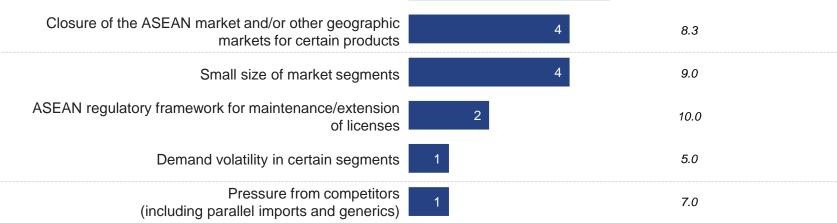
Maintenance of registration of existing products – challenges faced

E1. Below is a list of FACTORS RELEVANT TO THE MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS in the animal health industry in your country/ASEAN. Which of these, if any, are significant in preventing efficient commercialization of your existing products? © Kynetec June 11, 2019 | ASEAN Animal Health Regulatory Benchmarking Survey – Stage 3 (Online Quantitative)

for some products are also pain-points experiencedImportanceBase, N=6, Data shown no. of mentionsNo. of mentions(10=most important, 1=least important)Excessive and unharmonized inspections and inspection
requirements within ASEAN58.4The need for all packaging materials in local languages58.8



Inadequate intellectual property protection (commercial data & patents)

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



229

6.0

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



Cignificant

| Base, N=6, Data shown no. of mentions | Significant (10=most significant, 1=least significant) |
|---|---|
| | No. of mentions |
| Create significant uncertainty | y 5 9.4 |
| Divert management time | e 3 8.3 |
| Remove profitable products from the marke | et 2 5.5 |
| Fail to protect IP (patents & commercial data) adequately | У 2 7.0 |
| Increase the cost of production | n 1 8.0 |
| Increase the cost of distribution and marketing | |
| Limit the use of innovative marketing methods Create disproportionate costs for maintaining/ extending | |
| marketing authorizations Restrict the extension of existing technologies to additiona | s 10.0 |
| Divert financial resources away from the development of new | s 9.0 |
| innovative products | |

N-6 Data shown no of mentions

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

REGIONAL: Impact of different govt. regulations on ability to maintain registration of AH product successfully Packaging/labelling modification rules, manufacturing inspection and import regulation / inspection are said be least helpful in maintaining registration of AH products. In contrast, harmonization are said to be able to be helpful in maintaining registration of AH product successfully



| Base, N=6, Data shown no. of mentions | No. of | menti | ons | | | | Mean (5=very helpful, 1=very unhelpful) | Very helpful + helpful | Very unhelpful + unhelpful |
|---|--------|-------|-----|---|---|-----|---|---------------------------|-------------------------------|
| Licence maintenance (National Procedures) | | 2 | | | 3 | 1 | 3.2 | 2 | 1 |
| Maximum residue limits | | | 3 | | | 3 | 2.5 | | 3 |
| Manufacturing inspections | 1 | | | | 5 | | 2.3 | 1 | 5 |
| Product quality inspection | | | 4 | | | 2 | 2.7 | | 2 |
| Quality inspection of imported products | 1 | | 1 | | 3 | 1 | 2.3 | 1 | 4 |
| GMP (including manufacturing inspections) | | 2 | | 2 | | 2 | 3.0 | 2 | 2 |
| Variations regulation with respect to manufacturing changes | 1 | | 2 | | | 3 | 2.7 | 1 | 3 |
| Import regulations | | 2 | | | L | ł | 2.3 | | 4 |
| Environmental regulations | | | | 5 | | 1 | 2.8 | | 1 |
| Harmonization measures | 1 | | 2 | | 2 | 2 1 | 3.5 | 3 | 1 |
| Packaging/Labelling modification rules | 1 | | | 4 | | 1 | 2.0 | | 5 |
| Disease resistance regulations | 1 | | | 3 | | 1 1 | 2.7 | 1 | 2 |
| Protection of IP – commercial data | | | 3 | | | 3 | 2.5 | | 3 |
| Protection of IP – patents | | | 3 | | | 3 | 2.5 | | 3 |
| Pharmacovigilance | | | | 5 | | 1 | 2.8 | | 1 |

Very helpful = Helpful = No impact = Unhelpful = Very unhelpful

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

MALAYSIA: Factors preventing maintenance of registration of existing AH products Small market size is a concern to both MNC and non-MNC companies. Interestingly, demand kynetes volatility in certain segments and excessive only concern for non-MNCs.

| Base, N=9 (combined both MNC & Non-MNC) Data shown no. of mentions | No. of mentions | Importance (10=most important, 1=least important) | Importance (10=most important, 1=least important) | |
|--|-----------------|---|---|--|
| Small size of market segments | 4 | 3 9.0 | 9.0 | |
| The need for all packaging materials in local languages | 3 2 | 9.0 | 5.5 | |
| Pressure from competitors (including parallel imports and generics) | 2 2 | 8.0 | 7.0 | |
| Lack of skilled staff | 2 2 | 8.5 | 6.5 | |
| Demand volatility in certain segments | 4 | | 9.5 | |
| Legal restrictions on advertising, labels, trademarks and communication | 2 | 7.0 | | |
| Excessive and unharmonized inspections and inspection requirements | 2 | | 8.5 | |
| Negative consumer attitudes | 1 1 | 8.0 | 7.0 | |
| Country regulatory framework for maintenance/extension of licenses | | | 8.0 | |
| Closure of the ASEAN market and/or other geographic markets for certain products | | 9.0 | | |
| Lack of availability of financial resources | 1 MNC | | 7.0 | |
| Strict variation regulations | 1 Non-MNC | 10.0 | | |

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

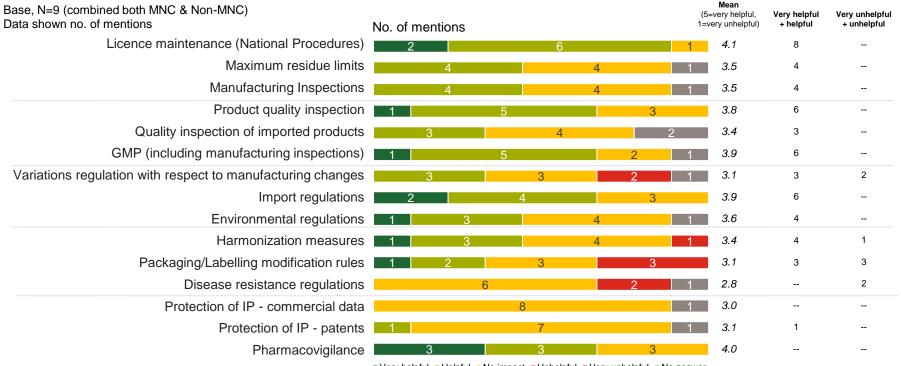
MALAYSIA: (Negative) effect on the AH business due to govt. regulations Significant uncertainly in the market is the 'output' due to govt. regulation. Additionally, 3 in 5 MNC regulatory managers also professed govt. regulation increase cost of distribution and marketing.

| Base, N=9 (combined both MNC & Non-MNC) Data shown no. of mentions | | MNC (n=5) Significant (10=most significant, | Non-MNC (n=4) Significant (10=most significant, |
|--|-----------------|---|---|
| | No. of mentions | 1=least significant) | 1=least significant) |
| Create significant uncertainty | 2 4 | 9.5 | 9.3 |
| Increase the cost of distribution and marketing | 3 2 | 9.0 | 8.5 |
| Remove profitable products from the market | 1 3 | 7.0 | 9.0 |
| Divert management time | 1 2 | 10.0 | 6.0 |
| Restrict the extension of existing technologies to additional species/indications | 1 2 | 8.0 | 5.5 |
| Create disproportionate costs for maintaining/ extending marketing authorizations | | | 6.5 |
| Limit the use of innovative marketing methods | 1 1 | 10.0 | 8.0 |
| Require customization for country specific label | 1 MNC | 10.0 | |
| Increase the cost of production | | | 9.0 |

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

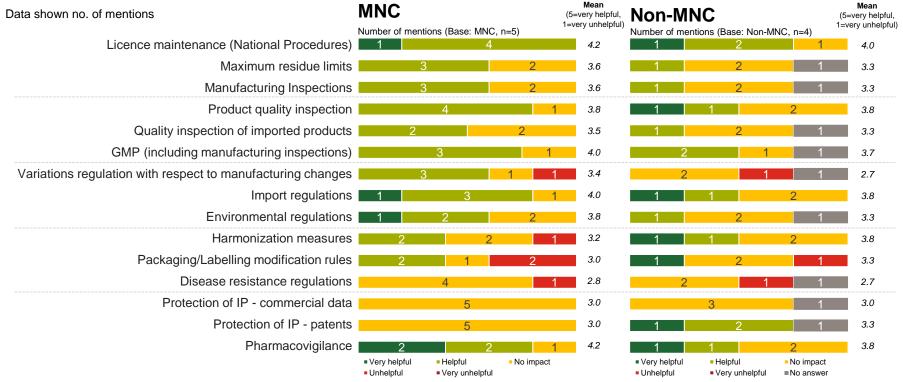


MALAYSIA: Impact of different govt. regulations on ability to maintain registration of AH product successfully Packaging/labelling modification rules, disease resistance regulations and variation kynetec regulation with respect to manufacturing changes said be least helpful in maintaining registration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



Very helpful = Helpful = No impact = Unhelpful = Very unhelpful = No answer

E3. Thinking about Government Regulations in your country/ASEAN, how would you assess the impact of each of the areas of regulation listed below on your ABILITY TO PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS successfully? © Kynetec June 11, 2019 | ASEAN Animal Health Regulatory Benchmarking Survey – Stage 2 (Online Quantitative) MALAYSIA: Impact of different govt. regulations on ability to maintain registration of AH product successfully Packaging/labelling modification rules, disease resistance regulations, variation regulation with respect to manufacturing changes said be least helpful in maintaining registration of AH products.



E3. Thinking about Government Regulations in your country/ASEAN, how would you assess the impact of each of the areas of regulation listed below on

your ABILITY TO PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS successfully?

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INDONESIA: Factors preventing maintenance of registration of existing AH products The main challenge faced seems to be related to current regulatory framework for maintenance / extension of licenses and to lesser extend, pressure from competitors (norallal importa 8 gaparias)

| (parallel imports & generics) | | | | | MNC | Non-MNC | |
|---|---|---|--------|---|---|---|--|
| Base, N=12 (combined both MNC & Non-MNC) Data shown no. of mentions | | | | | Importance (10=most important, 1=least important) | Importance (10=most important, 1=least important) | |
| Country regulatory framework for maintenance/extension of licenses | | | 5 | 2 | 9.6 | 9.5 | |
| Pressure from competitors (including parallel imports and generics) | 2 | | 3 | | 8.0 | 9.3 | |
| Small size of market segments | 2 | | 2 | | 8.0 | 8.0 | |
| Inadequate intellectual property protection (commercial data & patents) | 2 | | 1 | | 5.5 | 10.0 | |
| Demand volatility in certain segments | 2 | | 1 | | 8.0 | 7.0 | |
| Closure of the ASEAN market and/or other geographic markets for certain products | 2 | | 1 | | 9.5 | 9.0 | |
| The need for all packaging materials in local languages | 1 | 1 | | | 8.0 | 8.0 | |
| Excessive and unharmonized inspections and inspection requirements within ASEAN | 1 | 1 | | | 8.0 | 9.0 | |
| Negative consumer attitudes | 1 | 1 | | | 6.0 | 6.0 | |
| Legal restrictions on advertising, labels, trademarks and | 1 | | | | | 10.0 | |
| communication Lack of skilled staff | 1 | | MNC | | 7.0 | - | |
| Lack of availability of financial resources | 1 | | Non-MN | C | 8.0 | - | |
| Strong protectionism for local products | 1 | | | | | 10.0 | |

E1. Below is a list of FACTORS RELEVANT TO THE MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS in the animal health industry in your country/ASEAN. Which of these, if any, are significant in preventing efficient commercialization of your existing products? © Kynetec June 11, 2019 | ASEAN Animal Health Regulatory Benchmarking Survey – Stage 2 (Online Quantitative)

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INDONESIA: (Negative) effect on the AH business due to govt. regulations Managers felt that govt. regulation of remove profitable products from market has impacted their AH business. Other aspects include create significant uncertainty and divert financial resources away from development of new, innovative products.

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| Base, N=12 (combined both MNC & Non-MNC) Data shown no. of mentions | | MNC (n=6) Significant (10=most significant, | Non-MNC (n=6) Significant (10=most significant, |
|--|-----------------|---|---|
| | No. of mentions | 1=least significant) | 1=least significant) |
| Remove profitable products from the market | 5 2 | 9.2 | 10.0 |
| Create significant uncertainty | 3 1 | 10.0 | 10.0 |
| Divert financial resources away from the development of new, innovative products | 3 1 | 8.3 | 10.0 |
| Increase the cost of production | 1 2 | 6.0 | 8.5 |
| Limit the use of innovative marketing methods | 2 1 | 8.0 | 10.0 |
| Increase the cost of distribution and marketing | 1 1 | 8.0 | 9.0 |
| Create disproportionate costs for maintaining/ extending marketing authorizations | | 8.0 | 8.0 |
| Restrict the extension of existing technologies to additional species/indications | 1 1 • MNC | 9.0 | 9.0 |
| Divert management time | Non-MNC | 6.0 | |
| Registration validity is limited | 1 | 10.0 | |

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

INDONESIA: Impact of different govt. regulations on ability to maintain registration of AH product successfully By and large, there are very few area of regulation that have adverse impact in maintain registration of AH products successfully. The main complaint is – import regulation.

