

# The report of “Survey about counterfeit medicines”

January 16, 2013

International committee IFPMA•

International cooperation working group

Global health group

## Survey summary

- Purpose:** Conduct a survey for member companies in order to understand the efforts of each company against counterfeit medicines
- Surveyed subject:** Member companies of Japan Pharmaceutical Manufacturers Association
- Surveyed area:** All parts of Japan
- Survey method:** Internet survey
- Survey period:** From September 14 (Fri.), 2012 to October 12 (Fri.), 2012
- Number of valid responses:**  
67
- Survey conducting organization:**  
Macromill Inc.

# Profiles of responders

## List of responding companies

Asahi Kasei Pharma Corporation  
Ajinomoto Pharmaceuticals Co., Ltd.  
ASKA Pharmaceutical Co., Ltd.  
Astellas Pharma Inc.  
Astra Zeneca  
Eisai Co., Ltd.  
Otsuka Pharmaceutical Co., Ltd.  
Ono Pharmaceutical Co.,Ltd.  
KAKETSUKEN  
KAKEN PHARMACEUTICAL CO.,LTD.  
Kissei Pharmaceutical Co., Ltd.  
Kyoto Pharmaceutical Industries Co.,Ltd.  
Kyorin Pharmaceutical Company, Limited  
Kyowa Hakko Kirin Co., Ltd.  
Kracie Pharma, Ltd.  
Kowa Company, Limited  
SANTEN PHARMACEUTICAL CO., LTD.  
SANWA KAGAKU KENKYUSHO CO.,LTD.  
Shionogi & Company, Limited  
SEIKAGAKU CORPORATION  
Zeria Pharmaceutical Co., Ltd.  
SENJU PHARMACEUTICAL CO.,LTD.  
Daiichi Sankyo Company, Limited  
Taisho Pharmaceutical Co., Ltd.  
Dainippon Sumitomo Pharma Co.,Ltd.  
TAIHO Phamaceutical Co.,Ltd.  
Takeda Pharmaceutical Company Limited  
Mitsubishi Tanabe Pharma Corporation

Teikoku Seiyaku co.,ltd.  
Teijin Pharma Ltd.  
TERUMO CORPORATION  
Toa Eiyo Ltd.  
Toray Industries  
Toyama Chemical Co., Ltd.  
Torii Pharmaceutical Co., Ltd.  
Nippon Kayaku Co.,Ltd.  
Nippon Chemiphar Company, Limited  
Nippon Shinyaku Co., Ltd.  
NIHON PHARMACEUTICAL CO., LTD.  
Nippon Zoki Pharmaceutical Co., Ltd.  
JAPAN TABACCO INC.  
Hisamitsu Pharmaceutical Co., Inc.  
Fujimoto Pharmaceutical Corporation  
Fuso Pharmaceutical Industries, Ltd.  
POLA-Pharma  
Maruishi Pharmaceutical Co.Ltd.  
Maruho Co.,Ltd.  
Minophagen Pharmaceutical Co., LTD.  
Meiji Seika Pharma Co., Ltd.  
MOCHIDA PHARMACEUTICAL CO.,LTD.  
Yakult Honsha Company, Limited  
Wakamoto Pharmaceutical Co., Ltd.

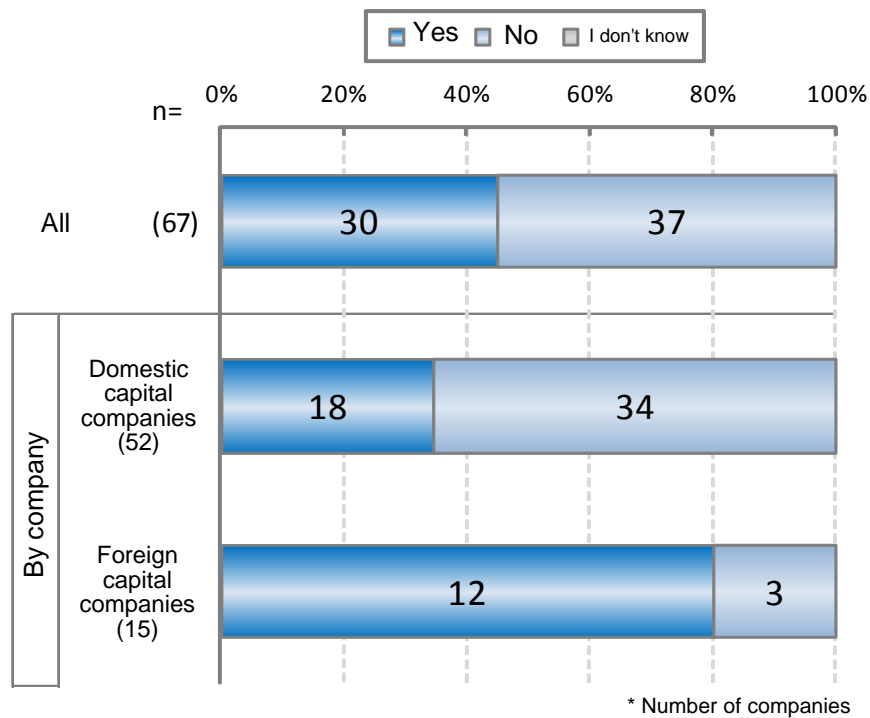
Abbott Japan Co., Ltd.  
MSD K.K.  
Glaxo Smithkline K.K.  
Sanofi K.K.  
Genzyme Japan K.K.  
Celgene K.K.  
Chugai Pharmaceutical Co., Ltd.  
Eli Lilly Japan K.K.  
Nippon Boehringer Ingelheim Co ., Ltd.  
Novartis Pharma K.K.  
Novo Nordisk Pharma Ltd.  
Bayer Yakuhin, Ltd.  
Baxter  
Pfizer Japan Inc.  
Janssen Pharmaceutical K.K.

# 1 Existence or non-existence of departments dealing with counterfeit medicines

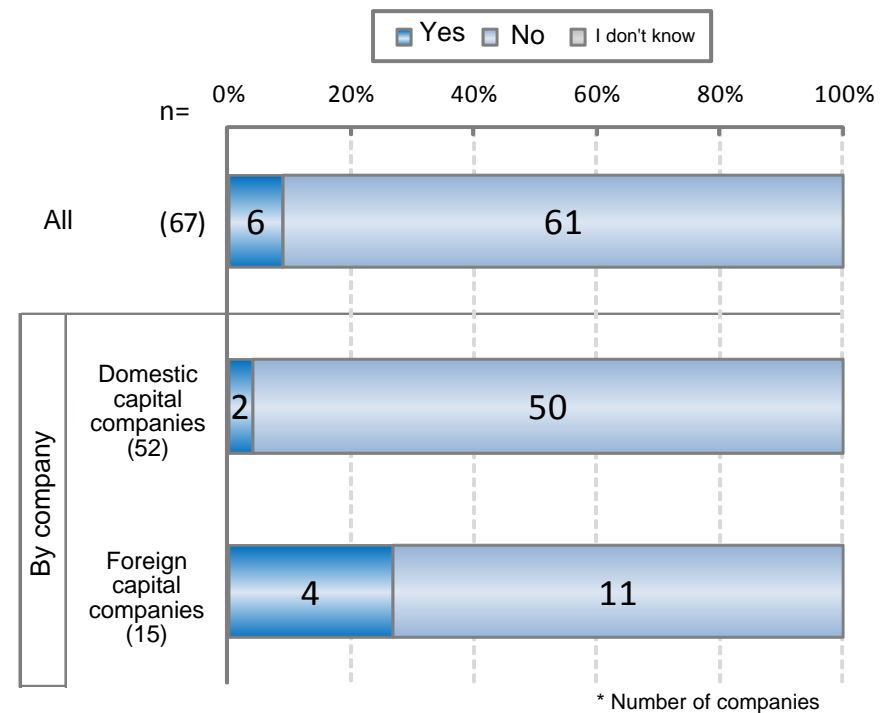
SA

Q3 Does your company (including a parent company) have departments which deal with countermeasures against counterfeit medicines domestically and globally?

[Domestic] Does your company have organizations or departments which are dealing with countermeasures against counterfeit medicines?



[Domestic] Does your company have organizations or departments which exclusively or mainly deal with countermeasures against counterfeit medicines?



< Domestic >

Thirty out of 67 (44.8%) companies answered that they had departments which dealt with countermeasures against counterfeit medicines. Break down was 18/52 (34.6%) for domestic capital companies and 12/15 (80%) for foreign capital companies.

Companies that had departments which exclusively or mainly dealt with counterfeit medicines were 2/52 (3.8%) for domestic capital and 4/15 (26.6%) for foreign capital.

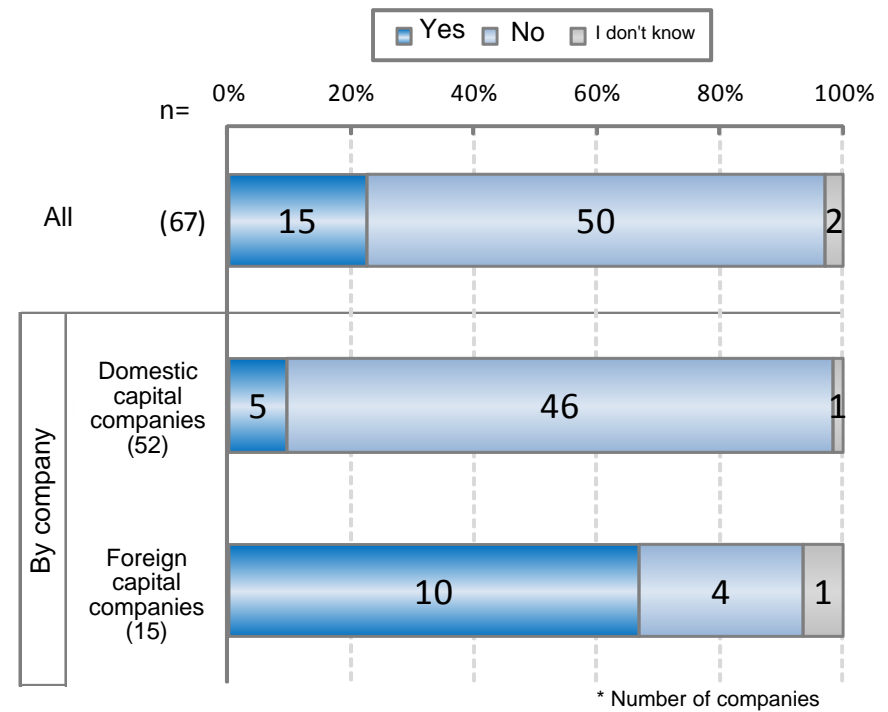
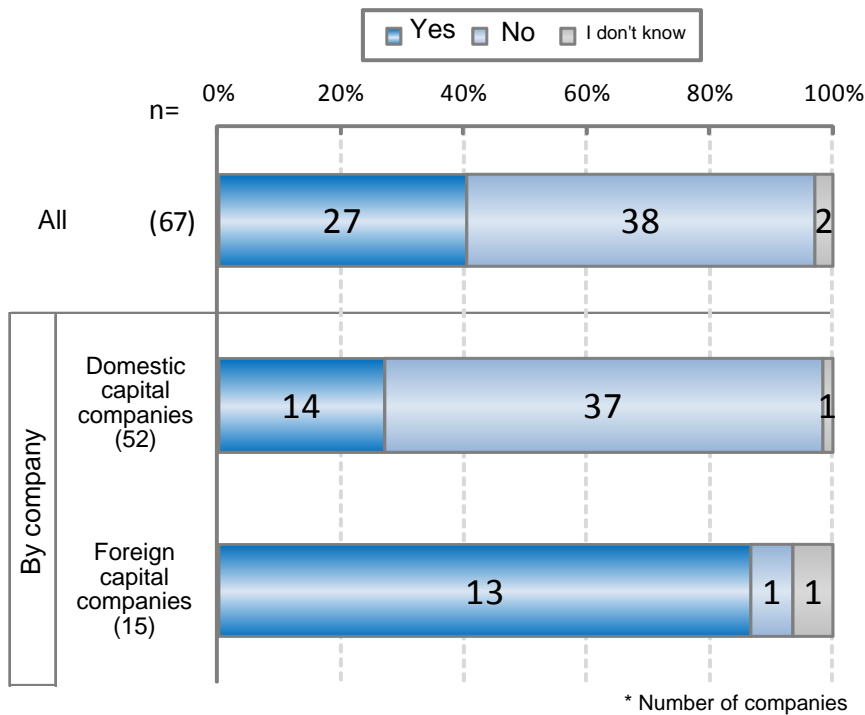
# 1 Existence or non-existence of departments dealing with counterfeit medicines

