

## **Report on the 2<sup>nd</sup> Survey about Counterfeit Medicines**

March 19, 2015

JPMA International Affairs Committee  
Global Health Sub-Committee  
Anti-Counterfeit Medicine Working Group

### **[Background]**

Issues regarding counterfeit medicines are global in nature and countermeasures are required not only at the global level but also at the national and corporate level. The Japan Pharmaceutical Manufacturers Association (JPMA) has recently conducted its second survey on counterfeit medicines among its member companies in order to better understand the countermeasures currently being taken against counterfeit medicines.

We obtained valuable and insightful information concerning the relevant organizations and specific activities of each company, the current impact of counterfeit medicines, awareness of information activities, and awareness of the problem of counterfeit medicines.

We will share the results obtained with the member companies of the JPMA. In addition, through further collaboration with the JPMA committees and stakeholders involved in this issue, we would like to develop more effective and practical approaches to the problem of counterfeit medicines.

### **[Summary of the survey]**

Objectives: To understand the current activities concerning counterfeit medicines and the level of impact on member companies of the JPMA, and to prepare action plans for the future.

Survey subjects: Member companies of JPMA

Survey method: Internet survey

Survey period: November 13 to December 10, 2014

Number of valid responses: 53 /72 companies (73.6%)

Survey organization: Macromill Inc.

## [Executive Summary]

### **1. Organizational structures for planning actions against counterfeit medicines**

#### **-Anti-counterfeit strategy is led by specialized Security Departments at global companies-**

Countermeasures against counterfeit medicines involve coordination among various departments, such as the Quality Assurance Department, Production Department, Legal Department, and Intellectual Property Department. Many companies responded that the leading department is the Quality Assurance Department.

At the global level, the most common leading department is the Security Department. (A total of 7 companies among Foreign capital companies and Domestic capital companies.)

11 out of 12 Foreign capital companies (92%) indicated that there was a department responsible for this issue in Japan, while 19 out of 41 Domestic capital companies (46%) have a department that exclusively or mainly deals with counterfeit medicines. The number of companies that selected “Department that is devoted to, or has a principal/leadership role in efforts” was 10 out of 12 (83%) Foreign capital companies and 12 out of 41 (29%) Domestic capital companies. On the other hand, 18 out of 41 (44%) Domestic capital companies answered that there was no department responsible for this issue.

### **2. Status of medicines confirmed as being counterfeit (over the past 2 years)**

#### **-Counterfeit medicines are reported in many therapeutic fields on a Global basis-**

Domestically, the majority of counterfeit medicines were “drugs for improvement of sexual performance”. Globally, there are also many cases of counterfeiting “drugs for improving sexual performance”. However, the problem affects various therapeutic fields, and there have been reports of counterfeit “anticancer drugs”, “antidiabetic drugs”, and “antihypertensives”. It is expected that global business has a higher risk of being affected by counterfeit medicines.

### **3. Health problems due to counterfeit medicines**

#### **-Serious adverse reactions have been reported-**

Concerning health problems resulting from the use of counterfeit medicines in Japan, 4 companies reported problems related to “drugs for improvement of sexual performance” and 1 company reported such problems for another product. 2 companies reported reactions that were considered to be critical, 1 company reported significant reactions that were not critical, and 2 companies reported reactions that were not significant.

### **4. Countermeasures against counterfeit medicines**

#### **-Strengthening of information collection activities and cooperation with public institutions and industry groups-**

Domestically, many companies indicated that “We are altering our products in some way as a measure against counterfeits,” as well as selecting “Coordination with other pharmaceutical companies/industry groups,” and “Other information gathering activities aimed at understanding the state of counterfeit medicine.” On the other hand, 24 companies (45%) answered “No action has been taken at the product level.”

Globally, in addition to the answers from Domestic companies, the following responses were also provided:

“Cooperation in investigations by judicial authorities such as police or Interpol,” and “Countermeasures through coordination with industry professionals.\*” However, 26 companies (49%) answered “No action has been taken at the product level.”

\*) The companies conducting surveillance and authentication of Internet-based pharmacies.