Mean Base, N=12 (combined both MNC & Non-MNC) (5=verv helpful. Verv helpful Verv unhelpful Data shown no. of mentions No. of mentions 1=verv unhelpful) + helpful + unhelpful Licence maintenance (National Procedures) 4.5 12 ---6 Maximum residue limits 3.5 6 ---Manufacturing Inspections 3.8 8 Product quality inspection 3.8 8 --Quality inspection of imported products 3.7 6 --GMP (including manufacturing inspections) 4.1 10 Variations regulation with respect to manufacturing changes 3.7 8 1 Import regulations 3.9 10 2 **Environmental regulations** 3.5 6 1 Harmonization measures 3.9 9 1 Packaging/Labelling modification rules 3.8 8 Disease resistance regulations 3.7 7 1 Protection of IP - commercial data 3.8 8 --Protection of IP - patents 3.8 8 4.0 Pharmacovigilance 9

Very helpful = Helpful = No impact = Unhelpful = Very unhelpful = No answer

E3. Thinking about Government Regulations in your country/ASEAN, how would you assess the impact of each of the areas of regulation listed below on your ABILITY TO PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS successfully? © Kynetec June 11, 2019 | ASEAN Animal Health Regulatory Benchmarking Survey – Stage 2 (Online Quantitative)

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

Mean Mean **MNC** Data shown no. of mentions (5=very helpful, Non-MNC (5=verv helpful. 1=verv unhelpful) 1=very unhelpful) Number of mentions (Base: MNC, n=6) Number of mentions (Base: Non-MNC, n=6) Licence maintenance (National Procedures) 4.5 4.5 Maximum residue limits 3.3 3.7 Manufacturing Inspections 3.7 3.8 Product quality inspection 3.5 4.0 Quality inspection of imported products 3.5 3.8 GMP (including manufacturing inspections) 3.7 4.5 Variations regulation with respect to manufacturing changes 3.3 4.0 Import regulations 3.5 4.3 Environmental regulations 3.2 3.8 Harmonization measures 3.5 4.3 Packaging/Labelling modification rules 3.7 3.8 Disease resistance regulations 3.3 4.2 Protection of IP - commercial data 3.5 4.0 Protection of IP - patents 3.5 4.2 Pharmacovigilance 3.5 4.5 Verv helpful Helpful No impact Very helpful Helpful No impact Unhelpful Very unhelpful Unhelpful Very unhelpful ■No answer

E3. Thinking about Government Regulations in your country/ASEAN, how would you assess the impact of each of the areas of regulation listed below on

your ABILITY TO PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS successfully?

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THAILAND: Factors preventing maintenance of registration of existing AH products Factors are significant in preventing efficient commercialization of existing products include – country regulation framework, legal restriction on advertising, label, trademark and communication and demand volatility in certain segments. MNC Non-MNC

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

| Data shown no. of mentions | | | (10=most important, | (10=most important, | |
|---|-------------|-----------|---------------------|---------------------|--|
| | No. of ment | ions | 1=least important) | 1=least important) | |
| Country regulatory framework for maintenance/extension of licenses | | 3 1 | 8.7 | 8.0 | |
| Legal restrictions on advertising, labels, trademarks and communication | | 3 | 9.0 | | |
| Demand volatility in certain segments | 2 | 2 1 | 8.5 | 7.0 | |
| Excessive and unharmonized inspections and inspection requirements within ASEAN | 2 | 2 | | 9.0 | |
| Difficult GMP clearance | 2 | 2 | 10.0 | | |
| Pressure from competitors (including parallel imports and generics) | 2 | 2 | 9.0 | | |
| The need for all packaging materials in local languages | 1 1 | | 7.0 | 10.0 | |
| Inadequate intellectual property protection (commercial data & patents) | 1 | | 10.0 | | |
| Lack of skilled staff | 1 | | | 10.0 | |
| Small size of market segments | 1 | MNC | 9.0 | | |
| Negative consumer attitudes | 1 | ■ Non-MNC | 9.0 | | |

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

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Importance

Importance

THAILAND: (Negative) effect on the AH business due to govt. regulations The main drawback of govt. regulations in commercialization of your existing products is creating significant uncertainty to their business.



| Base, N=8 (combined both MNC & Non-MNC) Data shown no. of mentions | | MNC (n=6) Significant (10=most significant, | Non-MNC (n=2) Significant (10=most significant, |
|--|-----------------|---|---|
| | No. of mentions | 1=least significant) | 1=least significant) |
| Create significant uncertainty | 5 2 | 2 10.0 | 9.5 |
| Restrict the extension of existing technologies to additional species/indications | 2 1 | 9.5 | 9.0 |
| Create disproportionate costs for maintaining/ extending marketing authorizations | 2 | 8.5 | |
| Increase the cost of distribution and marketing | 1 1 | 8.0 | 8.0 |
| Limit the use of innovative marketing methods | 2 | 9.0 | |
| Divert management time | 1 1 | 8.0 | 10.0 |
| Increase the cost of production | 1 1 | 9.0 | 8.0 |
| Fail to protect intellectual property (patents & commercial data) adequately | 1 MNC Non-MN | 9.0 | |

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

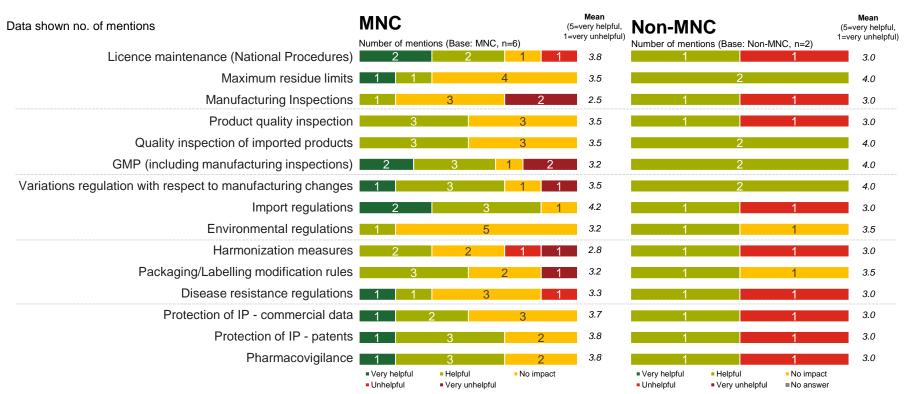
THAILAND: Impact of different govt. regulations on ability to maintain registration of AH product successfully Manufacturing inspections and harmonization measures are considered 2 areas of regulation that are not helpful in maintaining registration of existing products



| Base, N=8 (combined both MNC & Non-MNC) Data shown no. of mentions | No. of mentions | Mean (5=very helpful, 1=very unhelpful) | Very helpful + helpful | Very unhelpful + unhelpful |
|---|---|--|---------------------------|-------------------------------|
| Licence maintenance (National Procedures) | 2 3 1 2 | 3.6 | 5 | 2 |
| Maximum residue limits | 1 3 4 | 3.6 | 4 | |
| Manufacturing Inspections | 2 3 1 2 | 2.6 | 2 | 3 |
| Product quality inspection | 4 3 11 | 3.4 | 4 | 1 |
| Quality inspection of imported products | 5 3 | 3.6 | 5 | |
| GMP (including manufacturing inspections) | 2 3 1 2 | 3.4 | 5 | 2 |
| Variations regulation with respect to manufacturing changes | 5 1 1 | 3.6 | 6 | 1 |
| Import regulations | 2 4 1 1 | 3.9 | 6 | 1 |
| Environmental regulations | 2 6 | 3.3 | 2 | |
| Harmonization measures | 3 2 2 1 | 2.9 | 3 | 3 |
| Packaging/Labelling modification rules | 4 3 1 | 3.3 | 4 | 1 |
| Disease resistance regulations | 1 2 3 2 | 3.3 | 3 | 2 |
| Protection of IP - commercial data | <u> </u> | 3.5 | 4 | 1 |
| Protection of IP - patents | 4 2 1 | 3.6 | 5 | 1 |
| Pharmacovigilance | 4 2 1 | 3.6 | 5 | 1 |
| | = \(onv holpful = Holpful = No import = Unholpful = \(onv unholpful = No ono) | vor | | |

Very helpful = Helpful = No impact = Unhelpful = Very unhelpful = No answer

E3. Thinking about Government Regulations in your country/ASEAN, how would you assess the impact of each of the areas of regulation listed below on your ABILITY TO PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS successfully? © Kynetec June 11, 2019 | ASEAN Animal Health Regulatory Benchmarking Survey – Stage 3 (Online Quantitative) THAILAND: Impact of different govt. regulations on ability to maintain registration of AH product successfully Manufacturing inspections and harmonization measures are considered 2 areas of regulation that are not helpful in maintaining registration of existing products

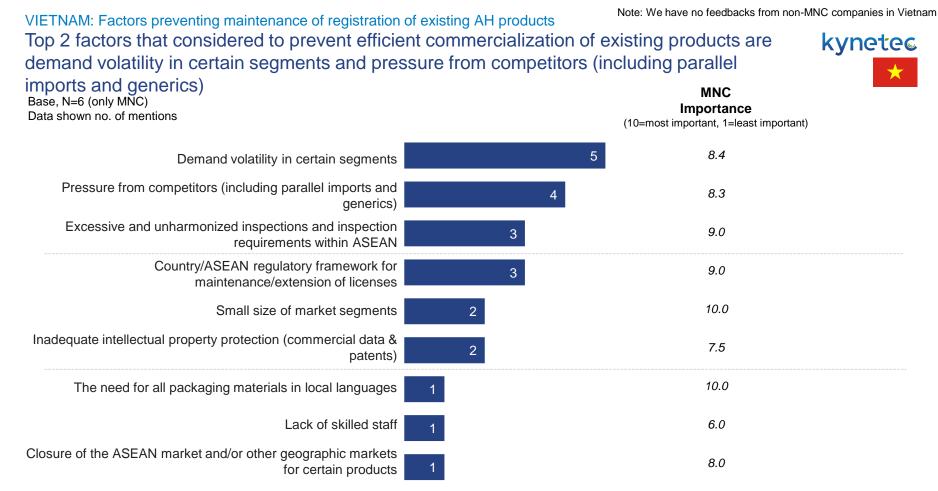


E3. Thinking about Government Regulations in your country/ASEAN, how would you assess the impact of each of the areas of regulation listed below on

your ABILITY TO PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS successfully?

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E1. Below is a list of FACTORS RELEVANT TO THE MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS in the animal health industry in your country/ASEAN. Which of these, if any, are significant in preventing efficient commercialization of your existing products? © Kynetec June 11, 2019 | ASEAN Animal Health Regulatory Benchmarking Survey – Stage 3 (Online Quantitative)

Note: We have no feedbacks from non-MNC companies in Vietnam

VIETNAM: (Negative) effect on the AH business due to govt. regulations Govt. regulations are said to restrict the extension of existing technologies to additional species/indication, increase cost of distribution of marketing and fail to protect IP.

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MNC (n=6) Significant (10=most significant, 1=least significant)

| Base, N=6 (only MNC) | | (10=most significant, 1=least significant) |
|--|-----------------|--|
| Data shown no. of mentions | No. of mentions | (10=most significant, 1=least significant) |
| Restrict the extension of existing technologies to additional species/indications | 4 | 9.8 |
| Increase the cost of distribution and marketing | 3 | 9.0 |
| Fail to protect intellectual property (patents & commercial data) adequately | 3 | 6.7 |
| Create disproportionate costs for maintaining/ extending marketing authorizations | 2 | 8.5 |
| Limit the use of innovative marketing methods | 2 | 6.0 |
| Divert management time | 1 | 5.0 |
| Increase the cost of production | 1 | 6.0 |
| Remove profitable products from the market | 1 | 10.0 |
| Limitation in having high technology equipment's to test product | 1 | 8.0 |
| Create significant uncertainty | 1 | 9.0 |
| Limitation in introducing products with totally new active ingredients | 1 | 9.0 |

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

Note: We have no feedbacks from non-MNC companies in Vietnam VIETNAM: Impact of different govt. regulations on ability to maintain registration of AH product successfully Most managers said harmonization measures have no impact on their ability to maintain registration of AH product successfully. They are concerns with quality inspection of imported products.



| Base, N=6 (only MNC) Data shown no. of mentions | No. of mentions | Mean (5=very helpful, 1=very unhelpful) | Very helpful + helpful | Very unhelpful + unhelpful |
|---|-----------------|--|---------------------------|-------------------------------|
| Licence maintenance (National Procedures) | 1 3 2 | 2 3.8 | 4 | |
| Maximum residue limits | 4 | 1 3.0 | 1 | 1 |
| Manufacturing Inspections | 2 3 | 1 3.0 | 2 | 1 |
| Product quality inspection | 3 2 | 1 3.3 | 3 | 1 |
| Quality inspection of imported products | 3 1 1 | 1 3.0 | 3 | 2 |
| GMP (including manufacturing inspections) | 2 3 | 1 4.2 | 5 | |
| Variations regulation with respect to manufacturing changes | 4 2 | 2 3.7 | 4 | |
| Import regulations | 3 2 | 1 3.3 | 3 | 1 |
| Environmental regulations | 2 3 | 1 3.2 | 2 | 1 |
| Harmonization measures | 5 | 1 2.8 | | 1 |
| Packaging/Labelling modification rules | 4 2 | 2 3.7 | 4 | |
| Disease resistance regulations | 3 2 | 1 3.3 | 3 | 1 |
| Protection of IP - commercial data | 3 2 | 1 3.2 | 3 | 1 |
| Protection of IP - patents | 3 2 | 1 3.2 | 3 | 1 |
| Pharmacovigilance | 3 3 | 3.5 | 3 | |
| | | | | |

Very helpful = Helpful = No impact = Unhelpful = Very unhelpful = No answer

E3. Thinking about Government Regulations in your country/ASEAN, how would you assess the impact of each of the areas of regulation listed below on your ABILITY TO PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS successfully? © Kynetec June 11, 2019 | ASEAN Animal Health Regulatory Benchmarking Survey - Stage 3 (Online Quantitative)

PHILIPPINES: Factors preventing maintenance of registration of existing AH products Pressure from competitors and small size of market are the top 2 factors that could prevent efficient commercialization of existing AH products.

| Base, N=9 (combined both MNC & Non-MNC) Data shown no. of mentions | | MNC Importance (10=most important, 1=least important) | Non-MNC Importance (10=most important, 1=least important) | > |
|--|---------------------|--|--|-------------|
| Pressure from competitors (including parallel imports and generics) | No. of mentions 5 2 | 7.8 | 7.0 | |
| Small size of market segments | 6 | 8.5 | | |
| Legal restrictions on advertising, labels, trademarks and communication | 3 2 | 6.7 | 9.0 | |
| Excessive and unharmonized inspections and inspection requirements within ASEAN | 2 3 | 8.0 | 9.3 | |
| Negative consumer attitudes | 4 1 | 7.3 | 7.0 | |
| Demand volatility in certain segments | 4 1 | 8.5 | 9.0 | |
| Country regulatory framework for maintenance/extension of licenses | 2 2 | 8.5 | 9.0 | |
| Inadequate intellectual property protection (commercial data & | 2 | 5.0 | | |
| patents) Closure of the ASEAN market and/or other geographic markets | 1 1 | 9.0 | 5.0 | |
| for certain products | 1 | | 7.0 | |
| The need for all packaging materials in local languages Lack of skilled staff | 1 | | 7.0 | |
| Lack of availability of financial resources | ■ MNC ■ Non MN | IC 8.0 | | |
| Internal factor - unexpected change in formulation | 1 | 6.0 | | |

E1. Below is a list of FACTORS RELEVANT TO THE MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS in the animal health industry in your country/ASEAN. Which of these, if any, are significant in preventing efficient commercialization of your existing products? © Kynetec June 11, 2019 | ASEAN Animal Health Regulatory Benchmarking Survey - Stage 2 (Online Quantitative)

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PHILIPPINES: (Negative) effect on the AH business due to govt. regulations Increase of cost of distribution & marketing, limit use of innovative marketing methods and increase the cost of production are the outcome of govt. regulation on commercialization of existing products.