SA

Q3 Does your company (including a parent company) have departments which deal with countermeasures against counterfeit medicines domestically and globally?

[Global] Does your company have organizations or departments which are dealing with countermeasures against counterfeit medicines?

[Global] Does your company have organizations or departments which exclusively or mainly deal with countermeasures against counterfeit medicines



<Global>

Twenty seven out of 67 (40.2%) companies answered that they had departments which deal with counterfeit medicines.

Break down is that 14/52 (26.9%) for domestic capital companies and 13/15 (86.6%) for foreign capital companies.

Companies that have departments which exclusively or mainly deal with countermeasures against counterfeit medicines are 5/52 (9.6%) for domestic capital companies, and 10/15 (66.6%) for foreign capital companies.

## 2 Names of departments which deal with counterfeit medicines (Domestic/global)

FA

Q4 Please list names of departments or organizations within your company which deal with countermeasures against counterfeit medicines domestically and globally, respectively.

### < Domestic >

For most of the companies, the department which leads countermeasures against counterfeit medicines is a quality assurance department, however, there are some companies which have a security office as an exclusive department.

Departments which deal with countermeasures against counterfeit medicines include quality assurance, production, legal, intellectual property, marketing, public relations, and pharmaceutical departments.

### < Global >

For global, a security department mainly deals with countermeasures against counterfeit medicines.

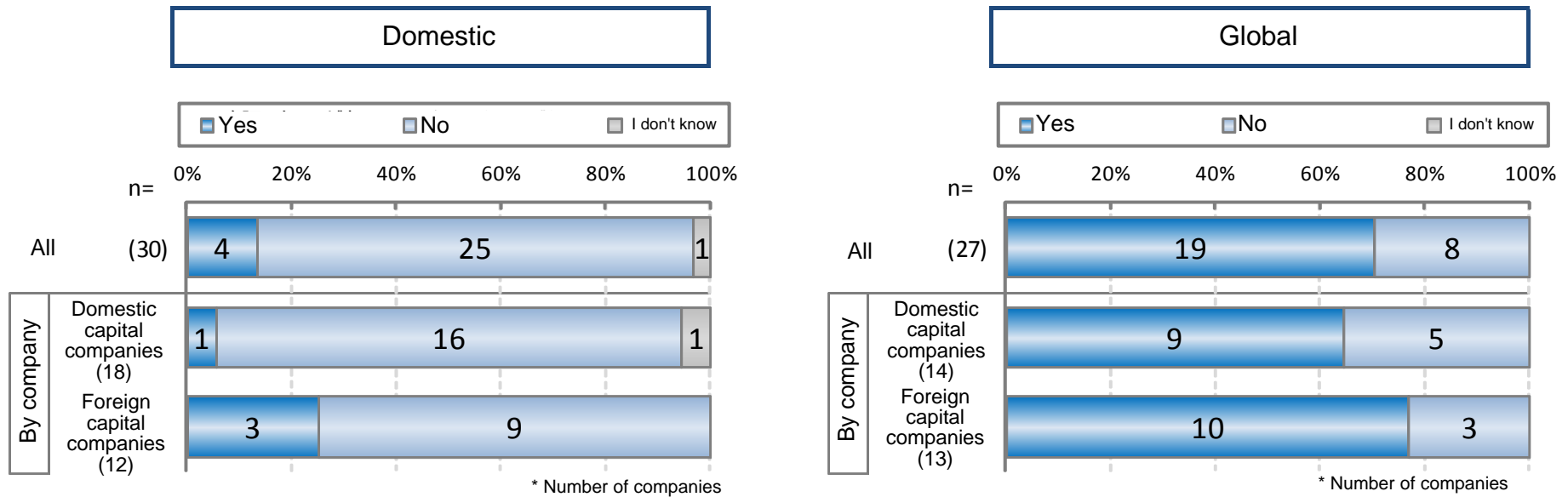
Departments which deal with countermeasures against counterfeit medicines include quality assurance, production, legal, intellectual property, compliance, public relations, and pharmaceutical departments, as well as an international business department and overseas subsidiaries.

### 3 Existence or non-existence of counterfeit medicines of your company's products

SA

Q5 Has your company (including a parent company) confirmed the existence of counterfeits of your company's products, domestically and globally?

\* Among the companies that have organizations or departments which deal with countermeasures against counterfeit medicines



< Domestic >

Domestically, 4 out of 30 companies (13.3%) have confirmed counterfeit medicine of their products.

< Global >

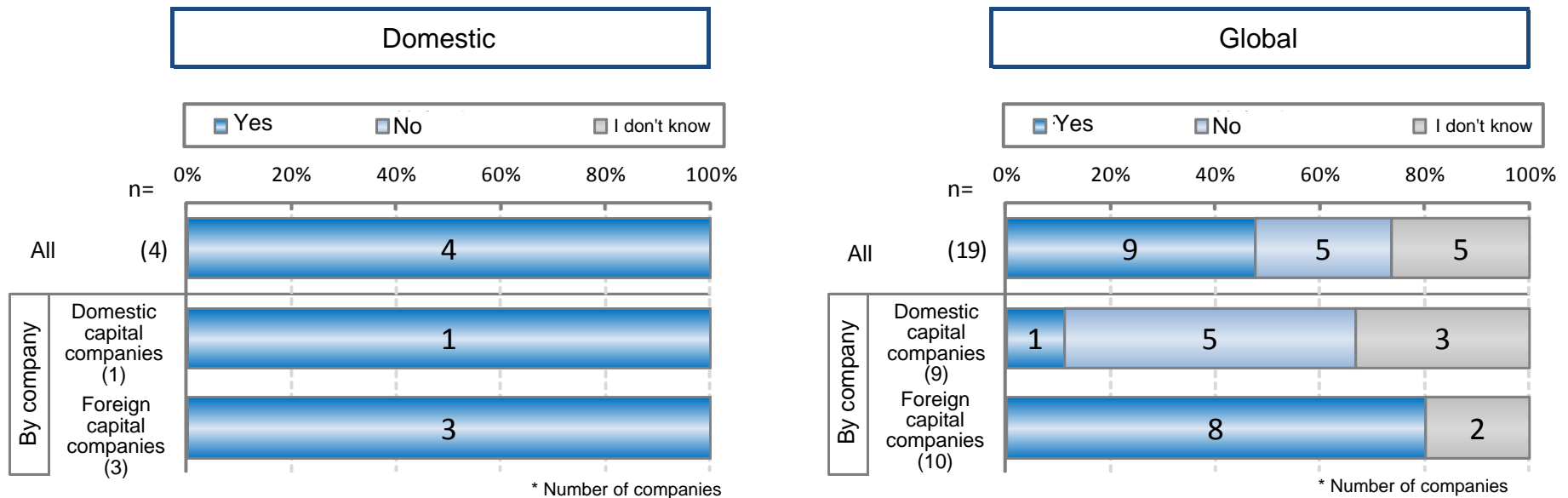
Globally, among the companies that had departments which deal with countermeasures against counterfeit medicines, 19 out of 27 companies (70.3%) have confirmed existence of counterfeit medicines of their products.

## 4 Existence or non-existence of health problems caused by counterfeit medicines

SA

Q6 You answered that you have "confirmed" the existence of counterfeits of your products domestically and globally in your company (including a parent company). Has your company suffered any damage in which health problems were suspected?

\* Among the companies which "have confirmed" existence of counterfeit medicines of their products



For cases in which existence of counterfeit medicines was confirmed, 9/19 cases (47.3%) for global and 4/4 cases (100%) for domestic were "confirmed" by the companies as "possible health problems", which raises concern of actual effects on "patient's health" by counterfeit medicines.