## **5. Increased awareness through events and changes to regulations**

### **-Awareness of the issue has been increased through seminars organized by the JPMA-**

Member companies of the JPMA have increased their awareness of the issue [13-15 out of 53 companies (about 25-28%)] of counterfeit medicines through participation in a media seminar organized by the JPMA, as well as various seminars for the member companies and changes of the regulations related to lifting the ban on sales of OTC drugs over the Internet and changes in government policy. On the other hand, some companies indicated that they were not aware of these events. Accordingly, it is believed that further activities are needed to increase industry awareness of the issues related to counterfeit medicines.

### **[Summary]**

On a global basis, issues related to counterfeit medicines are not only limited to “drugs for improvement of sexual performance”, but also affect other therapeutic fields such as lifestyle-related diseases, and patients have developed health problems due to such medicines.

In order to prevent future expansion of counterfeit medicines in Japan, with reference to actions taken by proactive companies and countermeasures taken globally, it is necessary to prevent health problems related to counterfeit medicines through cooperation with stakeholders.

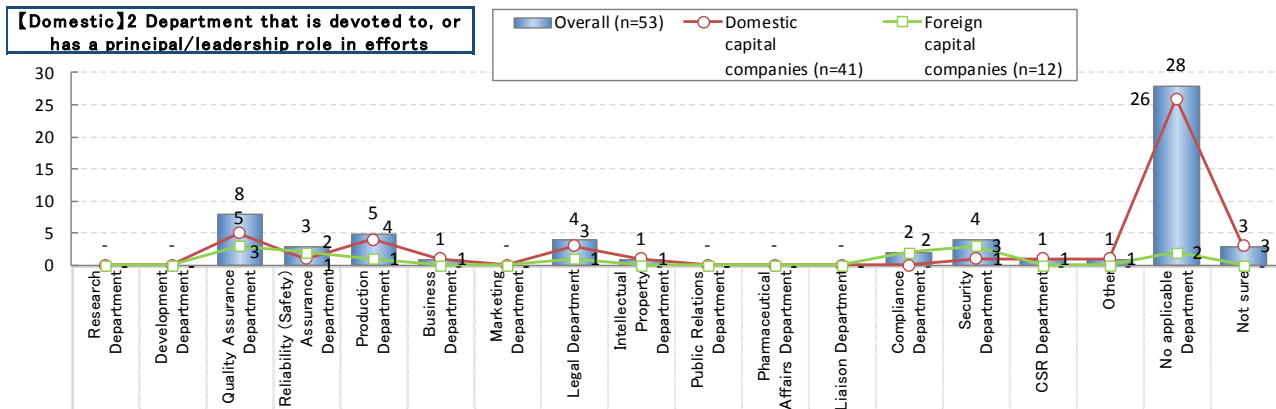
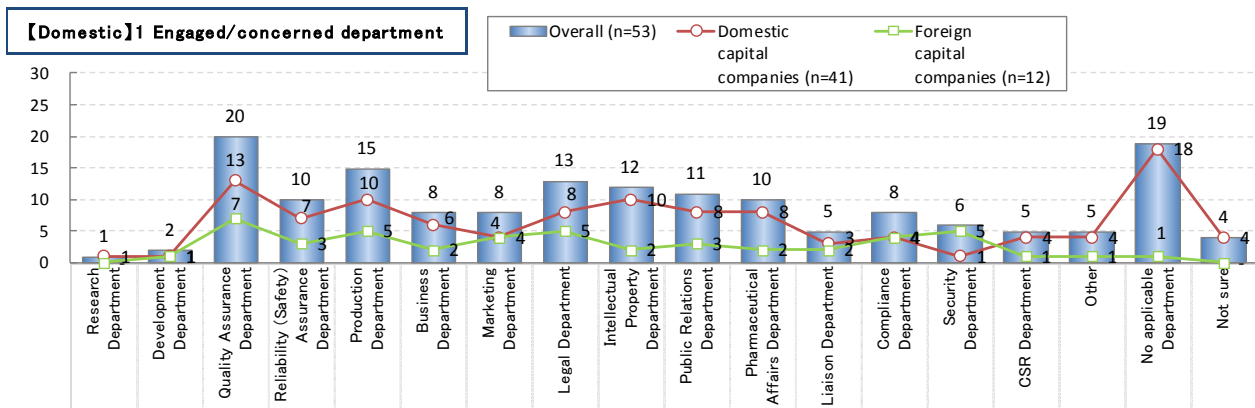
[Results and observations for each question]

o Department in charge of counterfeit medicines

**Q2 Does your company (including your parent company) have a department that is taking measures against counterfeit medicine in Japan or on a Global basis?**