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| Base, N=9 (combined both MNC & Non-MNC) Data shown no. of mentions | | MNC (n= Significa | nt Significant | |
|--|-----------------|---------------------------------|----------------|--|
| | No. of mentions | (10=most sign 1=least signif | | |
| Increase the cost of distribution and marketing | 3 | 3 8.0 | 9.7 | |
| Limit the use of innovative marketing methods | 3 1 | 9.3 | 8.0 | |
| Increase the cost of production | 2 2 | 6.5 | 9.5 | |
| Create significant uncertainty | 2 1 | 9.0 | 6.0 | |
| Create disproportionate costs for maintaining/ extending marketing authorizations | | 9.5 | 9.0 | |
| C C | | 7.5 | 7.0 | |
| Remove profitable products from the market | 2 1 | 8.0 | 8.0 | |
| Fail to protect intellectual property (patents & commercial data) adequately | 1 1 | 8.0 | | |
| Restrict the extension of existing technologies to additional species/indications | 2 | 10.0 ■ MNC | | |
| ASEAN variation with human standard | 1 | Non-MNC 8.0 | 9.7 | |

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

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





| Base, N=9 (combined both MNC & Non-MNC) Data shown no. of mentions | No. of mentions | | | Mean (5=very helpful, 1=very unhelpful) | Very helpful + helpful | Very unhelpful + unhelpful |
|---|---------------------------|---------------------------|-------------------------|--|---------------------------|-------------------------------|
| Licence maintenance (National Procedures) | 4 | 2 | 1 2 | 3.9 | 6 | 2 |
| Maximum residue limits | 1 | 5 | 3 | 3.2 | 1 | |
| Manufacturing Inspections | 3 | 4 | 2 | 4.1 | 7 | |
| Product quality inspection | 3 | 5 | 1 | 4.2 | 8 | |
| Quality inspection of imported products | 4 | 1 | 4 | 4.0 | 5 | |
| GMP (including manufacturing inspections) | 4 | 2 | 2 1 | 4.0 | 6 | 1 |
| Variations regulation with respect to manufacturing changes | 4 | 1 | 2 2 | 3.8 | 5 | 2 |
| Import regulations | 3 | 3 | 1 1 1 | 4.0 | 6 | 1 |
| Environmental regulations | 1 2 | 5 | 1 | 3.5 | 3 | |
| Harmonization measures | 2 | 3 | 2 2 | 3.0 | 2 | 2 |
| Packaging/Labelling modification rules | 3 | 1 | 4 1 | 3.3 | 3 | 4 |
| Disease resistance regulations | 1 1 | 3 | 3 1 | 3.0 | 2 | 3 |
| Protection of IP - commercial data | 2 1 | 4 | 2 | 3.7 | 3 | |
| Protection of IP - patents | 1 1 | 4 | 1 2 | 3.3 | 2 | 1 |
| Pharmacovigilance | 1 2 | 3 | 2 1 | 3.3 | 3 | 2 |
| | = V/ony holpful = Holpful | No impost El Inholoful EV | /on/unholpful = No onov | | | |

Very helpful = Helpful = No impact = Unhelpful = Very unhelpful = No answer

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

PHILIPPINES: Impact of different govt. regulations on ability to maintain registration of AH product successfully Amongst the non-MNC, packaging / labelling modification rules and disease resistance regulations are areas within regulation that could impact their ability to maintain the registration of existing AH products

Mean Mean **MNC** Data shown no. of mentions Non-MNC (5=very helpful, (5=verv helpful. 1=verv unhelpful) 1=very unhelpful) Number of mentions (Base: MNC, n=6) Number of mentions (Base: Non-MNC, n=3) Licence maintenance (National Procedures) 43 3.0 Maximum residue limits 3.3 3.0 Manufacturing Inspections 4.3 3 3.7 Product quality inspection 3 4.3 4.0 Quality inspection of imported products 4.5 3 3.0 GMP (including manufacturing inspections) 4.5 3.0 Variations regulation with respect to manufacturing changes 2.7 4.3 Import regulations 4.2 3.7 Environmental regulations 3.6 3.3 Harmonization measures 3.0 3.0 Packaging/Labelling modification rules 4.0 2.0 Disease resistance regulations 3.4 2.3 Protection of IP - commercial data 4.0 3.3 Protection of IP - patents 3.3 3.3 Pharmacovigilance 3.6 2.7 Very helpful Helpful Very helpful Helpful No impact No impact Unhelpful Very unhelpful ■No answer Unhelpful Very unhelpful ■No answer

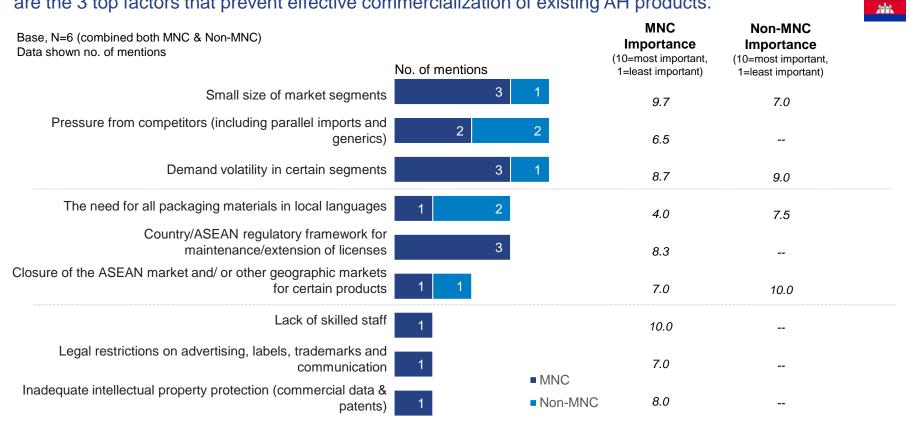
E3. Thinking about Government Regulations in your country/ASEAN, how would you assess the impact of each of the areas of regulation listed below on

your ABILITY TO PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS successfully?





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



E1. Below is a list of FACTORS RELEVANT TO THE MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS in the animal health industry in your country/ASEAN. Which of these, if any, are significant in preventing efficient commercialization of your existing products? © Kynetec June 11, 2019 | ASEAN Animal Health Regulatory Benchmarking Survey – Stage 3 (Online Quantitative)

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CAMBODIA: (Negative) effect on the AH business due to govt. regulations Government regulations are perceived to create significant uncertainty, increase cost of distribution & marketing and create disproportionate cost for maintaining/extending marketing authorizations.

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Non-MNC(n-2)

| Base, N=6 (combined both MNC & Non-MNC) Data shown no. of mentions | | Significant (10=most significant, | Non-MNC (n=2) Significant (10=most significant, |
|--|-----------------|--------------------------------------|---|
| | No. of mentions | 1=least significant) | 1=least significant) |
| Create significant uncertainty | 3 | 9.3 | 8.0 |
| Increase the cost of distribution and marketing | 2 1 | 8.0 | 7.0 |
| Create disproportionate costs for maintaining/ extending marketing authorizations | | 10.0 | 10.0 |
| Increase the cost of production | 1 1 | 9.0 | 9.0 |
| Divert financial resources away from the development of new, innovative products | | | 7.5 |
| Fail to protect intellectual property (patents & commercial data) adequately | <u> </u> | 9.5 | |
| Divert management time | . 1 | | 6.0 |
| Restrict the extension of existing technologies to additional species/indications | | | 8.0 |
| Remove profitable products from the market | 1 | MNC | 10.0 |
| Limit the use of innovative marketing methods | 1 | Non-MNC | 7.0 |
| | | | |

MNC(n-4)

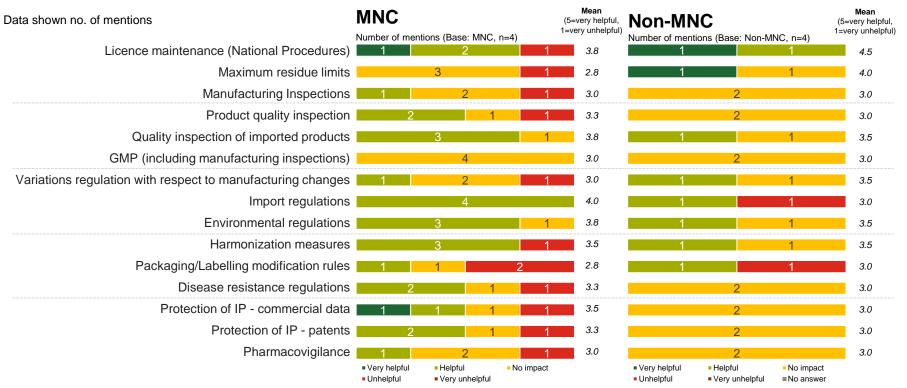
E2. Do government regulations in your country/ASEAN have any of the following effects on your business?

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



| Base, N=6 (combined both MNC & Non-MNC) Data shown no. of mentions | No. of mentions | | | Mean (5=very helpful, 1=very unhelpful) | Very helpful + helpful | Very unhelpful + unhelpful |
|---|-----------------|---------------------------------|---------------|--|---------------------------|-------------------------------|
| Licence maintenance (National Procedures) | 2 | 3 | 1 | 4.0 | 5 | 1 |
| Maximum residue limits | 1 | 4 | 1 | 3.2 | 1 | 1 |
| Manufacturing Inspections | 1 | 4 | 1 | 3.0 | 1 | 1 |
| Product quality inspection | 2 | 3 | 1 | 3.2 | 2 | 1 |
| Quality inspection of imported products | | 4 | 2 | 3.7 | 4 | |
| GMP (including manufacturing inspections) | | 6 | | 3.0 | | |
| Variations regulation with respect to manufacturing changes | 2 | 3 | 1 | 3.2 | 2 | 1 |
| Import regulations | | 5 | 1 | 3.7 | 5 | 1 |
| Environmental regulations | | 4 | 2 | 3.7 | 4 | |
| Harmonization measures | | 4 1 | 1 | 3.5 | 4 | 1 |
| Packaging/Labelling modification rules | 2 | 1 3 | | 2.8 | 2 | 3 |
| Disease resistance regulations | 2 | 3 | 1 | 3.2 | 2 | 1 |
| Protection of IP - commercial data | 1 1 | 3 | 1 | 3.3 | 2 | 1 |
| Protection of IP - patents | 2 | 3 | 1 | 3.2 | 2 | 1 |
| Pharmacovigilance | 1 | 4 | 1 | 3.0 | 1 | 1 |
| | Very helpful | No impact Unhelpful Very unhelp | pful = No ans | swer | | |

E3. Thinking about Government Regulations in your country/ASEAN, how would you assess the impact of each of the areas of regulation listed below on your ABILITY TO PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS successfully? © Kynetec June 11, 2019 | ASEAN Animal Health Regulatory Benchmarking Survey – Stage 3 (Online Quantitative) CAMBODIA: Impact of different govt. regulations on ability to maintain registration of AH product successfully Packaging / labelling modification rules is the area of regulation that considered unhelpful to maintenance of registration of existing products successfully.



E3. Thinking about Government Regulations in your country/ASEAN, how would you assess the impact of each of the areas of regulation listed below on

your ABILITY TO PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS successfully?