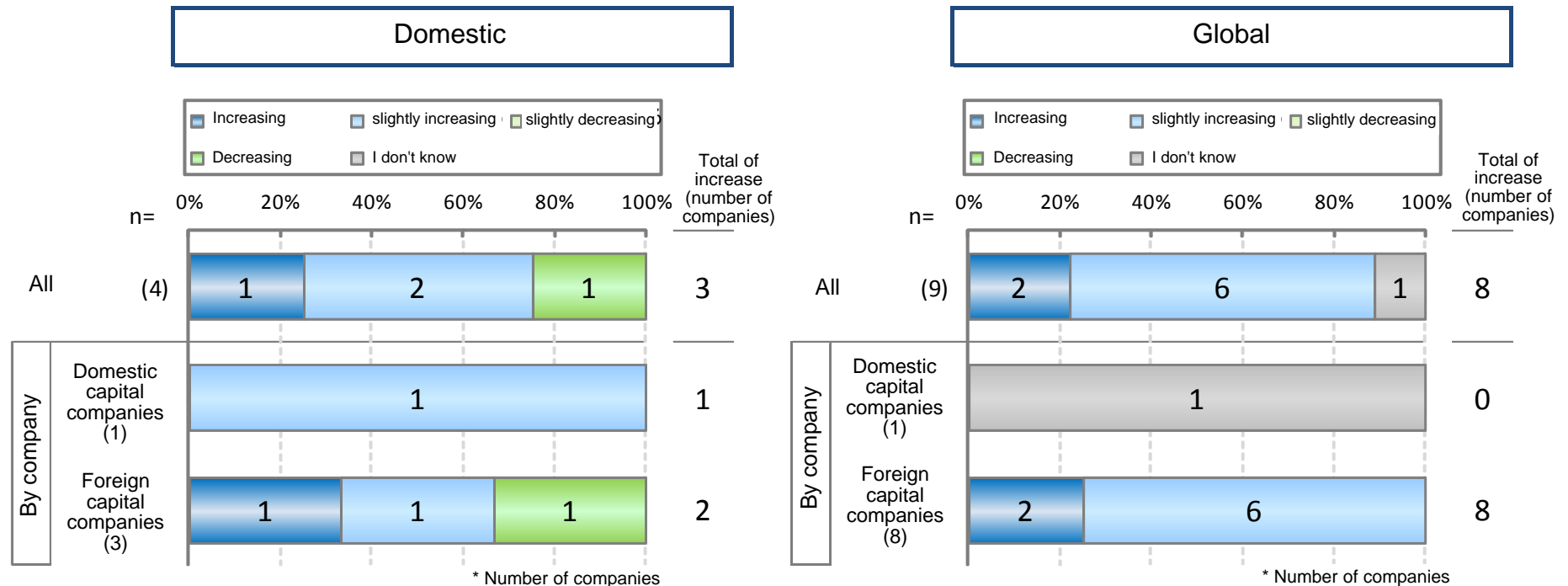
## 5 About the confirmed number of counterfeit medicines

SA

Q7 You answered that you have "experienced damage" by the existence of counterfeits of your products domestically and globally in your company (including a parent company).

Please indicate a trend of the number of confirmed cases of counterfeit medicines in the last 3-5 years.

\* Among the companies which "experienced damage" of health problems caused by existence of counterfeit medicines for their companies products



### < Domestic >

Among the companies which answered that they domestically experienced health problems caused by counterfeit medicines, 3/4 (75.0%) companies (2 foreign capital companies and 1 domestic capital company) stated that the number of confirmed cases of counterfeit medicines is increasing.

### < Global >

Among the companies which answered that they globally experienced damage caused by counterfeit medicines, 8/9 companies (88.9%) (8 foreign capital companies and 0 domestic capital company) stated that the the number of confirmed cases of counterfeit medicines is increasing, which indicates that the number of confirmed counterfeit medicines is on the increase.

# 6 Location and distribution channels which had counterfeit medicines

Q8 In your company (including a parent company) where or at which distribution channels did counterfeits of your company's products exist (or did you find them) domestically and globally? Please state all locations.

\* Among the companies which "have confirmed" existence of counterfeit medicines of their products



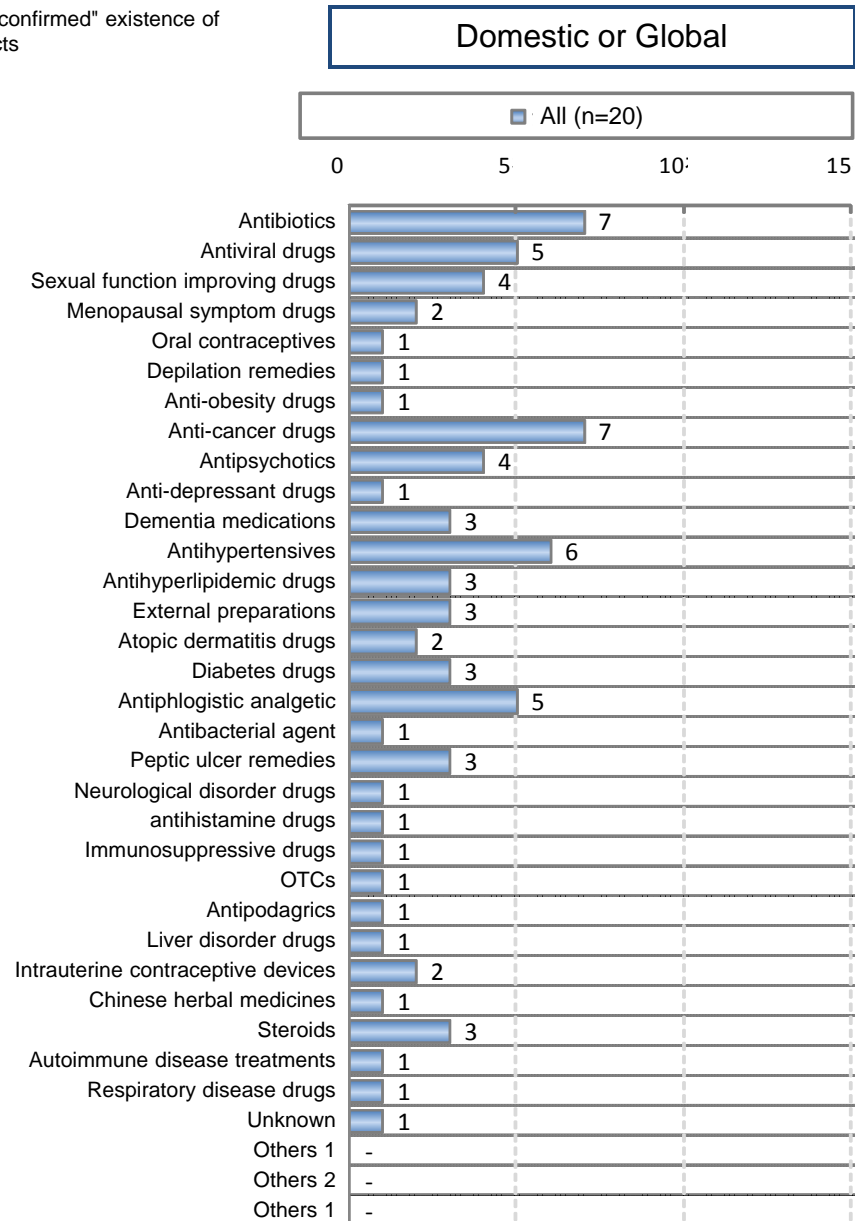
Within Japan, counterfeit medicines were confirmed by patients, customs, police and distribution channels for the internet. Globally, more than half of the cases were confirmed with police, customs, patients and internet. Then, counterfeits were confirmed at every step of drug distribution, such as agents, hospitals, and pharmacies.

# 7 Fields of counterfeit medicines, Domestic or Global [All]

MA

Q9 In which fields has your company (including a parent company) confirmed existence of counterfeits of your company's products, domestically and globally?

\* Among the companies which "have confirmed" existence of counterfeit medicines of their products



# 7 Field of counterfeit medicines

Q9 In which fields has your company (including a parent company) confirmed existence of counterfeits of your company's products, domestically and globally?

\* Among the companies which "have confirmed" existence of counterfeit medicines of their products



[In Japan]

- Among the companies which answered that they have confirmed counterfeit medicines in Japan, all companies including "domestic capital" and "foreign capital" indicated "sexual function improving drugs" as a field.

[Global]

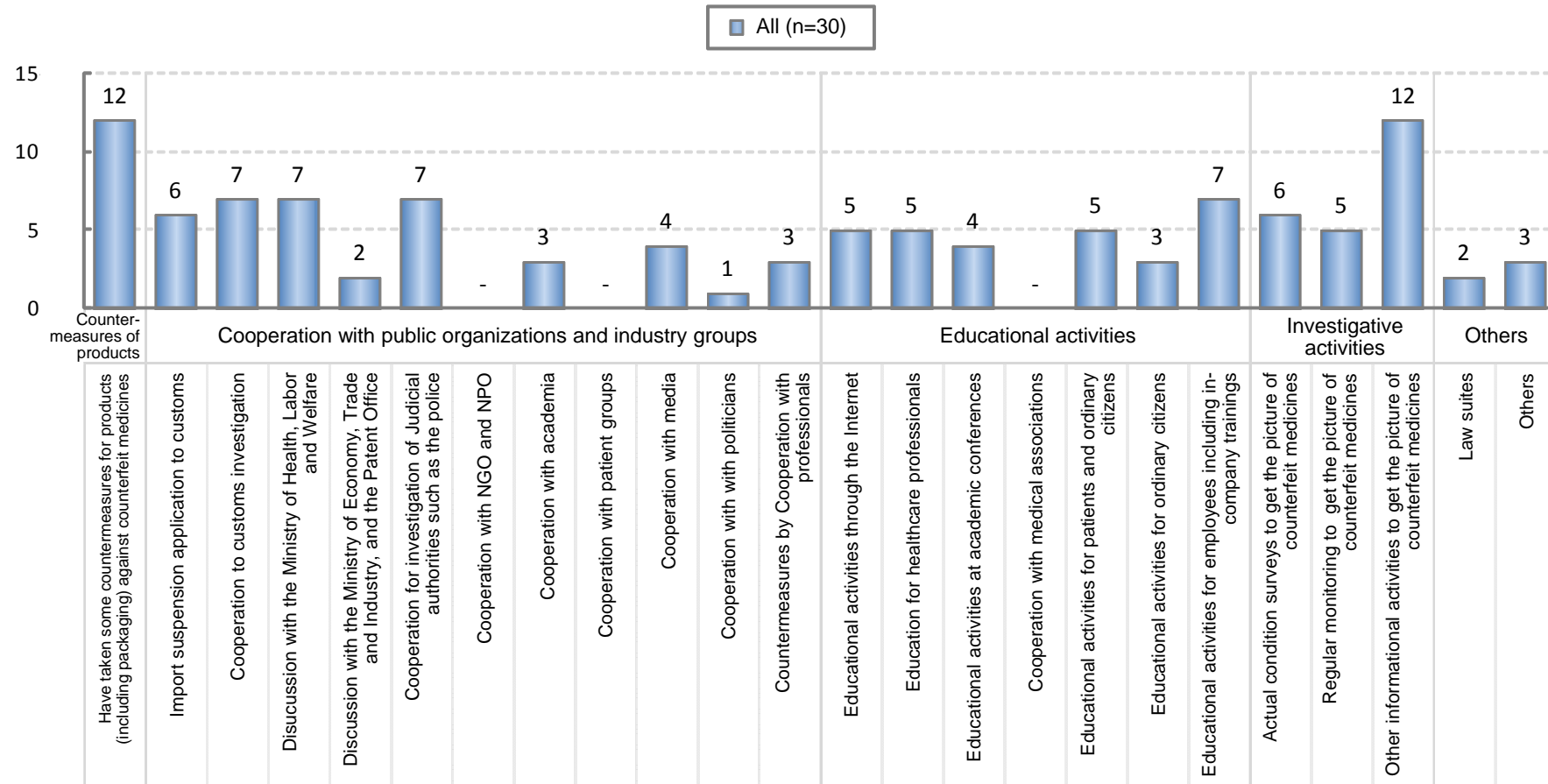
- Among the companies which answered that they have confirmed counterfeit medicines globally, "domestic capital companies" indicated "anticancer drugs", "antibiotics", and "antihypertensive drugs", and "foreign capital companies" indicated "antibiotics", "antiviral drugs", and "antiphlogistic analgetics, which cover a broader range of fields than those indicated by domestic capital companies.