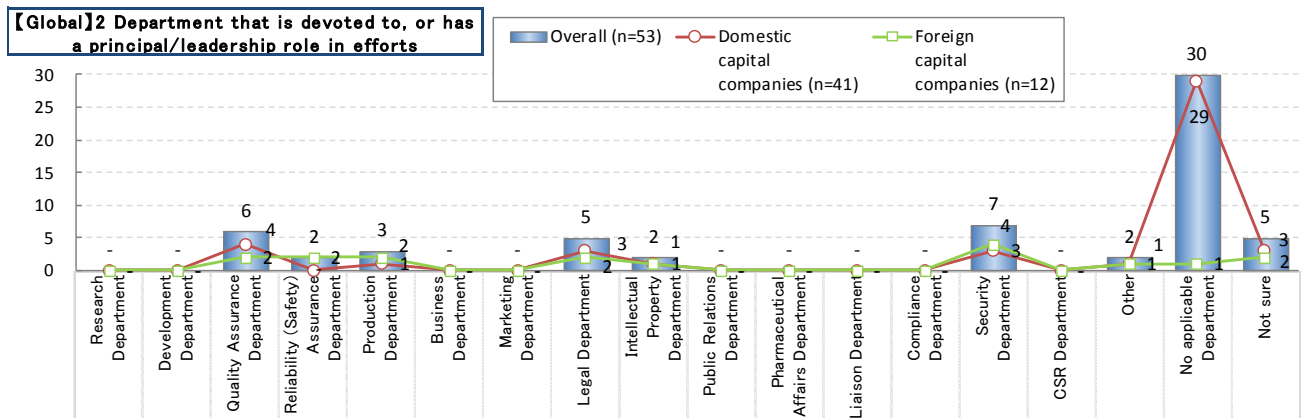
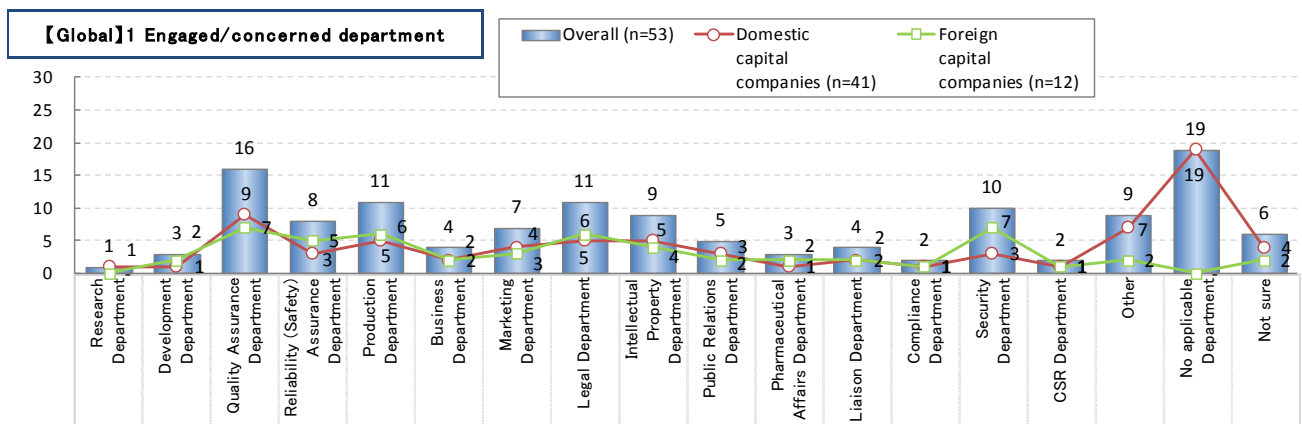
<Domestic>

- (1) 11 out of 12 (92%) Foreign capital companies answered that there is a department in charge of countermeasures against counterfeit medicines, and 19 out of 41 (46%) Domestic capital companies also gave this answer.
- (2) There is a department dedicated to countermeasures against counterfeit medicines in 10 out of 12 (83%) Foreign capital companies and in 12 out of 41 (29%) Domestic capital companies.
- (3) The results regarding the department in charge of/involved with counterfeit medicines (multiple choice) and the department that is dedicated to or primarily responsible for countermeasures against counterfeit medicines are shown in the graphs below.