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MYANMAR: Factors preventing maintenance of registration of existing AH products Small size of market and lesser extent, pressure from competitors are considered main factors that prevent effective commercialization of existing AH products.



| Base, N=6 (combined both MNC & Non-MNC) Data shown no. of mentions | | Importance (10=most important, 1=least important) |
|---|-----------------|---|
| | No. of mentions | |
| Small size of market segments | 4 1 | 10.0 |
| Pressure from competitors (including parallel imports and generics) | 2 | 7.5 |
| Lack of skilled staff | 1 | 8.0 |
| Excessive and unharmonized inspections and inspection requirements within ASEAN | | 10.0 |
| Closure of the ASEAN market and/or other geographic markets for certain products | 1 | 9.0 |
| Negative consumer attitudes | 1 | 5.0 |
| Inadequate intellectual property protection (commercial data & patents) | 1 | 7.0 |
| Country/ASEAN regulatory framework for maintenance/extension of licenses | 1 | 8.0 |
| The need for all packaging materials in local languages | 1 MNC | 9.0 |
| Demand volatility in certain segments | 1 Non-MNC | 9.0 |

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

MYANMAR: (Negative) effect on the AH business due to govt. regulations Government regulations is said to restrict the extension of existing technologies to additional species / indication and create significant uncertainty.



| Base, N=6 (combined both MNC & Non-MNC) Data shown no. of mentions | n=5 MNC + n=1 non-MIC Significant (10=most significant, 1=least significant) |
|---|---|
| Restrict the extension of existing technologies to additional species/indications | 9.5 |
| Create significant uncertainty | 2 10.0 |
| No impact 1 | 10.0 |
| Fail to protect intellectual property (patents & commercial data) adequately | 7.0 |
| Increase the cost of production 1 | |
| Remove profitable products from the market 1 | 8.0 |
| Divert management time 1 | 10.0 |
| Increase the cost of distribution and marketing 1 | ■ MNC ■ Non-MNC |

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

MYANMAR: Impact of different govt. regulations on ability to maintain registration of AH product successfully Maximum residue limits, variations regulation with respect to manufacturing changes and product quality inspections are key areas of regulation that impact the ability to perform maintenance of registration of existing products successfully.



| Base, N=6 (combined both MNC & Non-MNC) Data shown no. of mentions | No. of mentions | | Mean (5=very helpful, 1=very unhelpful) | Very helpful + helpful | Very unhelpful + unhelpful |
|---|---|---------|---|---------------------------|-------------------------------|
| Licence maintenance (National Procedures) | 1 4 | 1 | 4.0 | 5 | |
| Maximum residue limits | 2 2 2 | 2 | 3.0 | 2 | 2 |
| Manufacturing Inspections | 1 2 2 | 1 | 3.5 | 3 | 1 |
| Product quality inspection | <u> 1 2 1 </u> 2 | 2 | 3.3 | 3 | 2 |
| Quality inspection of imported products | 1 3 1 | 1 | 3.7 | 4 | 1 |
| GMP (including manufacturing inspections) | 1 4 | 1 | 3.8 | 5 | 1 |
| Variations regulation with respect to manufacturing changes | 3 1 2 | 2 | 3.2 | 3 | 2 |
| Import regulations | 2 2 1 | 1 | 3.8 | 4 | 1 |
| Environmental regulations | 1 2 2 | 1 | 3.5 | 3 | 1 |
| Harmonization measures | 1 3 2 | 2 | 3.8 | 4 | |
| Packaging/Labelling modification rules | 4 1 | 1 | 3.5 | 4 | 1 |
| Disease resistance regulations | 4 1 | 1 | 3.5 | 4 | 1 |
| Protection of IP - commercial data | 1 2 | 1 | 3.4 | 2 | 1 |
| Protection of IP - patents | 1 2 2 | 1 | 3.5 | 3 | 1 |
| Pharmacovigilance | 4 1 | 1 | 3.5 | 4 | 1 |
| | Very helpful = Helpful = No impact = Unhelpful = Very unhelpful | No answ | wer | | |

E3. Thinking about Government Regulations in your country/ASEAN, how would you assess the impact of each of the areas of regulation listed below on your ABILITY TO PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS successfully? © Kynetec June 11, 2019 | ASEAN Animal Health Regulatory Benchmarking Survey – Stage 3 (Online Quantitative)

Factors that impact registration achievement and maintaining registration of existing brands

improvement since 2014. Managers agreed that the product registration achievement in 2018 is more science based compared to 2014 Base, N=6 Current product registration achievement Data shown no. of mentions

Science based 2 Consistent & predictable 2 review process Honest, independent and free 2 from political/commercial Excellent Good influence Average Poor Very poor Base, N=6 Data shown mean score In comparison with 2014 (benchmark), is current product registration achievement better or worst (-5 = A lot worse, 0 = No change; +5=A lot better)Science based 1.2 Commentary: On all 3 metrics, current product registration Consistent & predictable 0.7 achievement are better compared to 5 years ago review process Honest, independent and free 0.2 from political/commercial influence

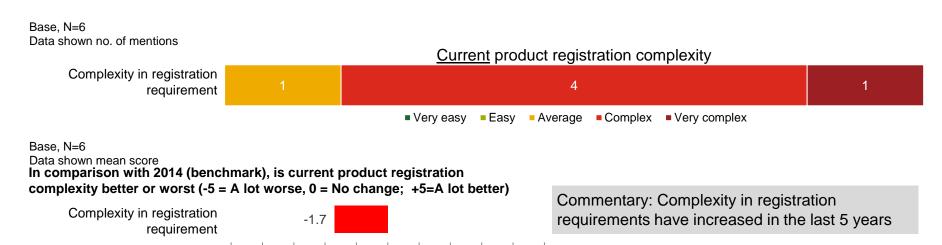
F1. Thinking about CURRENT PRODUCT REGISTRATION ACHIEVEMENT, how well do you consider it is conducted/done based on: science based, consistent & predictable review process, honest, independent & free from political / commercial influence. F1b: COMPARE TO 2014 and NOW on PRODUCT REGISTRATION ACHIEVEMENT,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

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REGIONAL: Assessment on current climate on product registration achievement

Half of the regional regulatory managers perceived current product registration process is somewhat inconsistent and unpredictable.. However, there is marginal REGIONAL: Assessment on current climate on product registration <u>complexity</u> 5 in 6 regional regulatory managers professed that current product registration is **kynetec** very complex, and had been worse compared to 2014



2

3

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

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.2

REGIONAL: Issues that have occurred, and would have (positive) impact product registration achievement Improvement of capability / knowledge & manpower of regulators, provision of feedback loop on new regulation before implementation and accept relevant/high quality test result from other sector/species/regions (10=most important, will have positive impact on product registration achievement 1=least important)

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

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

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Importance



REGIONAL: Issues that have occurred, and would have (positive) impact on performing maintenance of registration of existing products The adaptation of packaging and labelling requirements to small size of markets and ensuring that all types of products are subject to full regulatory approval requirements are hailed could have positive impact on maintaining registration of existing products.



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F3b. The following have been identified as ISSUES that would have impact on the industry's ability to PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS – which of these have occurred, and which have had or might still have the greatest positive impact on your ability to PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS? © Kynetec June 11, 2019 | ASEAN Animal Health Regulatory Benchmarking Survey – Stage 2 (Online Quantitative) 262

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

Base, N=6 Data shown no. of mentions

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





REGIONAL: Regulatory change since 2014 that has given most problems Difficult GMP clearance is considered the changes in regulatory since 2014 that caused most problem.

Base, N=6 Data shown no. of mentions

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

REGIONAL: Major decisions taken over the past 5 years due to regulations in place...(1)

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

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|---------|--|
|---------|--|



Base, N=6 Data shown no. of mentions Number of mentions Locate R&D facilities in ASEAN Switch R&D budgets to labs in ASEAN Invest in production in ASEAN Increase product range in ASEAN Reduce product range in ASEAN 2 Increase (geographic) market focus in ASEAN Restrict (geographic) market focus in 2 ASEAN Increase coverage of species or indications 2 in ASEAN Reduce coverage of species or indications in ASEAN Buy businesses in ASEAN Not done Done, but regulation has NO influence

Done & regulation has SOME influence

Done and regulation has CONSIDERABLE influence

F6. Have regulations played a major role in influencing you to take any of the following major decisions over the last five years? © Kynetec June 11, 2019 | ASEAN Animal Health Regulatory Benchmarking Survey – Stage 2 (Online Quantitative) REGIONAL: Major decisions taken over the past 5 years due to regulations in place...(2)

Base, N=6

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

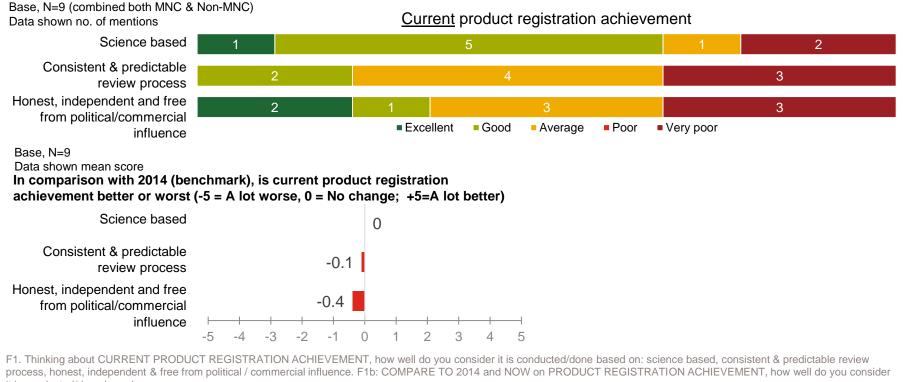
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Data shown no. of mentions Number of mentions Sell or close businesses in ASEAN Focus on new technologies in ASEAN 3 Focus on existing/older technologies in 2 ASEAN Introduce more 'breakthrough' products in 3 ASEAN Introduce fewer 'breakthrough' products in 2 ASEAN Develop certain product technologies in 2 ASEAN Avoid certain product technologies in ASEAN Not done Done, but regulation has NO influence Done & regulation has SOME influence Done and regulation has CONSIDERABLE influence

MALAYSIA: Assessment on current climate on product registration achievement

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

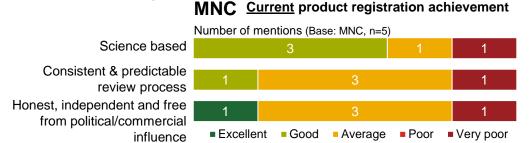


it is conducted/done based on:

MALAYSIA: Assessment on current climate on product registration achievement

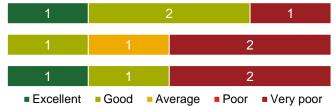
More than two thirds of managers do not considered current product registration achievement is conducted with honest, independent and free from political/commercial influence. It is also said that the review process is not consistent and predictable. Interestingly, this feedbacks are more

prominent amongst non-MNC companies

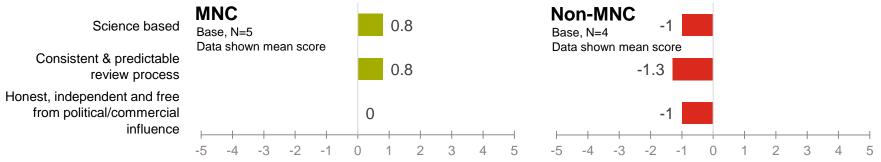


Non-MNC <u>Current</u> product registration achievement

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

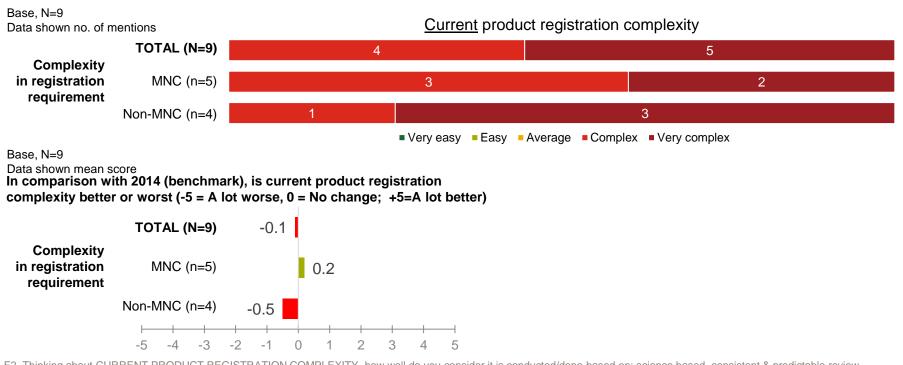


In comparison with 2014 (benchmark), is current product registration achievement better or worst (-5 = A lot worse, 0 = No change; +5=A lot better)



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

MALAYSIA: Assessment on current climate on product registration <u>complexity</u> All regulatory managers claimed current product registration is very complex. However, some MNCs have noticed some slight improvement compared to 5 years before



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

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

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| product registration achievement for MNC comp feedback loop on new regulation before implem | · · · · · · · · · · · · · · · · · · · | | Sion of Non-MNC (n=4) |
|--|---------------------------------------|---|---|
| Base, N=9 (combined both MNC & Non-MNC) Data shown no. of mentions | | (10=most important, 1=least important) | (10=most important, 1=least important) |
| Improvement of capability / knowledge & manpower of regulators | Number of mentions 4 3 | _ | 6.0 |
| Remove redundant and overlapping guidelines | 2 3 | 8.5 | 7.7 |
| Provision of feedback loop on new regulation before implementation | 1 4 | 6.0 | 7.8 |
| Use consultation & impact assessment when developing new guidelines | 2 2 | 7.5 | 7.5 |
| Less ad-hoc / frequent change of regulation | 2 2 | 7.5 | 6.0 |
| Better border control (to prevent illegal products entering the market) | 1 2 | 4.0 | 7.5 |
| Remove political involvement in testing and approval | 1 2 | 6.0 | 8.5 |
| Change test requirements only with scientific justification | 3 | 8.7 | - |
| Base quality standards solely on animal health industry requirements | 1 2 | 9.0 | 5.5 |
| Accept relevant/high quality test results from other sectors/species/regions | 2 1 | 8.5 | 6.0 |
| Less local protectionism (e.g. same standard applies to MNC/non-MNC) | 1 1 ■ MNC | 5.0 | 3.0 |
| Provision of a comprehensive data protection package covering all major investments in product enhancements other than product extensions | | - | 5.0 |

Improvement of capability / knowledge & manpower of regulators has positive impact on

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

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

MALAYSIA: Issues that have occurred, and would have (positive) impact on performing maintenance of registration of existing products Restricting the unjustified application of new guidelines to well-established products have huge positive impact in maintenance of registration of existing products

| Base, N=9 (combined both MNC & Non-MNC) Data shown no. of mentions | MNC (n=5) Importance (10=most important, | Non-MNC (n=4) Importance (10=most important, |
|---|--|--|
| Restricting the unjustified application of new guidelines to well-established products | 1=least important) | 1=least important) 9.0 |
| Adaptation of packaging and labelling requirements to small size of markets 2 2 | 7.5 | 6.0 |
| Based on need for dossier reviews solely on pharmacovigilance or relevant scientific advances | 9.0 | 9.0 |
| Ensuring that all types of products are subject to full regulatory approval requirements 3 | - | 9.3 |
| Reduction of restrictions on minor formulation and manufacturing changes 2 | 10.0 | 7.0 |
| Adapting test requirements to small size of markets 1 1 | 7.0 | 5.0 |
| Based on test requirements only on best available science and risk assessment 1 1 1 | 8.0 | 6.0 |
| Non-MNC Providing additional legal protection for data for new indications or species | - | 10.0 |

F3b. The following have been identified as ISSUES that would have impact on the industry's ability to PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS – which of these have occurred, and which have had or might still have the greatest positive impact on your ability to PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS? © Kynetec June 11, 2019 | ASEAN Animal Health Regulatory Benchmarking Survey – Stage 2 (Online Quantitative) 271