# 8 Countermeasures against counterfeit medicines (domestic) [All]

MA

Q10 Please specifically tell us the countermeasures against counterfeit medicines that your company (including a parent company) is taking domestically.

\* Among companies that have departments or organizations which deal with countermeasures against counterfeit medicines

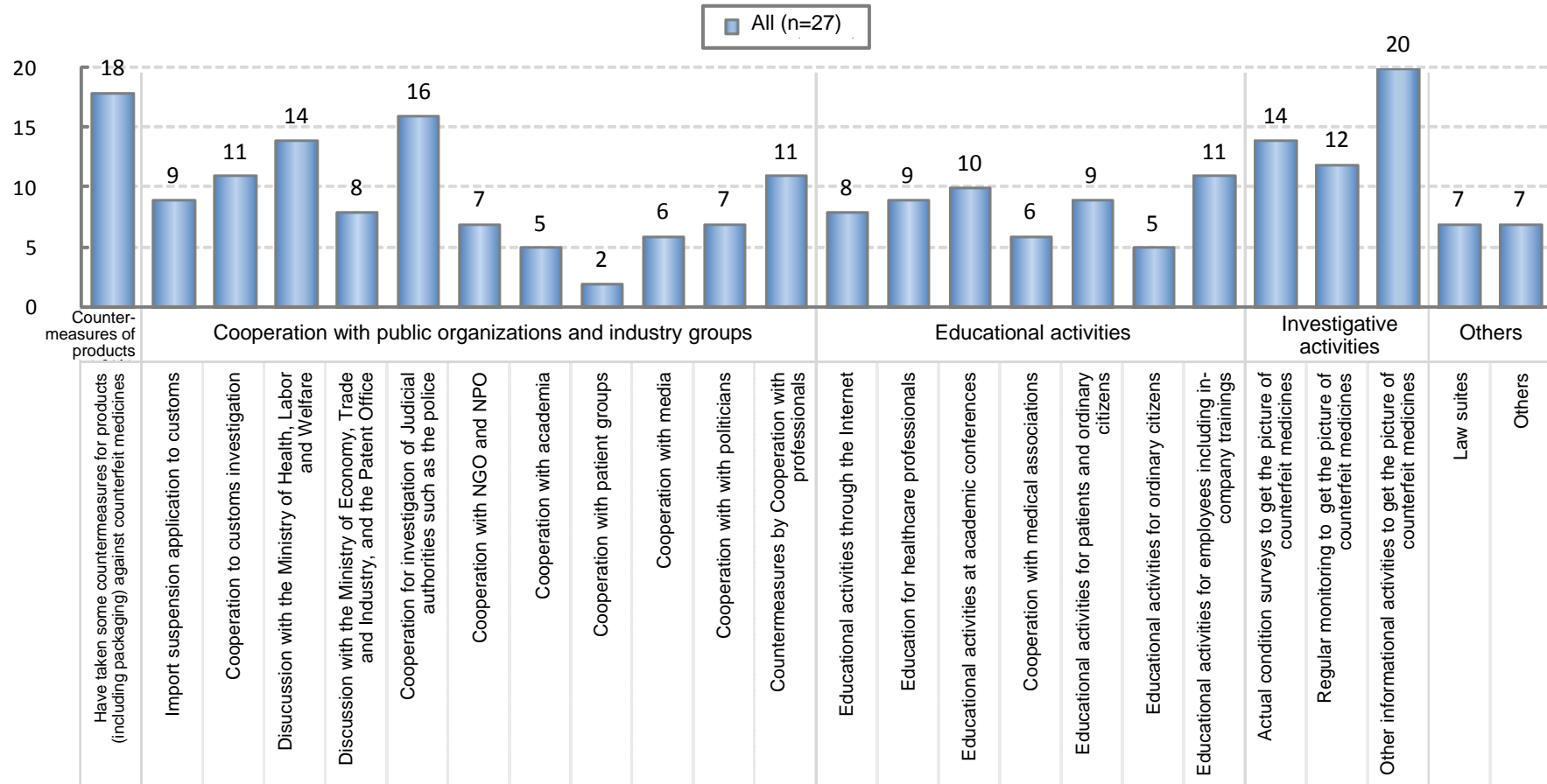


# 8 Countermeasures against counterfeit medicines (global) [All]

MA

Q11 Please specifically tell us the countermeasures against counterfeit medicines that your company (including a parent company) is taking globally.

\* Among the companies that have organizations or departments which deal with countermeasures against counterfeit medicines



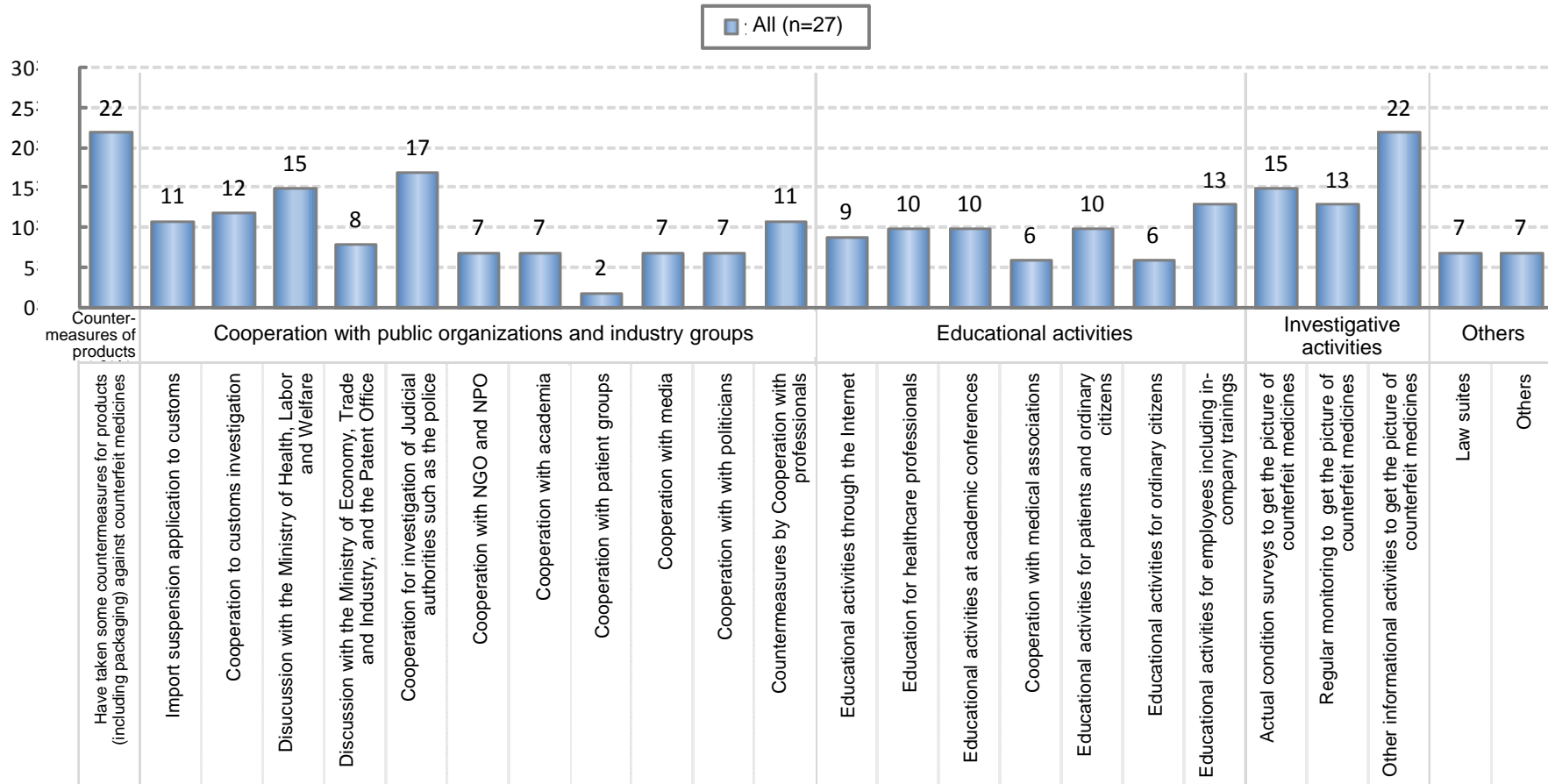
# Countermeasures against counterfeit medicines (domestic or global) [All]

MA

Q10 Please specifically tell us the countermeasures against counterfeit medicines that your company (including a parent company) is taking domestically.

Q11 Please specifically tell us the countermeasures against counterfeit medicines that your company (including a parent company) is taking globally.