<Global>

- (1) Similar to the Domestic situation, 10 out of 12 (83%) Foreign capital companies have a dedicated department. On the other hand, only 18 out of 41 (44%) Domestic capital companies have a dedicated department.
- (2) There is a global department that is dedicated to or primarily responsible for countermeasures against counterfeit medicines in 9 out of 12 (75%) Foreign capital companies, and 9 out of 41 (22%) Domestic capital companies.
- (3) The results regarding the department in charge of/involved with counterfeit medicines (multiple choice) and the department that is dedicated to or primarily responsible for countermeasures against counterfeit medicines are shown in the graphs below.



<Observations>

A smaller percentage of Domestic capital companies have a department responsible for countermeasures against counterfeit medicines compared with Foreign capital companies, and there is also a smaller percentage of Domestic capital companies with a department that is dedicated to or primarily responsible for countermeasures. This trend was similar both inside Japan and globally. This is possibly because the medical fields affected and the known types of counterfeit medicines are limited in Japan, so there is less need for countermeasures and a crackdown on counterfeiting. Companies whose business is mainly confined to the domestic market have less opportunity to obtain information related to counterfeit medicines that affect various fields in the global market. It is also considered that improving expertise in the handling of counterfeit medicines may not be an urgent priority.

○Department in charge of countermeasures against counterfeit medicines

**Q3 Please answer the following about organizations, general assemblies, etc. related to measures against counterfeit medicine concerning your products in your company (including your parent company), in Japan and on a Global basis.**

<Domestic>

- (1) The department responsible for planning and managing the budget for countermeasures against counterfeit medicines is usually the “Quality Assurance Department” or “Reliability (Safety) Assurance Department”. “The Legal Department” and/or “Global Security Department” are also responsible in some cases.
- (2) The department responsible for managing meetings about counterfeit medicines is usually the “Quality Assurance Department” or “Reliability (Safety) Assurance Department”. Some companies included other departments such as the “Legal Department” “Global Security Department”, or Supply Chain Department.
- (3) The manager responsible for countermeasures against counterfeit medicines is generally the head of the responsible department. Officers and Board members were also listed among the responses.
- (4) In addition to the above departments, various departments participate in meetings about counterfeit medicines, including the Pharmaceutical Affairs Department, Marketing Department, Corporate Strategy Department, Public Relations Department, and Research & Development Department.

<Global>

- (1) Unlike the situation in Japan, the Global Security Department often manages the budget for countermeasures against counterfeit medicines. Other departments that may be involved include the “Quality Assurance Department”, “Quality Control Department”, and “Legal Department”.
- (2) Similarly, the main department responsible for countermeasures is often the Global Security Department.
- (3) The manager responsible for countermeasures against counterfeit medicines is generally the head of the responsible department. Other replies included the global head and vice president.
- (4) In addition to the above departments, various departments participate in meetings about counterfeit medicines, including the Pharmaceutical Affairs Department, Marketing Department, Corporate Strategy Department, Public Relations Department, and Research & Development Department.

<Observations>

In Japan, the departments frequently responsible for planning and managing the budget for countermeasures against counterfeit medicines are the “Quality Assurance Department” or the “Reliability (Safety) Assurance Department”. Those departments are also responsible for internal meetings about counterfeit medicines. On the other hand, companies usually answered that the Global

Security Department was responsible on the Global level. This is considered to be due to the fact that not so many domestic capital companies have experience with counterfeit medicines and they are focused on preventive measures (actions for products: prevention of counterfeiting, evaluation / introduction of identification methods, and attention to the supply chain). In contrast, counterfeit medicines exist in many therapeutic fields globally and the Global Security Department serves as the key department for managing cross-functional activities such as sample analysis, cooperation with law enforcement officers, and legal actions.