MALAYSIA: Expected regulatory framework changes that have not occurred since 2014 Across the board, regulatory managers claimed improvement of quality of evaluation of products from govt. agencies has not happened

Data shown no. of mentions

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

F5. What regulatory changes SINCE 2014 have given you the most problems and why? © Kynetec June 11, 2019 | ASEAN Animal Health Regulatory Benchmarking Survey – Stage 2 (Online Quantitative)

MALAYSIA: Regulatory change since 2014 that has given most problems Lack of skilled dossier readers and very strict new product registration (new chemical entity) are changes in regulatory since 2014 that caused biggest problem

Data shown no. of mentions

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



MALAYSIA: Major decisions taken over the past 5 years due to regulations in place...(1) For MNC, reduced product range, restricted market focus and focus on new technologies had taken place due to regulations in place. For non-MNC some had located their R&D facilities in Malaysia and increased product range since 5 years ago



| Base, N=9 Data shown no. of mentions | MNC Number of mentions (| 5) | | Non-MNC Number of mentions (Base: Non-MNC, n=4) | | | | |
|---|--|--|------|--|----------------|---|--------------|---|
| Locate R&D facilities in Malaysia | | | 3 | | 1 | 1 | 2 | |
| Switch R&D budgets to labs in Malaysia | | 5 | | | | 3 | | 1 |
| Invest in production in Malaysia | | 5 | | | | 2 | 1 | 1 |
| Increase product range in Malaysia | 1 | 3 | | 1 | 1 | 1 | 2 | |
| Reduce product range in Malaysia | 2 | 1 | | 2 | | 3 | | 1 |
| Increase (geographic) market focus in Malaysia | | | 1 | 1 | | 2 | 1 | 1 |
| Restrict (geographic) market focus in Malaysia | | 2 | | 2 | | 3 | | 1 |
| ncrease coverage of species or indications in Malaysia | · · · · · · · · · · · · · · · · · · · | | 1 | 1 | | 2 | 1 | 1 |
| Reduce coverage of species or indications in Malaysia | • | 2 | | 1 | | 3 | | 1 |
| Buy businesses in Malaysia | 2 | | 3 | | | 3 | | 1 |
| | ■ Not done ■ Done, but regul ■ Done & regulati | ation has NO influ on has SOME infl | ence | | = Don = Don | done ne, but regulation has ne & regulation has S | NO influence | |

Done and regulation has CONSIDERABLE influence

Done and regulation has CONSIDERABLE influence

F6. Have regulations played a major role in influencing you to take any of the following major decisions over the last five years? © Kynetec June 11, 2019 | ASEAN Animal Health Regulatory Benchmarking Survey - Stage 2 (Online Quantitative)

MALAYSIA: Major decisions taken over the past 5 years due to regulations in place...(2)

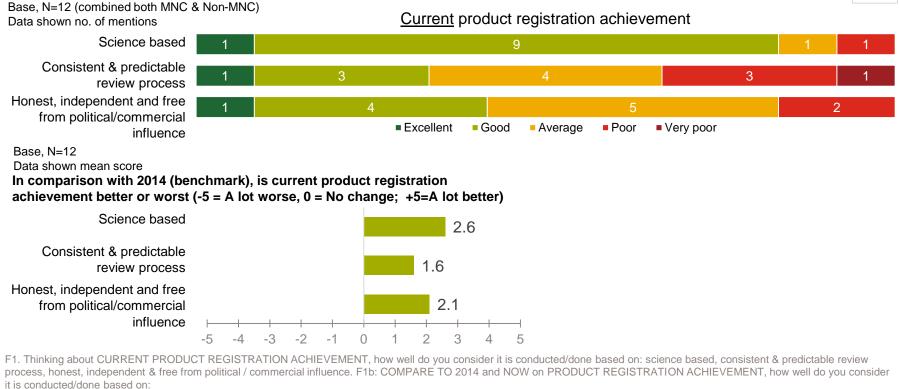
For MNC, reduced product range, restricted market focus and focus on new technologies had taken place due to regulations in place. For non-MNC some had located their R&D facilities in Malaysia and increased product range since 5 years ago



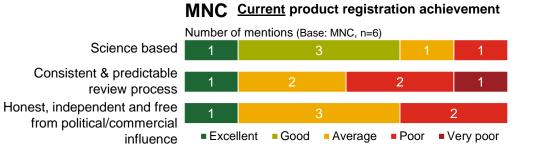
MNC Base, N=9 Non-MNC Data shown no. of mentions Number of mentions (Base: MNC, n=5) Number of mentions (Base: Non-MNC, n=4) Sell or close businesses in Malaysia Focus on new technologies in Malaysia 3 4 Focus on existing/older technologies in 2 Malaysia Introduce more 'breakthrough' products in Malaysia Introduce fewer 'breakthrough' products in Malaysia Develop certain product technologies in Malaysia Avoid certain product technologies in Malaysia Not done Not done Done, but regulation has NO influence Done, but regulation has NO influence Done & regulation has SOME influence Done & regulation has SOME influence Done and regulation has CONSIDERABLE influence Done and regulation has CONSIDERABLE influence

INDONESIA: Assessment on current climate on product registration achievement

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



INDONESIA: Assessment on current climate on product registration <u>achievement</u> Expectedly, non-MNC companies felt current climate on product registration achievement is more positive compared to MNC companies

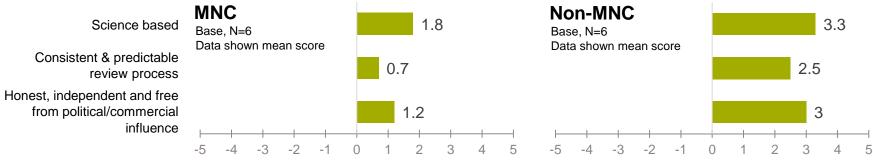


Non-MNC Current product registration achievement

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



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

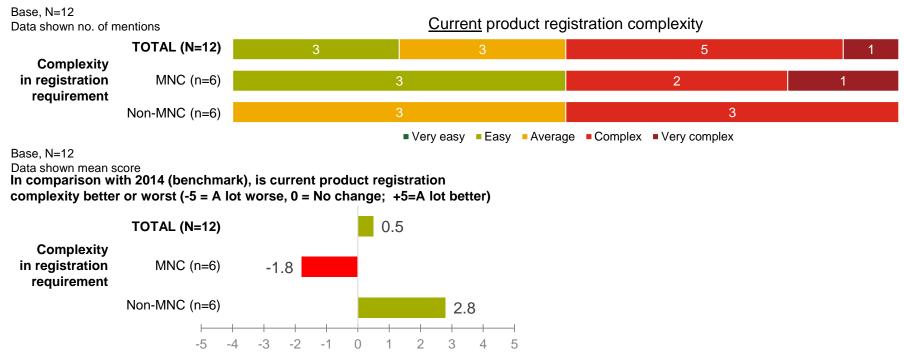


F1. Thinking about CURRENT PRODUCT REGISTRATION ACHIEVEMENT, how well do you consider it is conducted/done based on: science based, consistent & predictable review process, honest, independent & free from political / commercial influence. F1b: COMPARE TO 2014 and NOW on PRODUCT REGISTRATION ACHIEVEMENT,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

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INDONESIA: Assessment on current climate on product registration <u>complexity</u> Half of the regulatory managers claimed current product registration in Indonesia **kynetec** is complex. Only some MNC manages felt current product registration is not complex (easy), but it is more complex compared to 2014



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

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

Indonesia: Issues that have occurred, and would have (positive) impact product registration achievement Provision of feedback loops on new regulation before implementation and improvement on capability / knowledge & manpower of regulators are likely to have positive impact in achieving product registration

| Base, N=12 (combined both MNC & Non-MNC) Data shown no. of mentions | | MNC (n=6) Importance (10=most important, 1=least important) | Non-MNC (n=6) Importance (10=most important, 1=least important) |
|---|------------------------|--|--|
| Provision of feedback loop on new regulation before implementation | Number of mentions 6 3 | 7.7 | 7.7 |
| Improvement of capability / knowledge & manpower of regulators | 4 4 | 7.5 | 8.8 |
| Less ad-hoc / frequent change of regulation | 5 | 8.8 | |
| Remove political involvement in testing and approva | 4 1 | 6.3 | 5.0 |
| Remove redundant and overlapping guidelines | 2 3 | 10.0 | 7.3 |
| Accept relevant/high quality test results from other sectors, species or regions | 3 2 | 5.3 | 9.0 |
| Better border control (to prevent illegal products entering the market) | 2 3 | 4.0 | 8.0 |
| Use consultation & impact assessment when developing new guidelines | 2 2 | 5.5 | 8.0 |
| Change test requirements only with scientific justification | 3 1 | 8.3 | 7.0 |
| Base quality standards solely on animal health industry requirements | 1 2 MNC | 3.0 | 6.0 |
| Less local protectionism (e.g. same standard applies to both local and MNC companies) | | 7.0 | |

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

INDONESIA: Issues that have occurred, and would have (positive) impact on performing maintenance of registration of existing products Following best available science for disease resistance rules and ensuring all types of products are subject to full regulatory approval requirements are expected to have positive impact in maintaining registration of existing products MNC (n=6) Non-MNC (n=6)

Importance

(10-most important

Importance

(10-most important

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

| Data shown no. of mentions | 1=least important) | 1=least important) |
|---|--------------------|--------------------|
| Based disease resistance rules only on best available science (e.g. Antimicrobials) | 9.0 | 10.0 |
| Ensuring that all types of products are subject to full regulatory approval requirements | 8.3 | 8.6 |
| Restricting the unjustified application of new guidelines to well-established products | 9.5 | 6.0 |
| Based on test requirements only on best available science and risk assessment | 10.0 | 7.0 |
| Providing additional legal protection for data for new indications or species 2 1 | 8.6 | 9.3 |
| Adapting test requirements to small size of markets | | 7.3 |
| Reduction of restrictions on minor formulation and manufacturing changes | 9.3 | 6.0 |
| Adaptation of packaging and labelling requirements to small size of markets 1 1 | 7.5 | 7.5 |
| Based on need for dossier reviews solely on pharmacovigilance or relevant scientific advances 1 1 1 Non-MNC | C 8.0 | 3.0 |

F3b. The following have been identified as ISSUES that would have impact on the industry's ability to PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS – which of these have occurred, and which have had or might still have the greatest positive impact on your ability to PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS? © Kynetec June 11, 2019 | ASEAN Animal Health Regulatory Benchmarking Survey – Stage 2 (Online Quantitative)

F4. What expected changes have NOT occurred in regulatory frameworks SINCE 2014 despite of expectations of change? © Kynetec June 11, 2019 | ASEAN Animal Health Regulatory Benchmarking Survey – Stage 2 (Online Quantitative)

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

Data shown no. of mentions

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

INDNESIA: Regulatory change since 2014 that has given most problems New regulation on usage of medicated feed and hormones in feeds and lack of skilled dossier reader have caused problem since the change in regulation from 2014

Data shown no. of mentions

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

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INDONESIA: Major decisions taken over the past 5 years due to regulations in place...(1) In the past 5 years, non-MNC had taken more major decision due to regulation in place compared to MNC companies. This non-MNC widened their coverage (with

more products or cover more species) and introduced newer products / technologies



| Base, N=12 | MNC | | Non-MNC | | | |
|--|---|-----------------------------------|-----------------|--|--|---|
| Data shown no. of mentions | Number of mentions (Base: MNC, n=6 | 6) | Number of menti | ons (Base: Non-M | NC, n=6) | |
| Locate R&D facilities in Indonesia | 5 | 1 | 1 | 3 | 2 | |
| Switch R&D budgets to labs in Indonesia | 5 | 1 | 2 | | 4 | |
| Invest in production in Indonesia | 4 | 1 | 2 | 1 | 2 | 1 |
| Increase product range in Indonesia | 2 2 | 2 | 1 1 | 1 | 3 | |
| Reduce product range in Indonesia | 1 1 1 | 3 | 1 1 | 2 | 2 | |
| Increase (geographic) market focus in Indonesia | | 1 1 | 1 1 | 2 | 2 | |
| Restrict (geographic) market focus in Indonesia | | 2 | 1 | 2 | 3 | |
| Increase coverage of species or indications in Indonesia | · · · · · · · · · · · · · · · · · · · | 3 | 1 | 2 | 3 | |
| Reduce coverage of species or indications in Indonesia | 3 | 2 | 1 | 2 | 2 | 1 |
| Buy businesses in Indonesia | 5 | 1 | 2 | 1 | 2 | 1 |
| | Not done Done, but regulation has NO influe Done & regulation has SOME influ Done and regulation has CONSIDI | ence lence ERABLE influence | Done & r | t regulation has NO ir egulation has SOME i | ifluence influence SIDERABLE influence | |

F6. Have regulations played a major role in influencing you to take any of the following major decisions over the last five years? © Kynetec June 11, 2019 | ASEAN Animal Health Regulatory Benchmarking Survey – Stage 2 (Online Quantitative) INDONESIA: Major decisions taken over the past 5 years due to regulations in place...(2) In the past 5 years, non-MNC had taken more major decision due to regulation in place compared to MNC companies. Non-MNC widened their coverage (with more products or cover more species) and introduced newer products / technologies