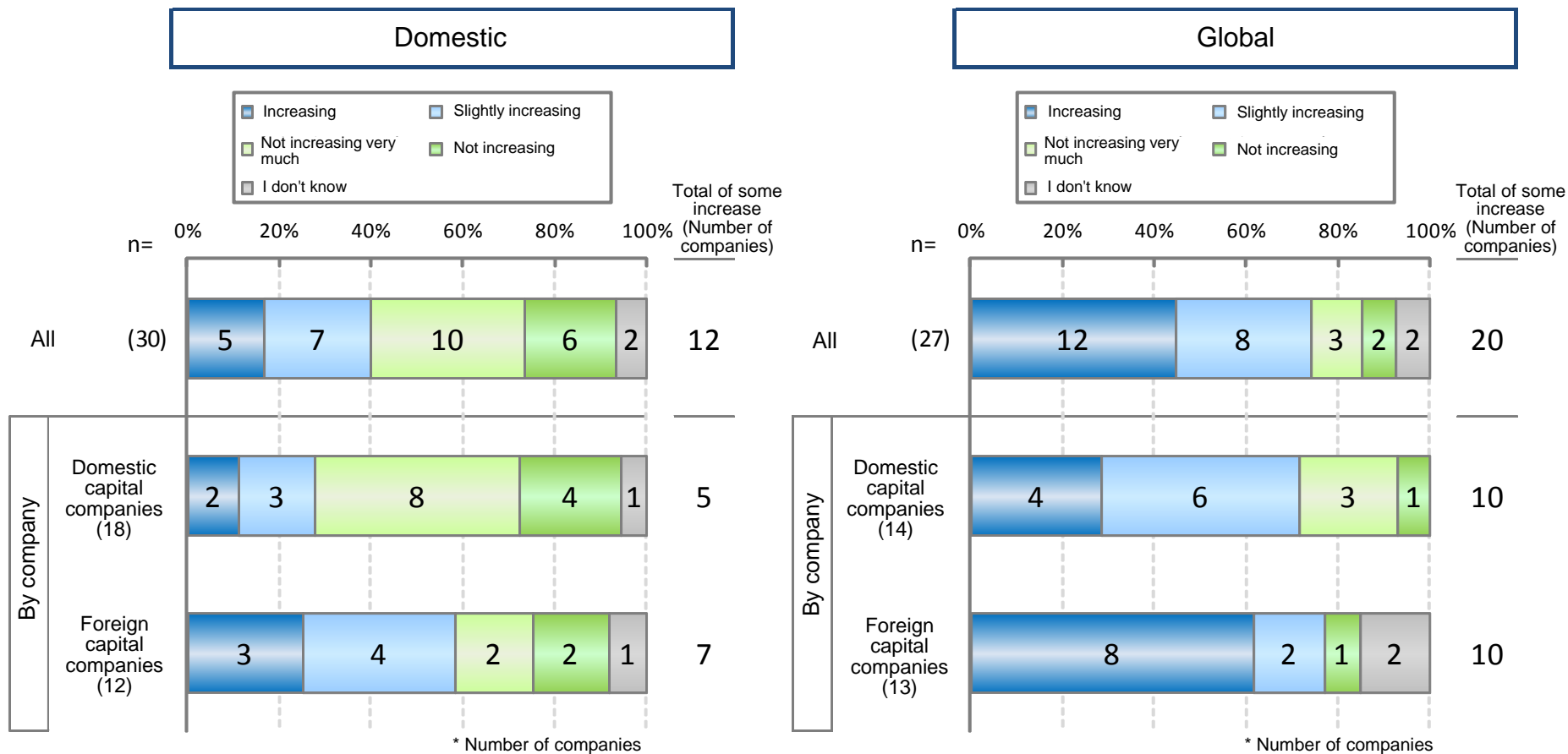
\* Among the companies that have organizations or departments which deal with countermeasures against counterfeit medicines



# 9 Direction of efforts against counterfeit medicines

Q12 Your company (including a parent company) has been domestically and globally making specific efforts against counterfeits of your company's products. Please tell us about the direction of the efforts against counterfeit medicines for the last three to five years.

\* Among the companies that have organizations or departments which deal with countermeasures against counterfeit medicines



Domestically, 12/30 companies (40.0%) are increasing efforts against counterfeit medicines, while 20/27 companies (74.0%) are increasing the efforts globally. More than half of the foreign capital companies are increasing the efforts domestically and globally. Ten out of 14 (71.4%) domestic capital companies are increasing the efforts globally, while only 5/18 (27.7%) of them are increasing the effort in domestically.

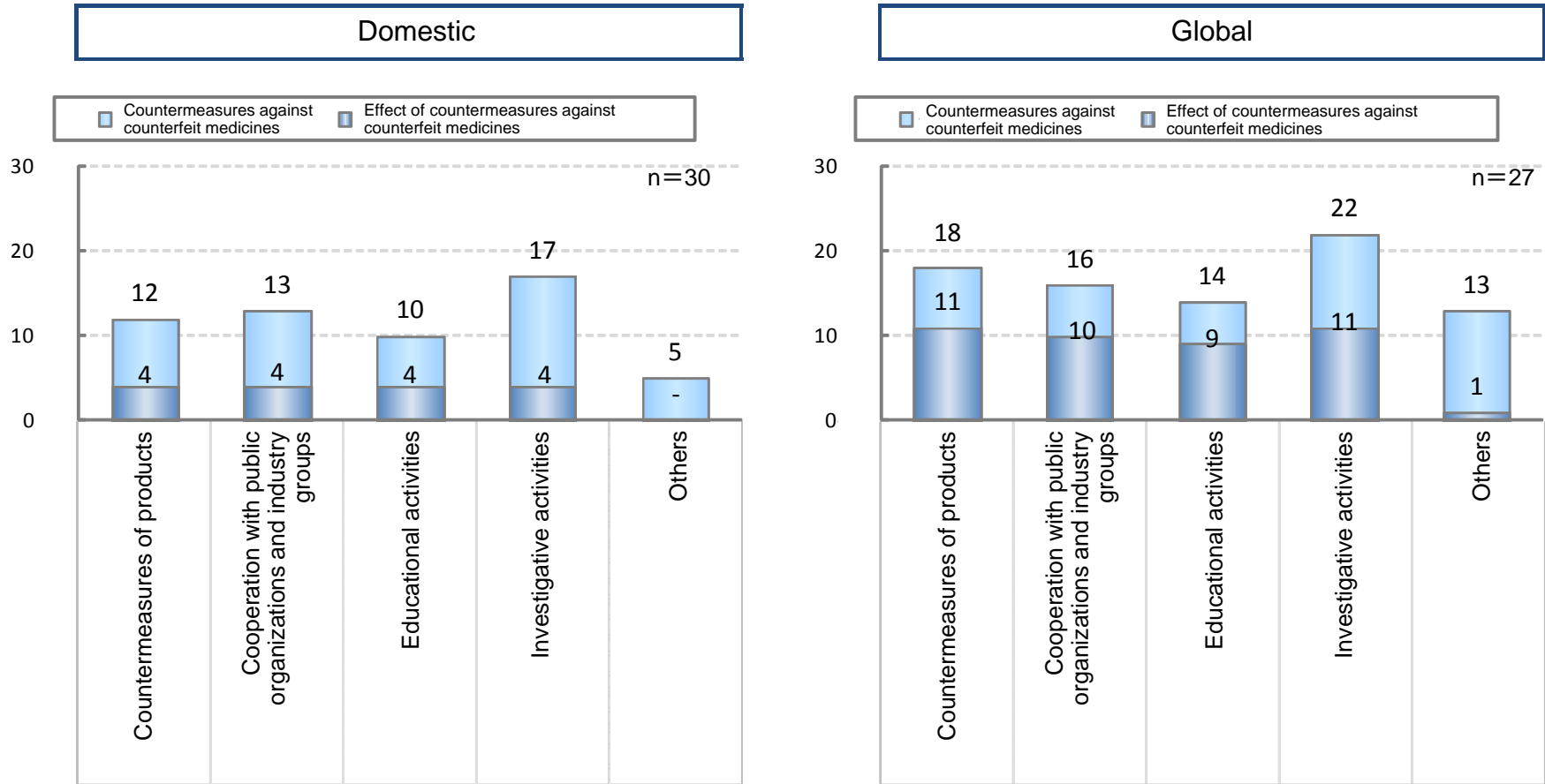


# 10 Effect of countermeasures against counterfeit medicines

MA/SA

Q10Q11 Please specifically tell us countermeasures against counterfeit medicines that your company (including a parent company) is taking domestically and globally.  
 Q13 Regarding the countermeasures taken against counterfeit medicines, how was the effect (outcome, results) for finding and suppressing counterfeit medicines?

\* Among the companies that have organizations or departments which deal with countermeasures against counterfeit medicines



< Domestic >

For countermeasures implemented in Japan, the results were investigative activities (17 companies), cooperation with public organizations and industry groups (13 companies), and countermeasures of products (12 companies). Four companies for each countermeasure answered that there was some effect by the measure (including educational activities).

< Global >

For countermeasures implemented globally, the results were investigative activities (22 companies), countermeasures of products (18 companies), and cooperation with public organizations and industry groups (16 companies). Numbers of companies which answered that they had some effect of the countermeasures are: 11 companies for investigative activities and countermeasures of products, 10 for cooperation with public organizations and industry groups, and 9 for educational activities. It appears that wide varieties of countermeasures implemented globally are more effective than those implemented in Japan.

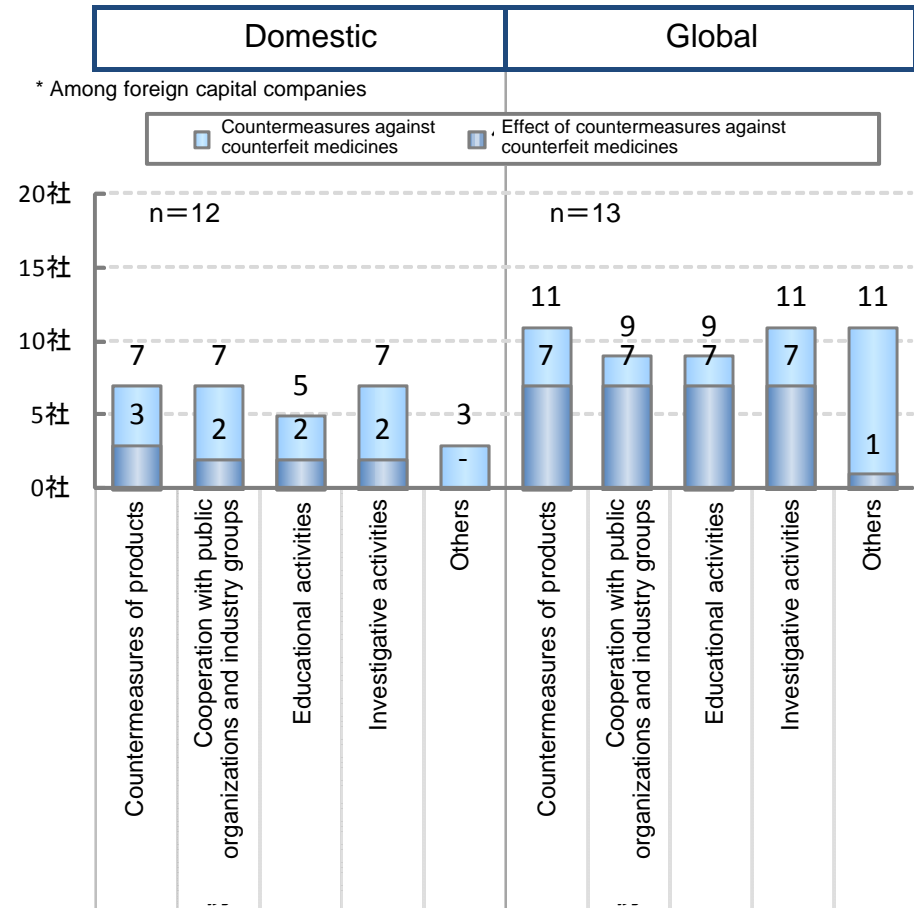
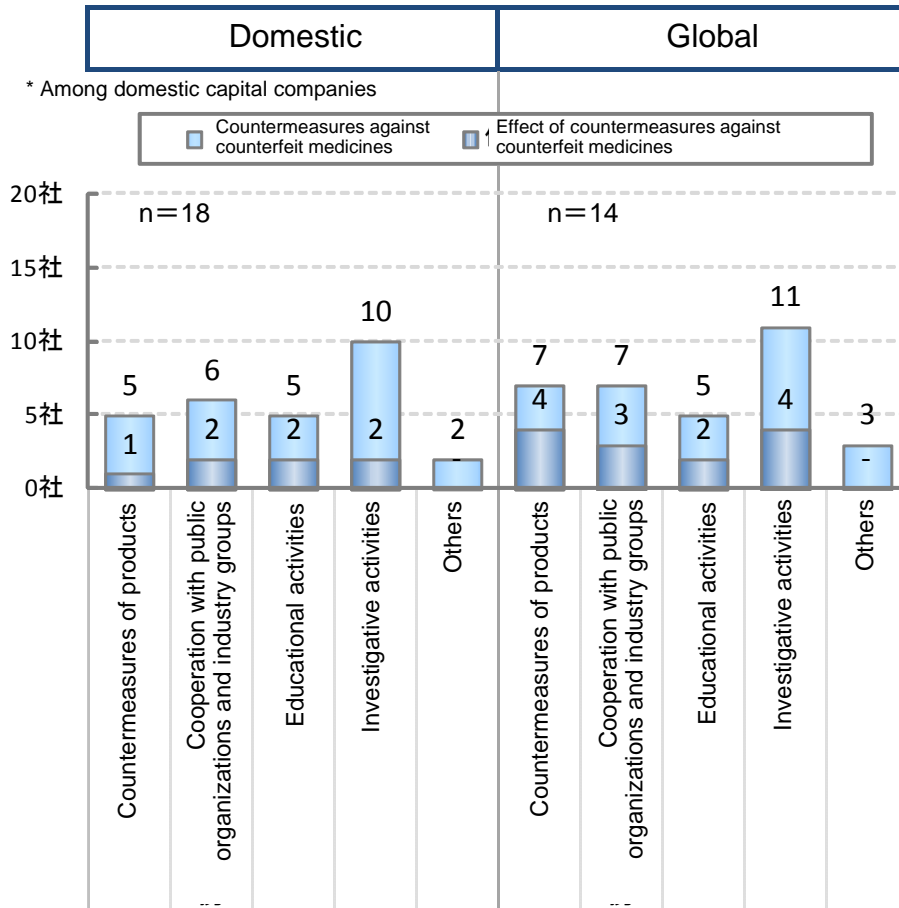
# 10 Effect of countermeasures against counterfeit medicines