○Experience with counterfeit medicines / fields affected

**Q4 Has your company (including your parent company) confirmed the existence of counterfeit versions of your medicinal products in the last two years?**

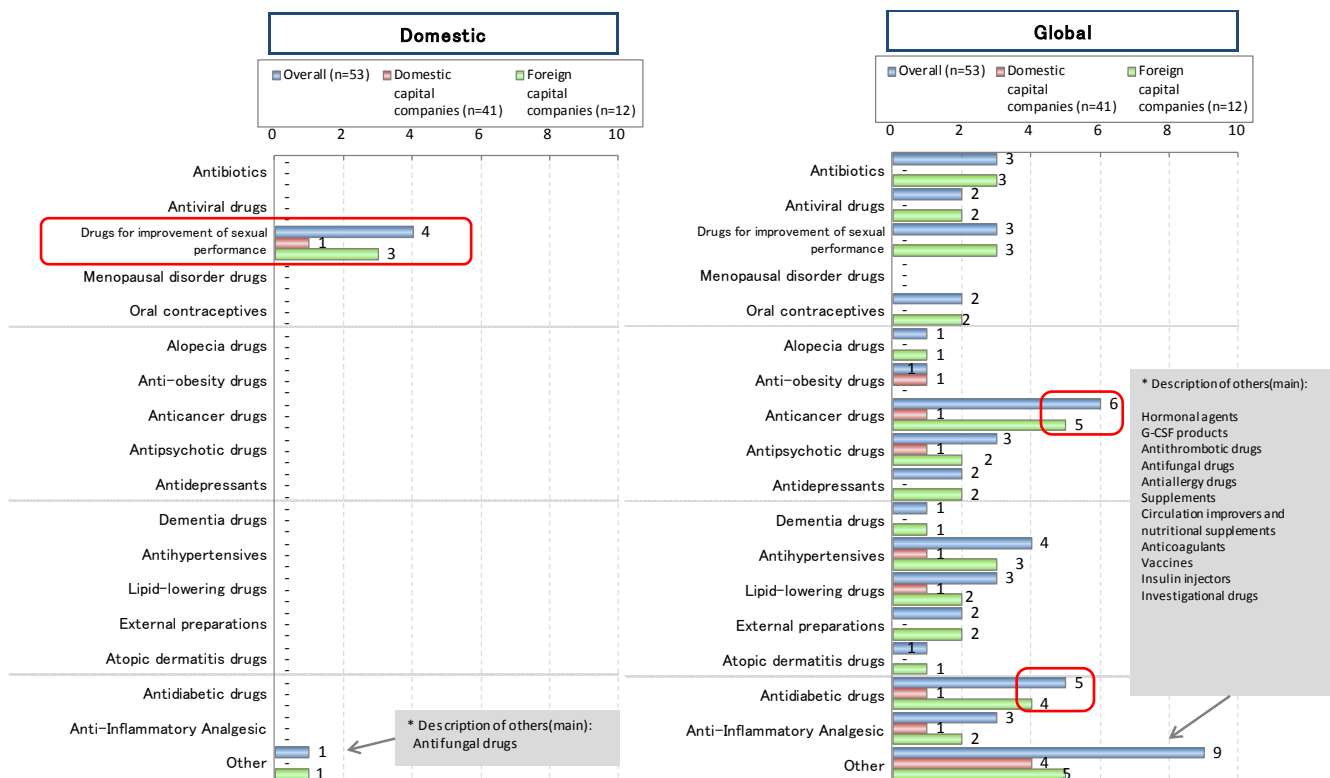
**Please indicate all items that apply to Japan or on a Global basis.**

<Domestic>

Domestically, 4 companies (1 domestically capital and 3 foreign capital) had encountered counterfeit drugs for improvement of sexual performance and 1 company (foreign capital) had experience with a counterfeit antifungal drug.

<Global>

Globally, both Domestic capital companies and Foreign capital companies had encountered counterfeit medicines in many fields. Specifically, 5 Foreign capital companies had encountered counterfeit “anticancer drugs”, 4 companies had encountered counterfeit “antidiabetic drugs”, and 3 Foreign capital companies each had encountered counterfeit “antibiotics”, “drugs for improvement of sexual performance”, and “antihypertensives”. In addition, 2 companies each had identified counterfeit “antiviral drugs”, “oral contraceptives”, “antipsychotic drugs”, “antidepressants”, “lipid-lowering drugs”, “External preparations”, and “anti-inflammatory analgesics”. Domestic capital companies had each encountered counterfeit medicines among 6 types of drugs (disease fields), except for “others”



<Observations>

Domestically, 4 companies had come across counterfeit drugs for improvement of sexual performance and 1 company had encountered a counterfeit “antifungal drug”. With regard to counterfeit drugs for improvement of sexual performance, these were also recognized in the 2013 survey. It is thought that counterfeit medicines have continued to exist.