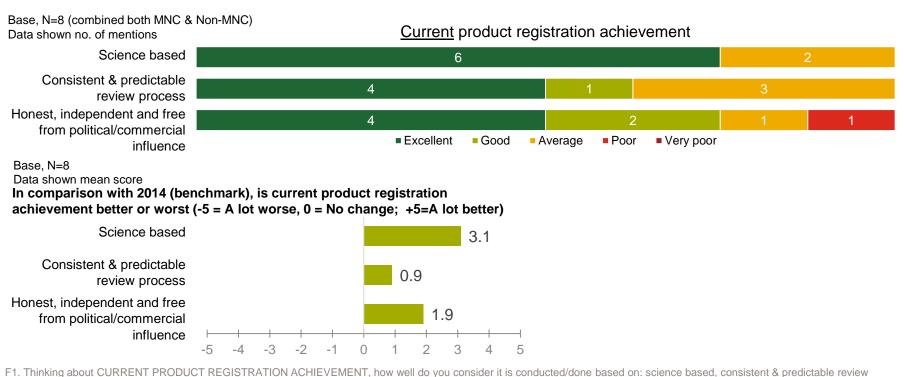




| Base, N=12 Data shown no. of mentions | MNC Number of mentions (Base: | MNC, n=6) | | | Non-MN Number of me | C entions (Base: No | on-MNC, n=6) | |
|---|--|--|-------------|---|---|-------------------------------|---|-----|
| Sell or close businesses in Indonesia | 5 | | | 1 | 2 | 1 | 2 | 1 |
| Focus on new technologies in Indonesia | 3 | 2 | | 1 | 1 | 1 1 | 3 | |
| Focus on existing/older technologies in Indonesia | 2 | 2 | 1 | 1 | 2 | | 3 | 1 |
| Introduce more 'breakthrough' products in Indonesia | 2 | 2 | 2 | | 1 | 1 | 4 | |
| Introduce fewer 'breakthrough' products in Indonesia | | | 2 | | 2 | | 3 | 1 |
| Develop certain product technologies in Indonesia | 3 | 1 | 1 | 1 | 1 | 2 | 3 | |
| Avoid certain product technologies in Indonesia | 5 | | | 1 | 1 | 3 | 1 | 1 |
| | Not done Done, but regulation has Done & regulation has Done and regulation has | as NO influence SOME influence as CONSIDERAB | LE influenc | e | Not do Done, Done Done Done | but regulation has N | IO influence ME influence CONSIDERABLE influe | nce |

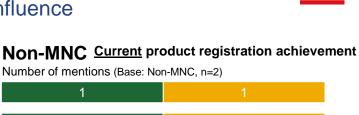
THAILAND: THAILAND: Assessment on current climate on product registration <u>achievement</u> Thailand is performing relatively well in all areas in creating a positive environment for AH companies to achieve product registration. This has brought a more positive change compared to 2014





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

THAILAND: Assessment on current climate on product registration <u>achievement</u> Both MNC and non-MNC managers note better product registration compared to year 2014. However, MNC companies do believe there are rooms to improve on honest, independent and free from political / commercial influence



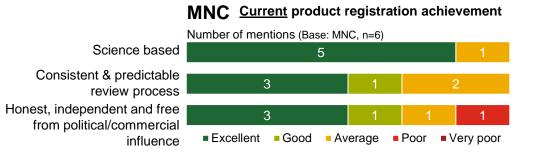
Average

Excellent

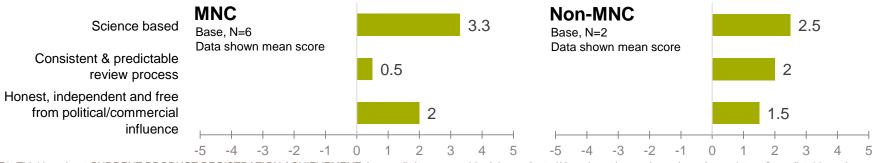
Good

kynetec

Poor Verv poor



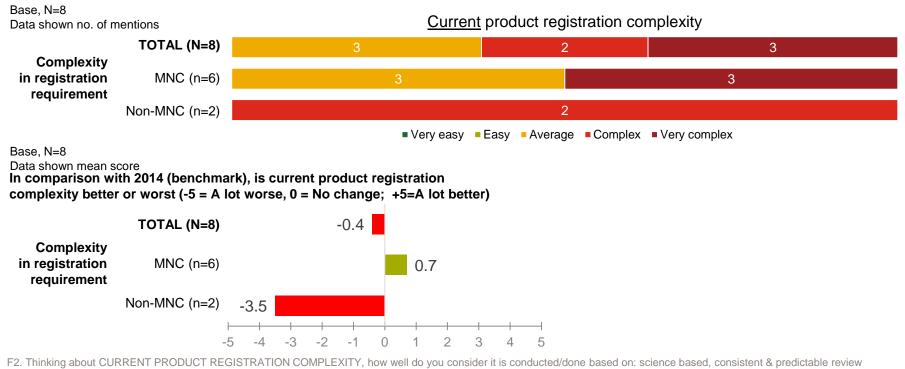
In comparison with 2014 (benchmark), is current product registration achievement better or worst (-5 = A lot worse, 0 = No change; +5=A lot better)



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

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





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

THAILAND: Issues that have occurred, and would have (positive) impact product registration <u>achievement</u> Using consultation & impact assessment when developing new guidelines is considered the most important factor to bring positive impact to product registration achievement

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| Base, N=8 (combined both MNC & Non-MNC) Data shown no. of mentions | | MNC (n=6) Importance (10=most important, 1=least important) | Non-MNC (n=2) Importance (10=most important, 1=least important) |
|--|------------------------|--|--|
| Use consultation & impact assessment when developing new guidelines | Number of mentions 4 2 | 8.5 | 10.0 |
| Remove redundant and overlapping guidelines | 4 2 | 7.5 | 8.5 |
| Accept relevant/high quality test results from other sectors, species or regions | 4 1 | 8.5 | 7.0 |
| Improvement of capability / knowledge & manpower of regulators | 4 1 | 8.5 | 7.0 |
| Less ad-hoc / frequent change of regulation | 1 2 | 6.0 | 8.5 |
| Provision of feedback loop on new regulation before implementation | 2 1 | 8.5 | 6.0 |
| Change test requirements only with scientific justification | 1 1 | 7.0 | 5.0 |
| Base quality standards solely on animal health industry requirements | 2 | 4.5 | |
| Remove political involvement in testing and approval | 1 | 2.0 | |
| Better border control (to prevent illegal products entering the market) | Non-MNC | 1.0 | |

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

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

Ensuring all types of products are subject to full regulatory approval requirement is **kynetec** deemed to be the most positive impact by MNCs while the non-MNCs think the most positive impact is reduction of restrictions on minor formulation **MNC** (n=6) **Non-MNC** (n=2)

Importance

(10=most important,

Importance

(10=most important,

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

| | Number of mentions | 1=least important) | 1=least important) |
|---|--------------------|--------------------|--------------------|
| Ensuring that all types of products are subject to full regulatory approval requirements | 4 1 | 9.8 | 9.0 |
| Based on Disease Resistance rules only on best available science (e.g. Antimicrobials) | 4 | 8.5 | |
| Based on need for dossier reviews solely on pharmacovigilance or relevant scientific advances | 2 1 | 8.5 | 7.0 |
| Based on test requirements only on best available science and risk assessment | 3 | 9.0 | |
| Adaptation of packaging and labelling requirements to small size of markets | 2 | 8.5 | |
| Reduction of restrictions on minor formulation and manufacturing changes | 2 | | 9.5 |
| Restricting the unjustified application of new guidelines to well-established products | | | 10.0 |
| Providing additional legal protection for data for new indications or species | 1 MNC | | 6.0 |
| Adapting test requirements to small size of markets | 1 Non- | MNC | 8.0 |

F3b. The following have been identified as ISSUES that would have impact on the industry's ability to PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS – which of these have occurred, and which have had or might still have the greatest positive impact on your ability to PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS? © Kynetec June 11, 2019 | ASEAN Animal Health Regulatory Benchmarking Survey – Stage 3 (Online Quantitative)

F4. What expected changes have <u>NOT</u> occurred in regulatory frameworks SINCE 2014 despite of expectations of change? © Kynetec June 11, 2019 | ASEAN Animal Health Regulatory Benchmarking Survey – Stage 3 (Online Quantitative)

THAILAND: Expected regulatory framework changes that have not occurred since 2014 Most MNCs expected the update of registration guidelines specific for animal industry but this has not occurred since 2014

Data shown no. of mentions

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



THAILAND: Regulatory change since 2014 that has given most problems

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



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

Data shown no. of mentions

THAILAND: Major decisions taken over the past 5 years due to regulations in place...(1) Most MNCs all non-MNC have increased their product range, market focus, develop new technologies in Thailand in the past 5 years due to regulations in



place

| Base, N=8 Data shown no. of mentions | | Non-MNC |
|---|---|---|
| Locate R&D facilities in Thailance | Number of mentions (Base: MNC, n=6) | Number of mentions (Base: Non-MNC, n=2) 1 |
| Switch R&D budgets to labs in Thailanc | 5 | 1 2 |
| Invest in production in Thailanc | 6 | 2 |
| Increase product range in Thailand | 1 1 1 3 | 2 |
| Reduce product range in Thailanc | 3 1 2 | 1 1 |
| Increase (geographic) market focus in Thailand | | 2 |
| Restrict (geographic) market focus ir Thailanc | | 1 1 1 |
| Increase coverage of species or indications in Thailance | | 1 1 |
| Reduce coverage of species or indications in Thailance | 5 | 1 1 1 |
| Buy businesses in Thailanc | 3 68 1 68 2 | 2 |
| | Not done Done, but regulation has NO influence Done & regulation has SOME influence Done and regulation has CONSIDERABLE influence | Not done Done, but regulation has NO influence Done & regulation has SOME influence Done and regulation has CONSIDERABLE influence |

F6. Have regulations played a major role in influencing you to take any of the following major decisions over the last five years? © Kynetec June 11, 2019 | ASEAN Animal Health Regulatory Benchmarking Survey - Stage 3 (Online Quantitative)

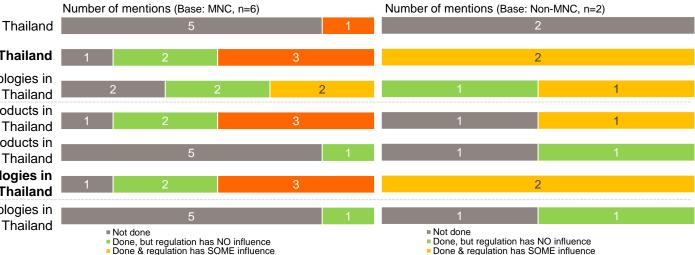
THAILAND: Major decisions taken over the past 5 years due to regulations in place...(1) Most MNCs all non-MNC have increased their product range, market focus, develop new technologies in Thailand in the past 5 years due to regulations in place



MNC Base, N=8 Non-MNC Data shown no. of mentions Number of mentions (Base: MNC, n=6) Sell or close businesses in Thailand Focus on new technologies in Thailand Focus on existing/older technologies in Thailand Introduce more 'breakthrough' products in Thailand Introduce fewer 'breakthrough' products in

Develop certain product technologies in Thailand

Avoid certain product technologies in Thailand



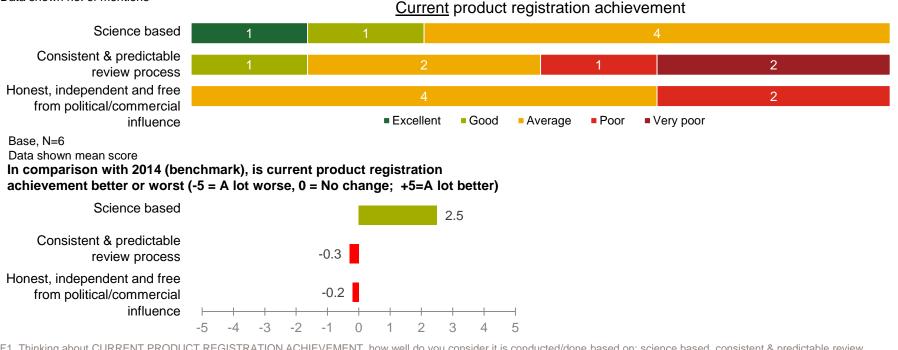
Done and regulation has CONSIDERABLE influence

Done and regulation has CONSIDERABLE influence

VIETNAM: Assessment on current climate on product registration <u>achievement</u> The current climate on product registration achievement has approved a lot better due to product evaluation that is more scientifically based

kynetes

Base, N=6 Data shown no. of mentions



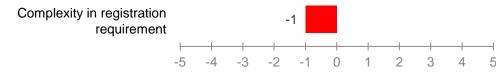
F1. Thinking about CURRENT PRODUCT REGISTRATION ACHIEVEMENT, how well do you consider it is conducted/done based on: science based, consistent & predictable review process, honest, independent & free from political / commercial influence. F1b: COMPARE TO 2014 and NOW on PRODUCT REGISTRATION ACHIEVEMENT,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

VIETNAM: Assessment on current climate on product registration <u>complexity</u> Overall speaking, product registration in considered complex and has become slightly worse compared to 2014





Base, N=6 Data shown mean score In comparison with 2014 (benchmark), is current product registration complexity better or worst (-5 = A lot worse, 0 = No change; +5=A lot better)



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

VIETNAM: Issues that have occurred, and would have (positive) impact product registration achievement Most believe that capacity building of regulators, removing redundant guidelines and accept relevant test results from other sectors will bring significantly positive impact to product registration achievement Base, N=6



(10=most important.