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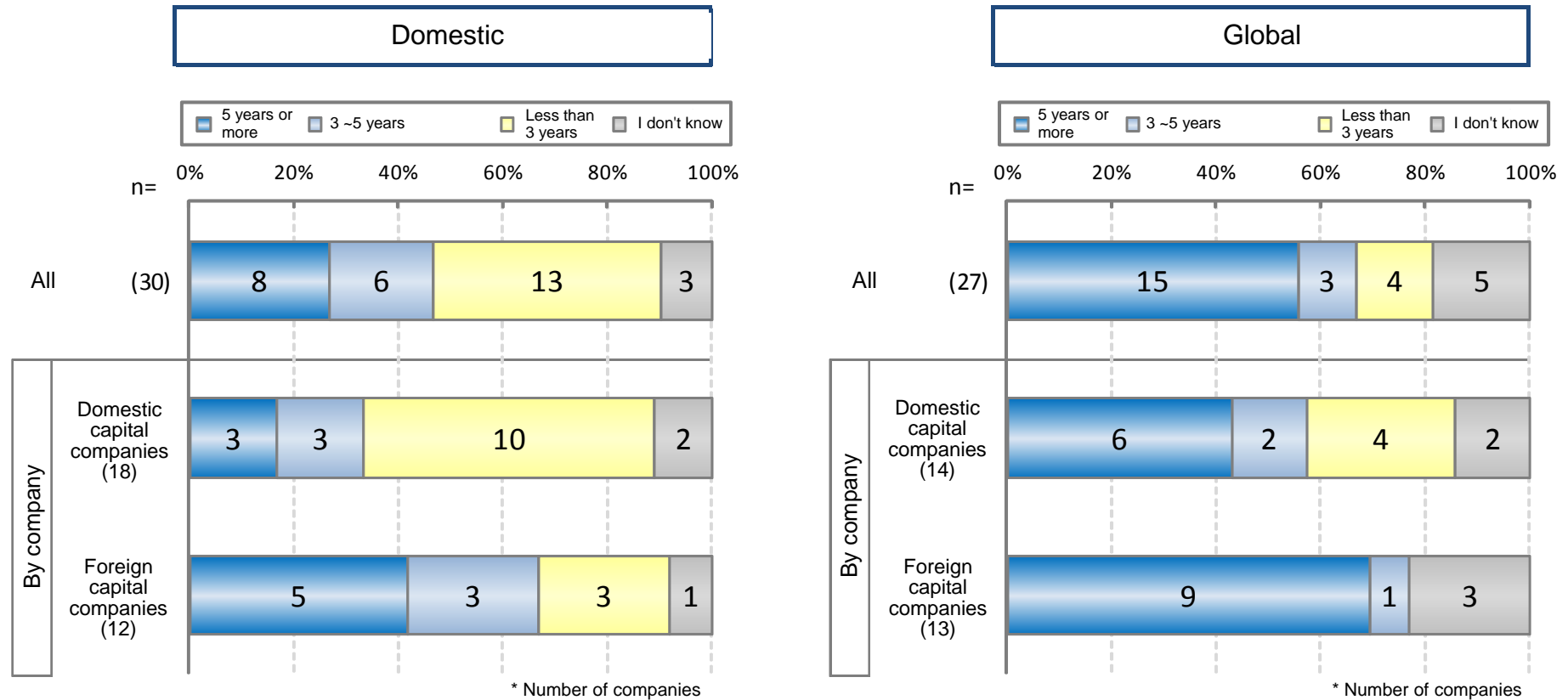


# 11 Time point that countermeasures against counterfeit medicines were started

SA

Q14 When did your company (including a parent company) start dealing with countermeasures against counterfeit medicines domestically and globally?

\* Among the companies that have organizations or departments which deal with countermeasures against counterfeit medicines



< Domestic >

Regarding the time point that countermeasures were started domestically, 13/27 companies (48.1%) answered less than 3 years ago, while <

< Global >

For globally, 15/22 companies (68.1%) answered that they started measures more than 5 years ago, which shows that they started dealing with this problem globally earlier than domestically.

For both domestically and globally, foreign capital companies started dealing with the problem earlier than domestic capital companies did.

# 12 Countermeasures against counterfeit medicines Cooperation with stakeholders (Domestic)

FA

Q15 What cooperation/coordination activities with stakeholders (industry groups, government and administrative agencies, academia, patient groups, NGO·NPO, and international organizations) does your company (including a parent company) do against counterfeit medicines? Please indicate specifically.

\* Among companies which are taking countermeasures with public organizations and industry groups against counterfeit medicines domestically

Cooperation and collaboration with stakeholders [ Q1 5S1 Domestic ]
<b>[Cooperation and lobbying to government]</b>
1. Cooperation for crackdown by the police and customs, 2. Educational activities by cooperating with local government's health authorities, 3. A crackdown and educational activities by cooperating with other sector peer companies, 4. Educational activities by cooperating with media, 5. Lobbying to the Health, Labor and Welfare Ministry and the Ministry of Economy, Trade and Industry, 6. Investigative cooperation, information provision and educational activity support for universities, healthcare professionals and academic associations.
When a large amount of counterfeit medicines were imported into Japan in the past, we requested cooperation from the Health, Labor and Welfare Ministry and the National Police Agency, and exchanged information with other sector peer companies.
Cooperation for investigation of Judicial authorities such as the police
We let the Health, Labor and Welfare Ministry know the actual situation by working with other companies which sell the same type of drugs, and encouraged the ministry to take action. Also, we are asking university professors cooperation for educational activities by disclosing the investigation results.
<b>[Sharing and exchanging information]</b>
We, as one of the leader companies, host information exchange meetings with voluntary domestic pharmaceutical companies.
Industry: Information exchange among sexual function improving drug sales companies, and joint authenticity judgment for imported products by individuals via the Internet Administrative agencies: Import suspension application to customs, cooperation with the police and customs investigations
Cooperation with Pharmaceutical Manufacturers' Association, and other companies, intelligence ties with 27 domestic companies, and exchange of opinions with World Customs Organization (WCO).
Conducting activities at the Pharmaceutical Manufacturers' Association, information provision to members of the Diet, information provision and lobbying to the Health, Labour and Welfare Ministry, cooperation for the police and customs investigations, and authenticity judgment training sessions for customs employees.
<b>[Import suspension at customs]</b>
Import suspension at customs for products which violate registered trademarks
Import suspension application at customs
<b>[Others]</b>
Request of lectures for educational purpose
Nothing particular
We are not cooperating.

[Industry] We host information exchange meetings which include information provided by companies that actually suffered damage, and lecture meetings for educational purposes.

[Government and administrative agencies] We host workshops for import suspension of products which violate registered trademarks at customs, police investigation, cooperation with customs investigation, and authenticity judgment training sessions for customs employees. When large amounts of counterfeit medicines were imported in Japan, we requested cooperation from the Health, Labor and Welfare Ministry and the National Police Agency. We also provide information to the Health, Labor and Welfare Ministry and members of the Diet.

[Others] We engage in educational activities via media and universities.

# 12 Countermeasures against counterfeit medicines Cooperation with stakeholders (Global)

FA

Q15 What cooperation/coordination activities with stakeholders (industry groups, government and administrative agencies, academia, patient groups, NGO·NPO, and international organizations) does your company (including a parent company) do against counterfeit medicines? Please indicate specifically.