Globally, on the other hand, counterfeit medicines have been recognized in many disease fields including counterfeit anticancer drugs and counterfeit drugs for lifestyle-related diseases. It is considered that this is due to the poor economic status of some countries / regions and inadequate health insurance systems. It would be reasonable to expect that the issues seen globally may affect Japan in the future.

○Experience with counterfeiting of the company's own products

**Q5** Please tell us more about the fields for which you answered that the existence of counterfeit medicine has been confirmed by your company (including your parent company) in Japan over the past two years.

If your company has confirmed the existence of counterfeit medicine, please indicate the number of confirmed cases.

**Q6** Please tell us more about the fields for which you answered that the existence of counterfeit medicine has been confirmed by your company (including your parent company) on a Global basis over the past two years.

If your company has confirmed the existence of counterfeit medicine, please indicate the number of confirmed cases.

<Domestic>

Domestically, 4 companies confirmed that counterfeit medicines had been detected, including 1 out of 41 Domestic capital companies (2%) and 3 out of 12 Foreign capital companies (25%). Domestically, there were 2129 cases of counterfeit drugs for improvement of sexual performance (99.5%, 1 Domestic capital company and 3 Foreign capital companies). There were 10 cases of other counterfeit products (an antifungal drug) (0.5%, 1 Foreign capital company).

Domestic						
	Overall		Domestic capital companies		Foreign capital companies	
	Number of relevant companies	Number of confirmed cases (n)	Number of relevant companies	Number of confirmed cases (n)	Number of relevant companies	Number of confirmed cases (n)
Drugs for improvement of sexual performance	4	2,129	1	27	3	2,102
Other	1	10	0	0	1	10
<b>total</b>	<b>4</b>	<b>2,139</b>	<b>1</b>	<b>27</b>	<b>3</b>	<b>2112</b>

<Global>

Globally, the number of companies that had encountered counterfeit medicines was 6 out of 41 (15%) Domestic capital companies and 7 out of 12 (58%) Foreign capital companies. Most of the Domestic capital companies had not had any experience with counterfeit medicines in Japan, but those companies encountered counterfeit medicines outside Japan. In the global sphere too, the majority of cases were related to “drugs for improvement of sexual performance” and there were 1643 cases of such counterfeit drugs (79.7%, 3 Foreign capital companies). Other counterfeit medicines that were detected by multiple companies were as follows: anti-inflammatory analgesics in 66 cases (3.2%, 1 Domestically owned company and 2 Foreign capital companies ), anticancer drugs in 59 cases (2.9%, 1 Domestically owned company and 5 Foreign capital companies ), antidiabetic drugs in 59 cases (2.9%, 1 Domestically owned company and 4 Foreign capital companies ), oral contraceptives in 38 cases (1.8%, 2 Foreign capital companies ), antibiotics in 22 cases (1.1%, 3 Foreign capital companies ), lipid-lowering drugs in 22 cases (1.1%, 1 domestically owned company and 2 Foreign capital companies ), and external preparations in 21 cases (1.0%, 2 Foreign capital companies ).

Global						
	Overall		Domestic capital companies		Foreign capital companies	
	Number of relevant companies	Number of confirmed cases (n)	Number of relevant companies	Number of confirmed cases (n)	Number of relevant companies	Number of confirmed cases (n)
Antibiotics	3	22	0	0	3	22
Antiviral drugs	2	5	0	0	2	5
Drugs for improvement of sexual performance	3	1,643	0	0	3	1,643
Oral contraceptives	2	38	0	0	2	38
Alopecia drugs	1	6	0	0	1	6
Anti-obesity drugs	1	2	1	2	0	0
Anticancer drugs	6	59	1	28	5	31
Antipsychotic drugs	3	6	1	3	2	3
Antidepressants	2	4	0	0	2	4
Dementia drugs	1	1	0	0	1	1
Antihypertensives	4	14	1	6	3	8
Lipid-lowering drugs	3	22	1	1	2	21
External preparations	2	21	0	0	2	21
Atopic dermatitis drugs	1	2	0	0	1	2
Antidiabetic drugs	5	59	1	7	4	52
Anti-Inflammatory Analgesic	3	66	1	11	2	55
Other	10	92	5	12	5	80
<b>total</b>	<b>13</b>	<b>2062</b>	<b>6</b>	<b>70</b>	<b>7</b>	<b>1992</b>