Data shown no. of mentions 1=least important) Number of mentions Improvement of capability / knowledge & manpower of regulators 7.5 Remove redundant and overlapping guidelines 9.7 Accept relevant/high quality test results from other sectors, species or 3 9.0 regions Use consultation & impact assessment when developing new guidelines 2 7.5 2 Provision of feedback loop on new regulation before implementation 7.0 Base quality standards solely on animal health industry requirements 2 9.5 Better border control (to prevent illegal products entering the market) 4.0 Provide specific incentives to develop new products for small markets 7.0 Less local protectionism (e.g. same standard applies to both local and MNC 10.0 companies) Change test requirements only with scientific justification 8.0 Remove political involvement in testing and approval 7.0 Harmonize test requirements internationally/ regionally 7.0

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

VIETNAM: Issues that have occurred, and would have (positive) impact on performing maintenance of registration of existing products Most companies believe that ensuring all types of products are subject to full regulatory approval requirements is the most important factor in bringing positive impact in product registration maintenance (10=most important,

Base, N=6 1=least important) Data shown no. of mentions Number of mentions Ensuring that all types of products are subject to full regulatory approval 10.0 requirements 9.0 Adaptation of packaging and labelling requirements to small size of markets 3 9.7 Reduction of restrictions on minor formulation and manufacturing changes 3 Restricting the unjustified application of new guidelines to well-established 8.3 3 products Based on Disease Resistance rules only on best available science (e.g. 6.0 Antimicrobials) Based on need for dossier reviews solely on pharmacovigilance or relevant 4.0 scientific advances Adapting test requirements to small size of markets 8.0 Providing additional legal protection for data for new indications or species 7.0 Based on test requirements only on best available science and risk 5.0 assessment

F3b. The following have been identified as ISSUES that would have impact on the industry's ability to PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS – which of these have occurred, and which have had or might still have the greatest positive impact on your ability to PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS? © Kynetec June 11, 2019 | ASEAN Animal Health Regulatory Benchmarking Survey – Stage 3 (Online Quantitative)

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

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

Base, N=6 Data shown no. of mentions

| kyne | etec |
|------|---------|
| | \star |

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



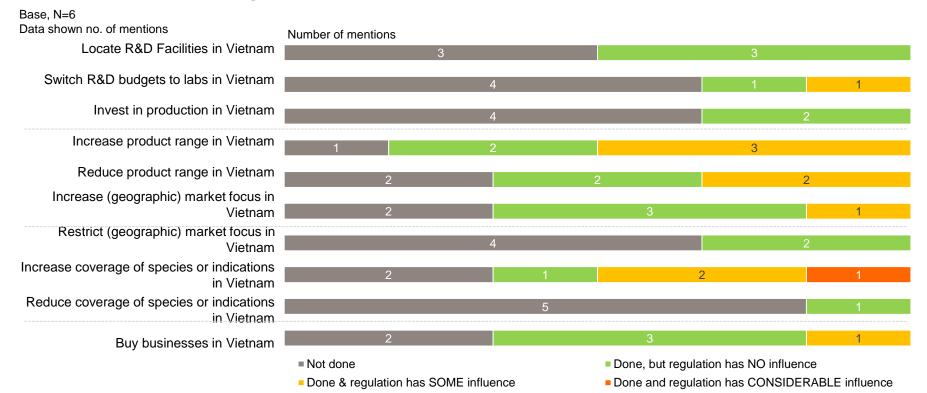
VIETNAM: Regulatory change since 2014 that has given most problems Echoing the failed expectation in having clear registration process, this issue has also posed a significant problem since 2014

Base, N=6 Data shown no. of mentions

| Regulatory change since 2014 that has given most problems | |
|---|---|
| Unclear registration processes | 2 |
| Circular 13 on inspection of imported goods and Circular 18 on conformity of regulations, regulations on studying update stability and update in production process | |
| Laboratories are incapable of conducting some testing methods | 1 |
| Requirement for regulatory trials for new products although Active Pharmaceutical (API) is not new because this is costly and time consuming | |

VIETNAM: Major decisions taken over the past 5 years due to regulations in place...(1) Some companies think regulations have placed considerable influence them focusing on existing/older technologies in Vietnam while others influenced the coverage of species or indications in Vietnam

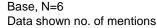


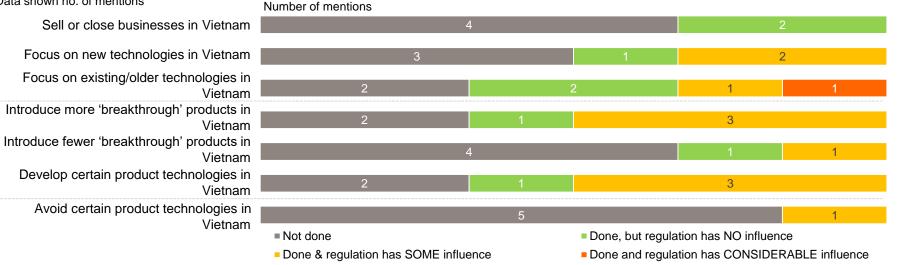


F6. Have regulations played a major role in influencing you to take any of the following major decisions over the last five years? © Kynetec June 11, 2019 | ASEAN Animal Health Regulatory Benchmarking Survey – Stage 3 (Online Quantitative)

F6. Have regulations played a major role in influencing you to take any of the following major decisions over the last five years? © Kynetec June 11, 2019 | ASEAN Animal Health Regulatory Benchmarking Survey – Stage 3 (Online Quantitative)

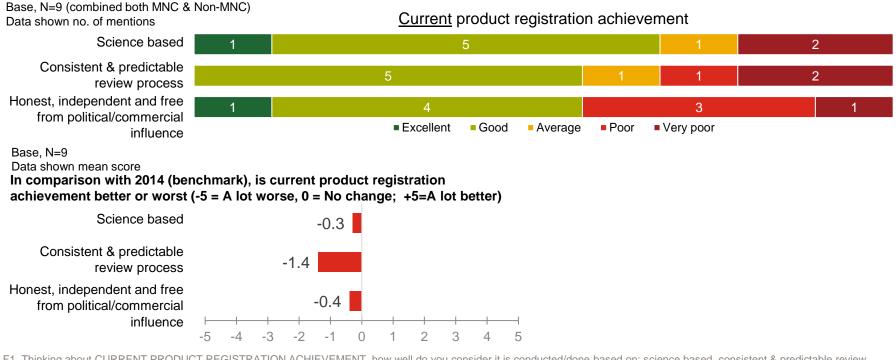
VIETNAM: Major decisions taken over the past 5 years due to regulations in place...(2) Some companies think regulations have placed considerable influence them focusing on existing/older technologies in Vietnam while others influenced the coverage of species or indications in Vietnam





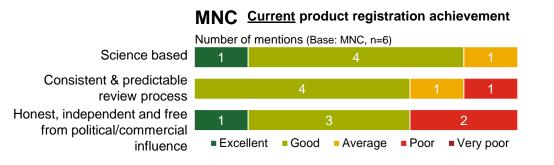
kynetec *

PHILIPPINES: Assessment on current climate on product registration <u>achievement</u> Although most companies think the current product registration achievement is quite **kynetes** good, it is still seen as performing slightly worse compared to 2014



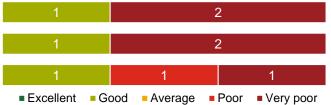
F1. Thinking about CURRENT PRODUCT REGISTRATION ACHIEVEMENT, how well do you consider it is conducted/done based on: science based, consistent & predictable review process, honest, independent & free from political / commercial influence. F1b: COMPARE TO 2014 and NOW on PRODUCT REGISTRATION ACHIEVEMENT,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

PHILIPPINES: Assessment on current climate on product registration <u>achievement</u> Non-MNCs consider their current product registration achievement to be poorer than **kynetes** the MNCs. However they still think that the regulatory is performing slightly better in honesty and independence from other influences

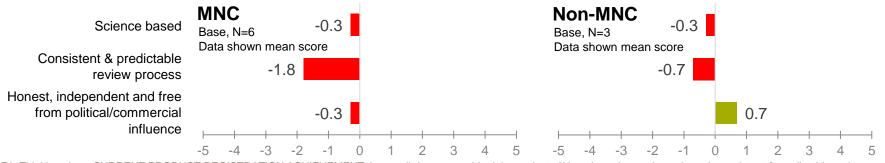


Non-MNC Current product registration achievement

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

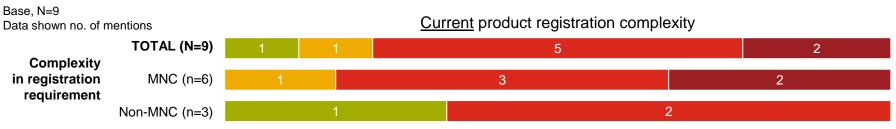


In comparison with 2014 (benchmark), is current product registration achievement better or worst (-5 = A lot worse, 0 = No change; +5=A lot better)



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

PHILIPPINES: Assessment on current climate on product registration <u>complexity</u> Almost all MNC and Non-MNCs think registration requirement is very complex and is seen as a step back to 5 years before

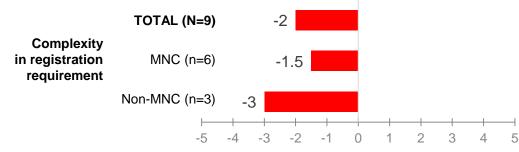


Very easy = Easy = Average = Complex = Very complex

Base, N=9

Data shown mean score

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



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

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

PHILIPPINES: Issues that have occurred, and would have (positive) impact product registration achievement...(1) Both MNC and non-MNC consider improvement in capability/knowledge and manpower of regulators to have the most positive impact on product registration achievement

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

| Data shown no. of mentions | | MNC (n=6) Importance (10=most important, 1=least important) | Non-MNC (n=3) Importance (10=most important, 1=least important) |
|---|------------------|--|--|
| Number | of mentions | | |
| Improvement of capability / knowledge & manpower of regulators | 4 2 | 7.5 | 7.5 |
| Provision of feedback loop on new regulation before implementation | 4 1 | 9.0 | 6.0 |
| Less ad-hoc / frequent change of regulation | 3 2 | 8.7 | 10.0 |
| Use consultation & impact assessment when developing new guidelines | 1 | 10.0 | 8.0 |
| Remove redundant and overlapping guidelines | 1 | 9.5 | 10.0 |
| Better border control (to prevent illegal products entering the market) | | 6.5 | |
| Base quality standards solely on animal health industry requirements | | 6.0 | 9.0 |
| Tailor test requirements to specific risks posed by each product | ■MNC ■Non-MNC | 8.0 | |

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





PHILIPPINES: Issues that have occurred, and would have (positive) impact product registration achievement...(2) Both MNC and non-MNC consider improvement in capability/knowledge and manpower of regulators to have the most positive impact on product registration achievement

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

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

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

PHILIPPINES: Issues that have/ would have occurred (positive) impact on performing maintenance of registration of existing products

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

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

Reduction of restrictions on minor formulation and manufacturing changes

Restricting the unjustified application of new guidelines to well-established

Adaptation of packaging and labelling requirements to small size of markets

Based on need for dossier reviews solely on pharmacovigilance or relevant

Ensuring that all types of products are subject to full regulatory approval requirements

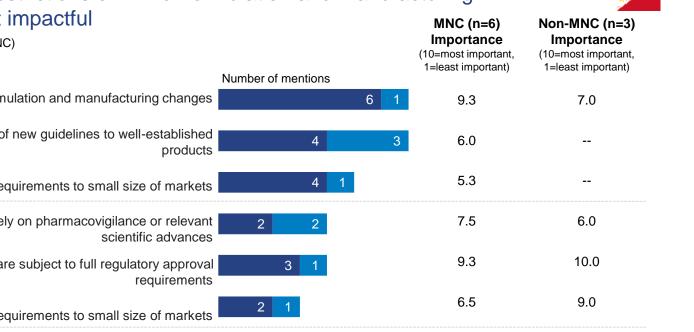
Adapting test requirements to small size of markets

Providing additional legal protection for data for new indications or species

Based on test requirements only on best available science and risk assessment

F3b. The following have been identified as ISSUES that would have impact on the industry's ability to PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS - which of these have occurred, and which have had or might still have the greatest positive impact on your ability to PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS? 307 © Kynetec June 11, 2019 | ASEAN Animal Health Regulatory Benchmarking Survey - Stage 2 (Online Quantitative)

3



MNC

Non-MNC

7.0

9.3

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8.0

9.7

F4. What expected changes have NOT occurred in regulatory frameworks SINCE 2014 despite of expectations of change? © Kynetec June 11, 2019 | ASEAN Animal Health Regulatory Benchmarking Survey - Stage 2 (Online Quantitative)

PHILIPPINES: Expected regulatory framework changes that have not occurred since 2014 kynetec Change of registration flow process to speed up registration time is most expected regulatory framework change but this has not occurred since 2014.

Data shown no. of mentions

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



F5. What regulatory changes SINCE 2014 have given you the most problems and why? © Kynetec June 11, 2019 | ASEAN Animal Health Regulatory Benchmarking Survey – Stage 2 (Online Quantitative)

PHILIPPINES: Expected regulatory framework changes that have not occurred since 2014 All non-MNC and more than half of the MNC managers faced problem with consistency and speed of dossier evaluation due to lack of skilled dossier readers

Data shown no. of mentions

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



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PHILIPPINES: Major decisions taken over the past 5 years due to regulations in place...(1) Major decisions take by MNCs due to regulations in place are increasing coverage of species or indications and introducing 'breakthrough' products

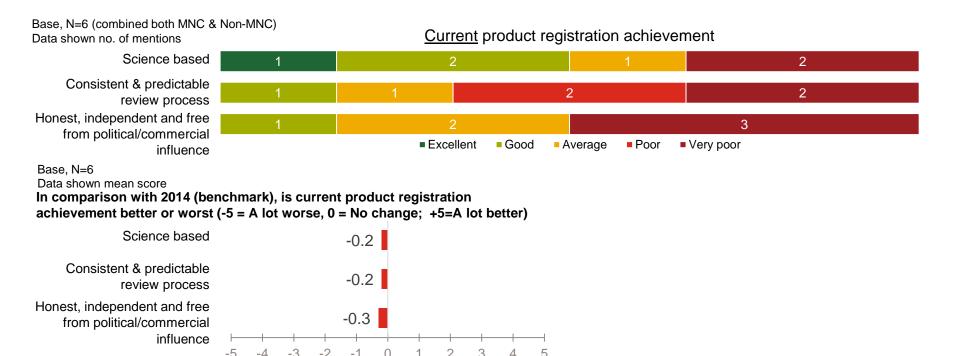


| Data shown no of mentions | MNC Number of mentions (Base: MN | C, n=6) | | Non-MNC Number of mentions (Ba | ase: Non-MNC, n=3) | 1 |
|---|--|--|---|-----------------------------------|---|-------------|
| Locate R&D facilities in Philippines | | | 1 | 2 | | 1 |
| Switch R&D budgets to labs in Philippines | 5 | | 1 | 1 | 2 | |
| Invest in production in Philippines | 4 | 2 | | 1 | 2 | |
| Increase product range in Philippines | 3 | 3 | | 2 | | 1 |
| Reduce product range in Philippines | 3 | 2 | 1 | 2 | | 1 |
| Increase (geographic) market focus in Philippines | 6 | - | | 1 | 1 | 1 |
| Restrict (geographic) market focus in Philippines | | 2 | | 2 | | 1 |
| Increase coverage of species or indications in Philippines | 3 | 1 2 | | | 3 | |
| Reduce coverage of species or indications in Philippines | | 1 | 1 | | 3 | |
| Buy businesses in Philippines | 5 | | 1 | 2 | | 1 |
| | Not done Done, but regulation has N Done & regulation has SOI Done and regulation has C | O influence ME influence ONSIDERABLE influence | | Done & regulation | on has NO influence has SOME influence on has CONSIDERABL | E influence |