\* Among companies which are taking countermeasures with public organizations and industry groups against counterfeit medicines globally

<b>Cooperation and collaboration with stakeholders [ Q1 5S2 Global]</b>
<b>[Information sharing and cooperation with various organizations and sector peer companies]</b>
Actively contributing to group activities by EFPIA, PhRMA in EU and international organizations in other countries
Activities at IFPMA, PhRMA, and EFPIA, and information provision and cooperation to investigations for each country's government, the police and customs authorities
Cooperation with PSI and member companies, and cooperation with judicial authorities through PSI
* Supporting the recommendations of national health authorities and WHO through International Medical Products Anti-Counterfeiting Taskforce, * Supporting the initiatives of EFPIA and EuropaBio papers on Counterfeit, * Cooperating with LiF, Denmark to further secure the distribution chain, * Member of Pharmaceutical Security Institute
We are exchanging information with the industry. We cooperate with government and administrative agencies for the investigations and detection.
Cooperation with wide range of the pharmaceutical industry regarding counterfeit medicine investigations. Enlightenment activities for international governments about increasing restrictions and penalties for counterfeit products. Activities such as creation of policies for countermeasures against counterfeit medicines, as a member of Pharmaceutical Security Institute (PSI), which conducts information collection and investigations. Activities for countermeasures against counterfeit medicines as a member of a group. Utilization of online tools (IPM). (Sent separately via email in English)
Sharing information regarding threat of counterfeit medicines. Conducting training regarding identifying and assessing counterfeit medicines.
Information exchange, sharing know-how, and information managing regarding counterfeit medicines (cooperation with corresponding working groups, in-house Internet sites regarding countermeasures against counterfeit medicines, cooperation with the authority's investigation, investigation of the Internet sites, participation to fund NGO groups such as EAASM and APM in Germany, member registration for PSI (Pharmaceutical Security Institute) ), cooperation with domestic and international groups, support for pilot programs such as the EFPIA coding project and the SecurPharm project in Germany, etc.
<b>[Cooperation and lobbying to government]</b>
Preparing laws and regulations through industry groups, and cooperation with key regulation authorities (the police, the Health, Labor and Welfare Ministry, and WHO etc.)
1. Cooperation for crackdown by the police and customs, 2. Educational activities by cooperating with local government's health authorities, 3. Educational activities by cooperating with media, 4. Lobbying activities to international organizations, Investigative cooperation, information provision and co-hosting of educational activities with universities, healthcare professionals and academic associations.
Information provision to government and administrative agencies. We actively exchange ideas and provide information by becoming a member of the Pharmaceutical Security Institute and the International Federation of Pharmaceutical Manufacturers & Associations.
We have established a coordination system with the police world wide to exchange information and track counterfeit medicines.
Cooperation with administrative agencies and agents
<b>[Others]</b>
We had a few cases in which counterfeit medicines were found, however, since they were sporadic, we did not take specific coordinated action with stakeholders.
Nothing particular
None

[Industry] We prepare laws and regulations, exchange information, and share know-how through industry groups such as IFPMA, EFPIA and hRMA.  
 [Government and administrative agencies] We provide information to the police and customs authority, cooperate with investigations, and provide information to foreign governments.  
 [Investigative body] We conduct investigations and collect information utilizing PSI (Pharmaceutical Security Institute).  
 [Others] We engage in educational activities by working with academia and cooperating with media.

# 13 Ideas for countermeasures against counterfeit medicines (Domestic)

Q16 What countermeasures do you think should be taken to minimize the occurrence and distribution of counterfeit medicines (including internet) domestically and globally? Please tell us your ideas.

Ideas are listed except for "nothing particular" and "I don't know".

What countermeasure do you think should be taken? [Q1 6 S1 Domestic]
<b>[Tightening of regulations and reformation of systems]</b>
Our company has not had an experience with counterfeit medicines, so we don't have any department to deal with it and have not considered any specific countermeasures. Therefore, in my personal opinion, I would suggest: 1. tightening of regulations for pharmaceutical sales on the Internet (especially increase surveillance on the Internet to detect suspicious products and sellers with illegal sale), and 2. efforts to share information and tighten regulations regarding counterfeit medicines by strengthening conventions between governments. I think countermeasures done by single companies have limitations.
A registration system of private import management companies on the Internet, educational activities for patients and medical institutions, issuing of GDP guidelines, and enhanced inspections at customs.
Introduction of an appropriate registration system for import management companies and pharmacies using the Internet, and increased enforcement.
I think we need to ask the government to tighten/adjust regulations and review the whole concept of private import.
Domestic regulations should be tightened so that the private import of medicines for personal use will not be permitted in principle.
Increased enforcement by administrative agencies including the police
Increased penalties
Restriction of private import managing companies (a permit system of companies which handle medicines)
Prohibition of drug sales on the Internet, and educational activities to publicize the safety of original medicines by calling for risk of counterfeit medicines.
Spreading related knowledge and information, and tightening enforcement
Restriction of internet trades
Tightening of regulations regarding agency service of private import of drugs which are approved in Japan. Cooperation with measures and policies of the Ministry of Health, Labor and Welfare.
An approval system of authorized import management agents as indicated in EU regulations, because private import is the problem in Japan.
Tightening of sales and distribution of drugs via the Internet. Banning of private import of drugs in principle.
Development of laws which would enable the customs and the police to make arrests with follow-up investigations of counterfeit medicines (control delivery) and undercover investigations. Toughening of the penalties for counterfeit medicine crimes (increase of punishment, and abolishment of suspension of a sentence. System revisions which make it easy to stop inflow of the funds to bank accounts (mostly accounts for internet banks) for payments.
I don't have any experience, so I don't know. Only thing I can think of is increasing enforcement based on the law.
Increased restrictions for sales and import agency service via the Internet.
Strengthen checking systems for wholesale and retailers when making purchases, as well as internet sales. Internet sales should be monitored more thoroughly.
<b>[Educational activities]</b>
Increase educational activities regarding counterfeit medicines.
Educational activities
1. Increased educational activities for consumers regarding preventing purchase of counterfeit medicines, 2. increased cooperation with administrative agencies, judicial authorities and the police, and 3. introduction of anticounterfeit and anti-modification technology
Countermeasures of products, cooperation with public organizations and industry groups, and educational activities.
Countermeasures of products, regular monitoring investigation and pressuring for removal of suspicious sites on the Internet, and continuous educational activities for general consumers.
Restriction of information which the general public can obtain for foreign drugs. Disclose specific cases and call for attention for internet purchases.
With normal distribution routes, I think the possibility that counterfeit medicines are slipped into ethical drugs is low. I think we should let not only people in the field but the general public know about what makes it illegal and the risk for mail order and online sales.
Educational activities for risks, and implementation of security measures for products.
Sharing cases initiated by the sector, sharing countermeasures, and conducting educational activities.
Promote patients and the general public's awareness for counterfeit medicines using media. Also, block access to illicit sites by cooperating with providers.
Large attention-seeking campaigns for counterfeit medicines by government and the mass media, •Have people recognize the risk of counterfeit medicines by featuring the theme in school education.

What countermeasure do you think should be taken? [Q1 6 S1 Domestic]
<b>[Cooperation with relevant parties]</b>
Cooperation with the regulation authorities and the media
In cases of our biological products, most of the products (human vaccines and blood preparations) are national assay products and they are sealed with seals issued by the government. Animal vaccines are national assay products, but they are governed by the Ministry of Agriculture, Forestry and Fisheries. In a way, they can be considered qualified products of national institutions, which plays a great part for anticounterfeit.
Conduct regular sampling investigation on the Internet to track distribution routes of counterfeit medicines, and make efforts to eliminate them. Conduct more frequent inspections of imported goods with cooperation and understanding of the customs.
Cooperate globally as necessary.
<b>[Collection of information]</b>
Enhancement of investigative activities and expansion of intellectual property rights
Development of a system in which an identification number is assigned to every packaging unit, and it can be electronically tracked using IT.
Enhancement of traceability, such as two dimensional bar codes.
Enhancement of information collection systems and surveillance systems, for example, setting up a contact point to collect information from someone who noticed counterfeit medicines (including healthcare professionals and general consumers).
1. Information sharing of counterfeit medicines among companies, 2. Approach to public organizations such as the Health, Labour and Welfare Ministry, the police, the Ministry of Finance (the customs), and the Ministry of Economy, Trade and Industry by the industry groups to ask them to enhance enforcement and toughen/modify the laws, 3. Education activities by the industry groups.
<b>[Others]</b>
Counterfeit medicines are causing problems in a limited area in Japan. I think enhancement of countermeasures in the area will result in preventing counterfeit medicines from spreading in other areas.
I don't have any ideas particularly for Japan. I think it is the same for global.
Sealing using special seals and packaging with special films
I think patients as well as medical institutions should be able to check information for drug packaging on the company home page. I think management with two dimensional bar codes is necessary as well.
You would be able to tell if a drug is a counterfeit or not by reading the special printing with, for example, a smart phone, and confirming if the drug is already used on a informed website.
Individual packaging of a product or sealing of a box with an anti-counterfeit tape.

# 13 Ideas for countermeasures against counterfeit medicines (Global)

Q16 What countermeasures do you think should be taken to minimize the occurrence and distribution of counterfeit medicines (including internet) domestically and globally? Please tell us your ideas.

Ideas are listed except for "nothing particular" and "I don't know".

What countermeasure do you think should be taken? [Q1 6 S2 Global]
<b>[Enhancement of regulations and enforcement]</b>
Registration system of internet pharmacies and enhancement of surveillance. Increased penalties for counterfeit medicines.
Enhancement of enforcement by the authorities in the country, expansion of intellectual property rights.
Increased penalties
Regulate import in developed countries (tightening of import at private level)
Development of systematic regulations, implementation of regular audits for suppliers to confirm material sources.
Increase the monitoring of supply chain with Track & Trace of products. Enhancement of regulations for parallel import.
Measures as indicated in the EU regulations.
Pharmaceutical companies coordinate on issuing certification for drug sale sites on the Internet, and recommending sale sites which have certification.
Confiscate production factories of counterfeits to stop the production by working with the governments of producing countries and exporting countries, and prevent the export by regulating at post offices, carriers, and the customs of the exporting countries.
1) Higher punishment for dealing with counterfeit drugs, 2) Improve the robustness of the legitimate supply chain in especially China.
Enhanced enforcement at customs
Track and trace of distribution routes, and implementation of registration system of wholesale, importers and exporters, and packaging companies
<b>[Introduction of anticounterfeit and anti-modification technology]</b>
For products sold in foreign countries, I think self-defense measures, such as implementation of a packaging design with advanced fabrication that is difficult to counterfeit, are necessary.
Security measure enhancement of products, enhanced online monitoring functions, and restraint mechanism against further criminal activities.
1. Introduction of anticounterfeit and anti-modification technology, 2. increased cooperation with administrative agencies, judicial authorities and the police, and 3. Increased educational activities for consumers regarding preventing purchase of counterfeit medicines.
Development of a system in which an identification number is assigned to every packaging unit, and it can be electronically tracked using IT.
Internet pharmacies which are controlled by serialization in the field and certification.
1. Anti-modification and anticounterfeit measures for drug packaging (modification prevention by packaging, management with two dimensional bar codes, counterfeit identification measures for packaging materials, distribution management of products). 2. Sharing information with stakeholders (information sharing on websites, and authenticity judgment). 3. Management based on legal framework.
We don't have a department which exclusively deals with counterfeits, but our labels have some features that identify our products. I think it's a good idea.
Sealing using special seals and packaging with special films
You would be able to tell if a drug is a counterfeit or not by reading the special printing with, for example, a smart phone, and confirming if the drug is already used on a informed website.

