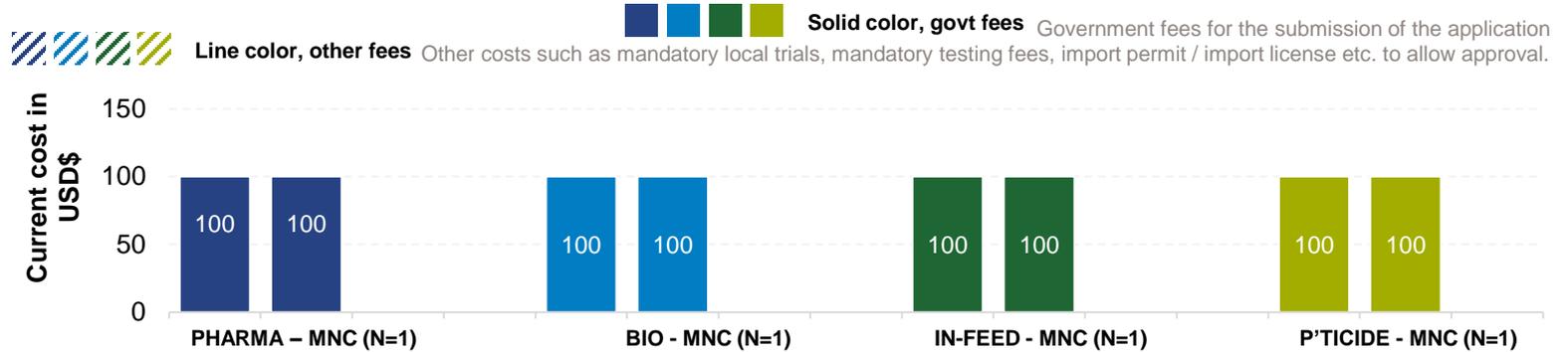
New regulations

B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

# All the AH products for production animals remain no change for new AH product registration compared to 2014



Data showed the average cost (in USD)



Fee changes vs. 2014 (avg. score given out of 5-point)	No Change	No Change	No Change	No Change
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We have excluded major and minor variation as we understood all variations will be treated as a new registration

B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

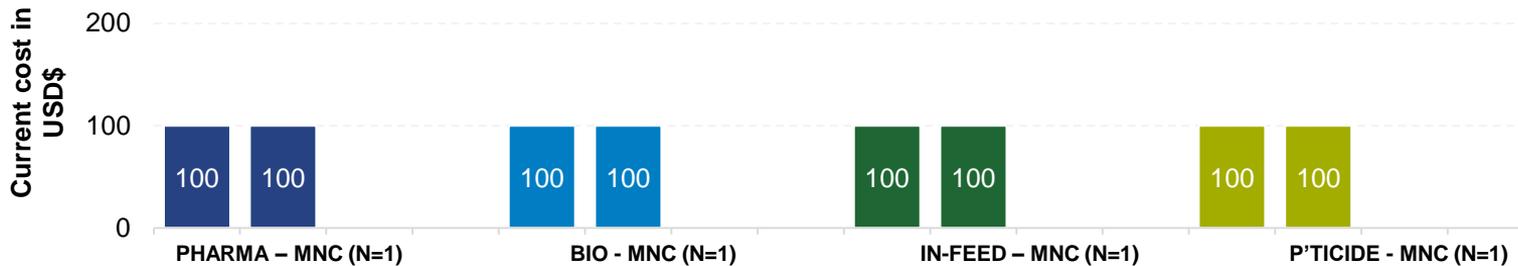
# The fees for generic AH product registration stays the same since 2014 across different species



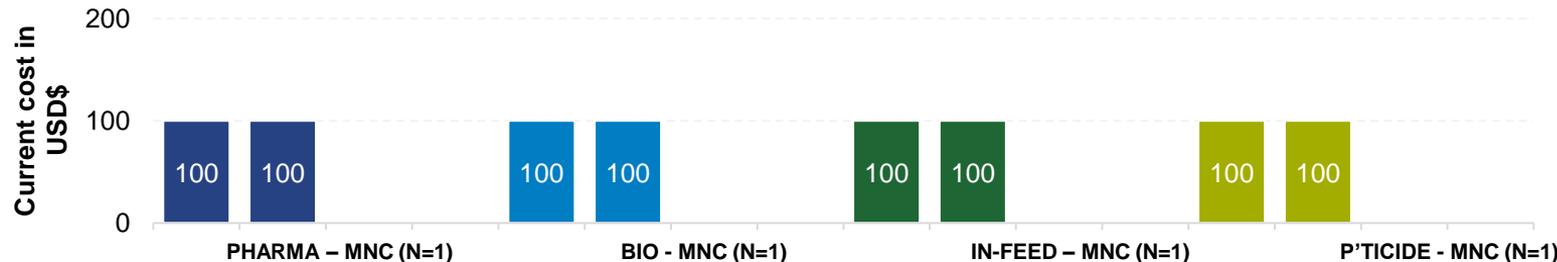
Data showed the average cost (in USD)



Companion animals



Production animals

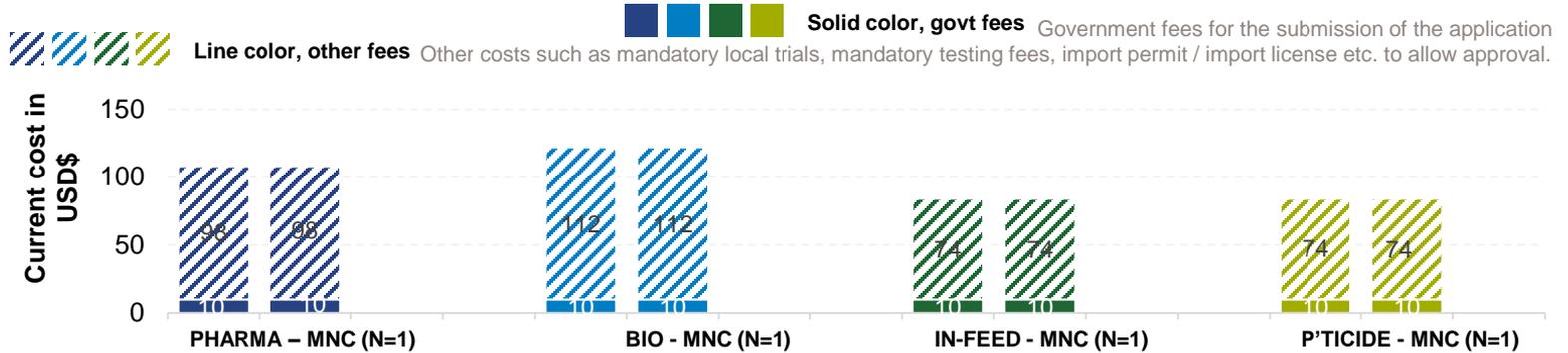


B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below from your company's own experience. B1b: Which of the following statement best indicates how your (cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?

# There is only slight increased in fees to register AH products for production **kynetec** animal compared to the fee in 2014



Data showed the average cost (in USD)



Fee changes vs. 2014 (avg. score given out of 5-point)	Increased slightly, <10% increase	Increased slightly, <10% increase	Increased slightly, <10% increase	Increased slightly, <10% increase
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New regulations

B1a. Please provide the typical cost for registration of.....in your country / ASEAN in the categories given below form your company's own experience. B1b: Which of the following statement best indicates how your cost of registration of.....in your country/ASEAN in the categories given below has changed since 2014? B1c. What factors have caused the change?