F6. Have regulations played a major role in influencing you to take any of the following major decisions over the last five years? © Kynetec June 11, 2019 | ASEAN Animal Health Regulatory Benchmarking Survey – Stage 2 (Online Quantitative) PHILIPPINES: Major decisions taken over the past 5 years due to regulations in place...(2) Major decisions take by MNCs due to regulations in place are increasing coverage of species or indications and introducing 'breakthrough' products



MNC Base, N=9 Non-MNC Data shown no. of mentions Number of mentions (Base: MNC, n=6) Number of mentions (Base: Non-MNC, n=3) Sell or close businesses in Philippines Focus on new technologies in Philippines Focus on existing/older technologies in Philippines Introduce more 'breakthrough' products in Philippines Introduce fewer 'breakthrough' products in Philippines Develop certain product technologies in Philippines Avoid certain product technologies in Philippines Not done Not done Done, but regulation has NO influence Done, but regulation has NO influence Done & regulation has SOME influence Done & regulation has SOME influence Done and regulation has CONSIDERABLE influence Done and regulation has CONSIDERABLE influence Companies find the poor consistency and predictability of review process to be a hindrance in product registration achievement. This issue has slightly worsened since 2014



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

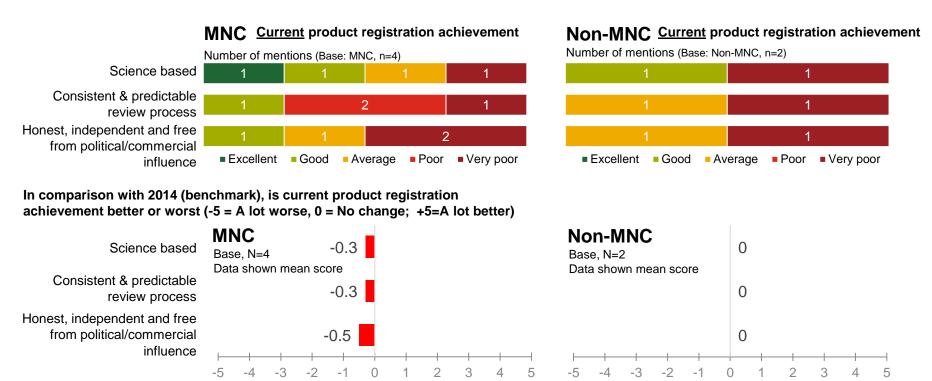
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CAMBODIA: Assessment on current climate on product registration achievement

CAMBODIA: Assessment on current climate on product registration <u>achievement</u> While all MNCs think the current climate on product registration achievement has slightly worsened compared to 2104, the non-MNCs do not see any difference





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

CAMBODIA: Assessment on current climate on product registration <u>complexity</u> Most companies think the product registration is easy but non-MNCs think it has become increasingly more complex compared to 2015. This could be due to the political involvement in registrations approvals





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

CAMBODIA: Issues that have occurred, and would have (positive) impact product registration achievement Removal of political involvement in testing and approval is highly critical to bring about positive impact of product registration achievement

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Non-MNC (n=2)

MNC (n=4)

| Base, N=6 (combined both MNC & Non-MNC) Data shown no. of mentions | Number of mentions | (10=most important, 1=least important) | Importance (10=most important, 1=least important) |
|---|--------------------|---|--|
| Remove political involvement in testing and approval | 3 1 | 9.0 | 10.0 |
| Accept relevant/high quality test results from other sectors, species or regions | | 9.0 | 8.0 |
| Better border control (to prevent illegal products entering the market) | 2 1 | 6.5 | 10.0 |
| Improvement of capability / knowledge & manpower of regulators | | 8.5 | 9.0 |
| Less local protectionism (e.g. same standard applies to both local and MNC companies) | | 8.0 | 7.0 |
| Less ad-hoc / frequent change of regulation | 1 | 10.0 | |
| Change test requirements only with scientific justification | 1 | | 9.0 |
| Use consultation & impact assessment when developing new guidelines | 1 | 9.0 | |
| Base quality standards solely on animal health industry requirements | 1 | 9.0 | |
| Provision of feedback loop on new regulation before implementation | 1 | | 7.0 |
| Remove redundant and overlapping guidelines | ■ MNC | | 8.0 |
| | Non-MNC | | |

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

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

Most companies mentioned that ensuring all types of products are subject to full regulatory approval requirements to bring positive impact in product registration maintenance MNC (n=4) Non-MNC (n=2)

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Importance

Importance

鱸

| Base, N=6 (combined both MNC & Non-MNC) Data shown no. of mentions | (10=most important, 1=least important) | (10=most important, 1=least important) | |
|---|---|---|--|
| Ensuring that all types of products are subject to full regulatory approval requirements 3 1 | 9.7 | 8.0 | |
| Adapting test requirements to small size of markets 1 1 | 9.0 | 9.0 | |
| Restricting the unjustified application of new guidelines to well-established products | 10.0 | 10.0 | |
| Providing additional legal protection for data for new indications or species 2 | 9.0 | | |
| Adaptation of packaging and labelling requirements to small size of markets 1 | | 10.0 | |
| Based on Disease Resistance rules only on best available science (e.g. Antimicrobials) | 8.0 | | |
| Based on need for dossier reviews solely on pharmacovigilance or relevant scientific advances 1 MNC Non-MNC | 9.0 | | |

F3b. The following have been identified as ISSUES that would have impact on the industry's ability to PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS - which of these have occurred, and which have had or might still have the greatest positive impact on your ability to PERFORM MAINTENANCE OF REGISTRATION OF EXISTING PRODUCTS? 316 © Kynetec June 11, 2019 | ASEAN Animal Health Regulatory Benchmarking Survey - Stage 3 (Online Quantitative)

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

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

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Base, N=6 Data shown no. of mentions

| | No. of mentions | | ons |
|---|----------------------|------------------------------|--------------------|
| Expected regulatory framework changes that have not occurred since 2014 | TOTAL (N=6) | MNC (n=4) | Non – MNC (n=2) |
| Reduction in registration fees to match with market opportunity | 1 | | 1 |
| Don't know | 5 | 4 | 1 |
| | | | |
| | No | o. of mentic | ons |
| Regulatory change since 2014 that has given most problems | No TOTAL (N=6) | D. of mentic MNC (n=4) | Non – MNC (n=2) |
| Regulatory change since 2014 that has given most problems No change in regulatory framework since 2014 | TOTAL | MNC | Non – MNC |

CAMBODIA: Expected regulatory framework changes that have not occurred since 2014 Some non-MNC expected to have reduction in registration fees to match with market opportunity but this change has not occurred since 2014



CAMBODIA: Major decisions taken over the past 5 years due to regulations in place...(1) The regulations in placed has influenced some companies to increase market focus **kynetec** and product range in Cambodia

| Base, N=6 Data shown no. of mentions | MNC Number of mentions (Base: MNC, n=4) | Non-MNC Number of mentions (Base: Non-MNC, n=2) |
|--|---|---|
| Locate R&D facilities in Cambodia | a 3 | 2 |
| Switch R&D budgets to labs in Cambodia | a 4 | 2 |
| Invest in production in Cambodia | a 4 | 2 |
| Increase product range in Cambodia | a 1 1 1 / | 1 1 |
| Reduce product range in Cambodia | a3 | 1 1 |
| Increase (geographic) market focus ir Cambodia | | 1 1 |
| Restrict (geographic) market focus ir Cambodia | | 1 1 |
| Increase coverage of species or indications in Cambodia | | 1 1 |
| Reduce coverage of species or indications in Cambodia | | 1 1 |
| Buy businesses in Cambodia | a 4 | 2 |
| | Not done Done, but regulation has NO influence Done & regulation has SOME influence Done and regulation has CONSIDERABLE influence | Not done Done, but regulation has NO influence Done & regulation has SOME influence Done and regulation has CONSIDERABLE influence |

F6. Have regulations played a major role in influencing you to take any of the following major decisions over the last five years? © Kynetec June 11, 2019 | ASEAN Animal Health Regulatory Benchmarking Survey – Stage 3 (Online Quantitative) CAMBODIA: Major decisions taken over the past 5 years due to regulations in place...(2) The regulations in placed has influenced some companies to increase market focus **kynetee** and product range in Cambodia

| Base, N=6 Data shown no. of mentions | MNC Number of mentions (Base: MNC, n=4) | | Non-MNC Number of mentions (Base: N | on-MNC, n=2) |
|--|--|----------|---|---|
| Sell or close businesses in Cambodia | 4 | | 1 | 1 |
| Focus on new technologies in Cambodia | 4 | | 1 | 1 |
| Focus on existing/older technologies in Cambodia | | 2 | 2 | 2 |
| Introduce more 'breakthrough' products in Cambodia | 2 1 | 1 | 1 | 1 |
| Introduce fewer 'breakthrough' products in Cambodia | | | | 2 |
| Develop certain product technologies in Cambodia | <u>A</u> | | | 2 |
| Avoid certain product technologies in | | 1 | 1 | 1 |
| Cambodia | Not done Done, but regulation has NO influence Done & regulation has SOME influence Done and regulation has CONSIDERABLE ir | nfluence | Not done Done, but regulation has Done & regulation has S0 Done and regulation has | NO influence DME influence CONSIDERABLE influence |

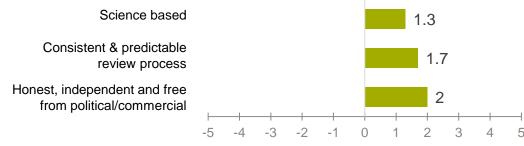
MYANMAR: Assessment on current climate on product registration achievement More than half thinks that the current climate of product registration is good and has kynetec improved in all areas since 2014



Data shown mean score

In comparison with 2014 (benchmark), is current product registration

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



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

MYANMAR: Assessment on current climate on product registration <u>complexity</u> Complexity of product registration is quite average with some nominal improvement **kynetec** over the past 5 years



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



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

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

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



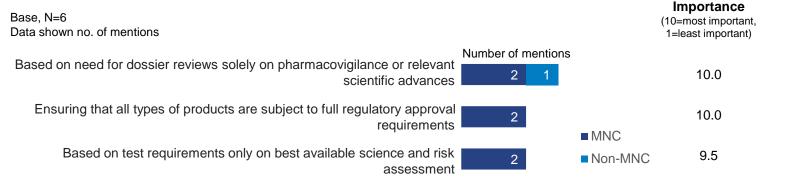
Importance (10=most important,

| Base, N=6 | 1=least important) |
|---|------------------------|
| Data shown no. of mentions | Number of mentions 9.7 |
| Base quality standards solely on animal health industry requirements | 2 1 |
| Less ad-hoc / frequent change of regulation | 9.0 |
| Improvement of capability / knowledge & manpower of regulators | 2 7.0 |
| Accept relevant/high quality test results from other sectors, species or regions | 2 8.0 |
| Remove redundant and overlapping guidelines | 9.5 |
| Better border control (to prevent illegal products entering the market) | 8.0 |
| Provide specific incentives to develop new products for small markets | 10.0 |
| Use consultation & impact assessment when developing new guidelines | 6.0 |
| Provision of feedback loop on new regulation before implementation | 7.0 |
| Change test requirements only with scientific justification | 9.0 |
| Remove political involvement in testing and approval | 1 MNC 6.0 |
| Less local protectionism (e.g. same standard applies to both local and MNC companies) | 1 Non-MNC 10.0 |

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

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

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





F4. What expected changes have <u>NOT</u> occurred in regulatory frameworks SINCE 2014 despite of expectations of change?
F5. What regulatory changes SINCE 2014 have given you the most problems and why?
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MYANMAR: Expected regulatory framework changes that have not occurred since 2014 Regulations in Cambodia have been unclear, possibly due to political issues – this has caused significant problems amongst some companies

Base, N=6 Data shown no. of mentions

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



MYANMAR: Major decisions taken over the past 5 years due to regulations in place...(1) Regulations in Myanmar has brought considerable influence in companies to increas ynetes product range and focusing on existing or older technologies in Myanmar

Base, N=6 Data shown no. of mentions

| Locate R&D Facilities in Myanmar | 4 | | | 1 | | 1 |
|--|--|---|---|---|-----------|---|
| Switch R&D budgets to labs in Myanmar | 4 | | | 1 | | 1 |
| Invest in production in Myanmar | 4 | | | | 2 | |
| Increase product range in Myanmar | 2 | 1 | 2 | 2 | | 1 |
| Reduce product range in Myanmar | 4 | | | | 2 | |
| Increase (geographic) market focus in Myanmar | 3 | | 1 | | 2 | |
| Restrict (geographic) market focus in Myanmar | | 5 | | | | 1 |
| Increase coverage of species or indications in Myanmar | 4 | | | | 2 | |
| Reduce coverage of species or indications in Myanmar | | 5 | | | | 1 |
| Buy businesses in Myanmar | | 5 | | | | 1 |
| | Not done = Done, but regulation has NO influence Done & regulation has SOME influence = Done and regulation has CONSII | | | | influence | |

F6. Have regulations played a major role in influencing you to take any of the following major decisions over the last five years? © Kynetec June 11, 2019 | ASEAN Animal Health Regulatory Benchmarking Survey – Stage 3 (Online Quantitative) MYANMAR: Major decisions taken over the past 5 years due to regulations in place...(2) Regulations in Myanmar has brought considerable influence in companies to increas ynetes product range and focusing on existing or older technologies in Myanmar

Base, N=6 Data shown no. of mentions

| Sell or close businesses in Myanmar | 5 | | 1 |
|---|---|---|---|
| Focus on new technologies in Myanmar | 3 | 1 | 2 |
| Focus on existing/older technologies in Myanmar | 3 | 2 | 1 |
| Introduce more 'breakthrough' products in Myanmar | 3 | 1 | 2 |
| Introduce fewer 'breakthrough' products in Myanmar | 5 | | 1 |
| Develop certain product technologies in Myanmar | 4 | | 2 |
| Avoid certain product technologies in | 5 | | 1 |
| Myanmar * | Not done Done, but regulation has NO influence Done & regulation has SOME influence Done and regulation has CONSIDERABLE i | | |