What countermeasure do you think should be taken? [Q1 6 S2 Global]
<b>[Cooperation with relevant parties]</b>
Cooperation with the regulation authorities
Cooperate with enforcement of counterfeit medicines by the government and the police in each country through reporting investigation results and analysis of confiscated products.
We will deal with it if the existence of counterfeit medicines is reported from our Asian local company.
Facilitate detection of counterfeit medicines by further activating a world wide network of pharmaceutical companies.
Anti-counterfeit measures, cooperation with public organizations and the industry groups, and educational activities.
Information sharing with other companies.
Requesting the customs to increase import prohibition measures, cooperation to the police investigations, and blocking illicit sites.
1. Information sharing of counterfeit medicines among companies, 2. Approach to public organizations by the industry groups to ask them to enhance enforcement and toughen/modify the laws, 3. Education activities by the industry groups.
<b>[Educational activities]</b>
Educational activities for patients and medical institutions, enhancement of inspections at the customs, increased cooperation with judicial authorities which are familiar with PSI, and increased penalties of pharmaceutical affairs laws and intellectual property laws.
Educational activities
We support the joint industry statement on "Internet Sales and Access to Safe Medicines" from IFPMA, PhRMA, EFPIA and JPMA. We would encourage an increase in public education and awareness as regard to the danger of buying pharmaceuticals over the internet and share information regarding known online counterfeit sellers. In addition, we would encourage stiffer penalties against the counterfeiters.
Disclose specific cases and call for attention for internet purchases.
<b>[Others]</b>
Implementation of regular audits and employee training for transport companies.
Implementation of countermeasures against counterfeit medicines, grasping of current circumstances with monitoring, and minimizing risks by cooperating with the governments of selling countries.
Analyze cases and repair weak points of regulations and distribution systems.
Patients should be able to check information for drug packaging on the company home page. I think management with two dimensional bar codes is necessary as well.

# 14 Risk awareness for counterfeit medicines (Domestic)

RANK

Q17 What do you think is your company's (including a parent company's) level of risk awareness for counterfeit medicines in Japan?

Please rank the following in descending order according to risk awareness. \* Regarding to ranking of risk awareness, please think as "if you were to rank them".

(Companies)

		n=	Loss of treatment opportunities for patients	Serious health problems to patients	Lead to deterioration of corporate brand	Lead to deterioration of product brand	Affect on revenues	Destroy practice/medical systems	Decrease patient morals	Weaken drug distribution systems
All		(67)	4	63	0	0	0	0	0	0
By company	Domestic capital	(52)	4	48	0	0	0	0	0	0
	Foreign capital	(15)	0	15	0	0	0	0	0	0

Among domestic capitals Risk awareness [domestic]	All	1	2	3	4	5
		Serious health problems to patients	Loss of treatment opportunities for patients	Lead to deterioration of corporate brand	Lead to deterioration of product brand	Destroy practice / medical systems
First	52	240	20	0	0	0
Second	52	16	144	12	4	28
Third	52	0	9	42	39	27
Fourth	52	0	6	30	38	10
Fifth	52	0	2	9	8	7
1st-5th total	52	256	181	93	89	72

Among foreign capitals Risk awareness [domestic]	All	1	2	3	4	5
		Serious health problems to patients	Loss of treatment opportunities for patients	Destroy practice / medical systems	Lead to deterioration of corporate brand	Lead to deterioration of product brand
First	15	75	0	0	0	0
Second	15	0	52	8	0	0
Third	15	0	0	12	12	9
Fourth	15	0	0	4	10	8
Fifth	15	0	0	3	1	2
1st-5th total	15	75	52	27	23	19

Sixty three out of 67 companies (94.0%) indicated "serious health problems to patients" as number one risk, which was most common among the responses. When we weighted the responses by the order (first is 5, second is 4, third is 3, fourth is 2 and fifth is 1) and added them up, the first was "serious health problems to patients" followed by "loss of therapeutic efficacy for patients", which indicates that many companies give first priority to risk awareness of problems to patients



# 15 Risk awareness for counterfeit medicines (Global)

RANK

Q18 What do you think is your company's (including a parent company's) level of risk awareness for counterfeit medicines globally?

Please rank the following in descending order according to risk awareness. \* Regarding to ranking of risk awareness, please think as "if you were to rank them".

\* Among the companies that have organizations or departments which globally deal with

(Companies)

		First							
		Loss of treatment opportunities for patients	Serious health problems to patients	Lead to deterioration of corporate brand	Lead to deterioration of product brand	Affect on revenues	Destroy practice/medical systems	Decrease patient morals	Weaken drug distribution systems
All	n=								
	(27)	2	25	0	0	0	0	0	0
By company	Domestic capital	(14)	2	12	0	0	0	0	0
	Foreign capital	(13)	0	13	0	0	0	0	0

Among domestic capitals Risk awareness [domestic]	All	1 Serious health problems to patients	2 Loss of treatment opportunities for patients	3 Lead to deterioration of corporate brand	4 Lead to deterioration of product brand	5 Destroy practice / medical systems
First	14	10	60	0	0	0
Second	14	36	8	8	0	0
Third	14	3	0	12	6	6
Fourth	14	2	0	2	12	4
Fifth	14	0	0	5	2	3
1st-5th total	14	51	68	27	20	13

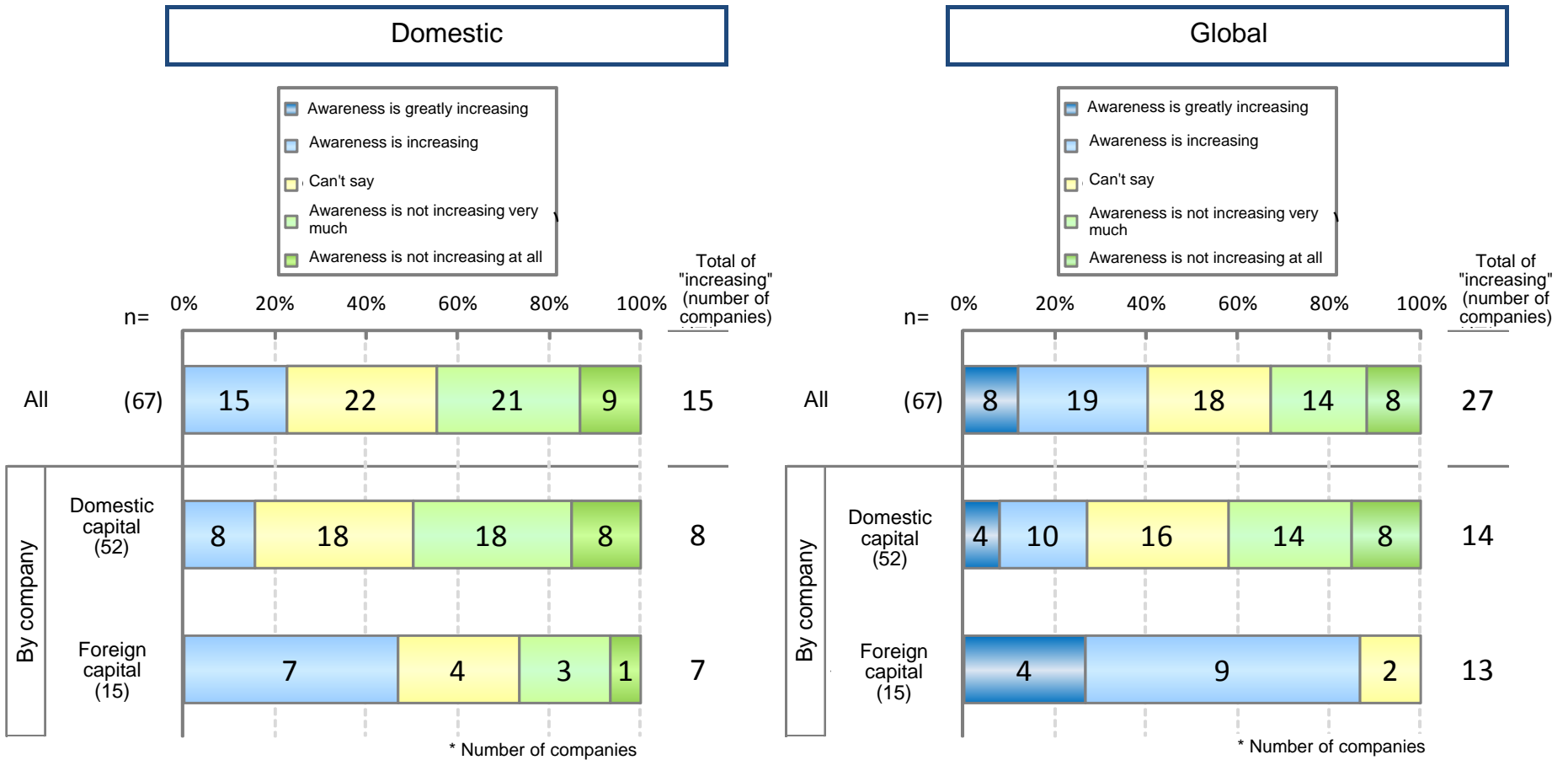
  

Among foreign capitals Risk awareness [domestic]	All	1 Loss of treatment opportunities for patients	2 Serious health problems to patients	3 Lead to deterioration of corporate brand	4 Lead to deterioration of product brand	5 Affect on revenues
First	13	0	65	0	0	0
Second	13	44	0	0	4	0
Third	13	0	0	15	3	0
Fourth	13	0	0	6	4	4
Fifth	13	0	0	1	4	1
1st-5th total	13	44	65	22	15	5

Results for global were the same as for domestic. Twenty five out of 27 companies (92.5%) indicated "serious health problems to patients" as number one risk of counterfeit medicines, which indicates that the majority of the companies consider that health problems caused by counterfeit medicines hold the highest risk. Then it was followed by "loss of therapeutic efficacy to patients", "lead to deterioration of corporate brand", and "lead to deterioration of product brand", which indicates that there is no difference between domestic and global in risk awareness for counterfeit medicines.

# 16 Awareness of counterfeit medicines

Q19 How has the awareness of counterfeit medicines been changing domestically and globally in your company (including a parent company) for the last several years?



< Domestic >

Fifteen out of 67 companies (22.3%) answered that awareness is "increasing". None of domestic or foreign capital companies responded as it is "greatly increasing".

< Global >

Twenty seven out of 67 companies (40.2%) responded that the awareness is "increasing (+ greatly increasing)", which indicates that the awareness of both domestic and foreign capital companies is increasing compared to domestic results. Especially, with foreign capital companies, majority of them (13 out of 15 (86.6%)) answered that the awareness is "greatly increasing" or "increasing".