<Observations>

Both domestically and globally, the majority of counterfeit medicines were drugs for the improvement of sexual performance. Especially in Japan, the characteristics of drugs for improving sexual performance (not covered by health insurance and difficulty of consulting with a specialist doctor) suggest that purchase from non-formal routes may be a cause. Globally, various counterfeit medicines were recognized. The current results should be perceived as a warning and each company should pay attention to the future situation in order to prevent the expansion and influx of counterfeit medicines into Japan.

○Experience with counterfeiting of the company's own products

**Q7** Please tell us more about the fields for which you answered that the existence of counterfeit medicine has been confirmed by your company (including your parent company) in Japan over the past two years. Please indicate all regions where cases were confirmed.

**Q8** Please tell us more about the fields for which you answered that the existence of counterfeit medicine has been confirmed by your company (including your parent company) on a global basis over the past two years. Please indicate all areas where cases were confirmed.

<Domestic>

Counterfeit drugs for improvement of sexual performance are recognized across Japan. Concerning other counterfeit medicines, “antifungal drugs” are recognized in many areas except for the “Chugoku/Shikoku region” and the “Kyushu region.”

\*Based on companies that have recognized the existence of counterfeit

	Total	Hokkaido/Tohoku region	Kanto region	Chubu region	Kinki region	Chugoku/Shikoku region	Kyushu region	Not sure
Unit: # of company								
Drugs for improvement of sexual performance	4	4	4	4	4	4	4	0
Other	1	1	1	1	1	0	0	0
<b>total</b>	4	4	4	4	4	4	4	0
	%	100.0	100.0	100.0	100.0	100.0	100.0	100.0

<Global>

Among the areas where counterfeit medicines were confirmed, the majority of drugs were found in the “Asian region.” Fewer drugs were reported in the “African region,” but it is likely that companies are not fully aware of the situation in that region. Counterfeit drugs for improvement of sexual performance, “anticancer drugs,” and “antidiabetic drugs” were recognized around the globe. Among 5 out of 6 companies that identified counterfeit medicines for “anticancer drugs,” these were found in the “Near East (Middle East) region” and the “Asian region”.

\*Based on companies that have recognized the existence of counterfeit

	Total	Asia region	North America region	Latin America (Mexico, Central and South America) region	Europe region	Oceania region	Near East (Middle East) region	Africa region	Other
Unit: # of company									
Antibiotics	3	3	0	3	0	0	0	2	0
Antiviral drugs	2	1	0	2	0	0	1	1	0
Drugs for improvement of sexual performance	3	3	3	3	3	3	3	2	0
Oral contraceptives	2	2	1	1	2	1	1	0	0
Alopecia drugs	1	0	0	1	1	0	0	0	0
Anti-obesity drugs	1	1	0	0	0	0	0	0	0
Anticancer drugs	6	5	2	1	3	1	5	2	0
Antipsychotic drugs	3	2	1	1	3	0	2	0	0
Antidepressants	2	2	0	0	0	0	1	0	0
Dementia drugs	1	1	0	0	0	0	0	0	0
Antihypertensives	4	4	0	3	1	0	2	0	0
Lipid-lowering drugs	3	1	2	2	1	0	1	0	0
External preparations	2	1	1	1	0	0	0	0	0
Atopic dermatitis drugs	1	1	0	1	0	0	0	0	0
Antidiabetic drugs	5	5	3	1	2	1	2	1	0
Anti-Inflammatory Analgesic	3	1	2	3	2	0	3	1	0
Other	9	7	3	3	4	2	4	3	2
<b>total</b>	<b>10</b>	<b>10</b>	<b>7</b>	<b>6</b>	<b>7</b>	<b>4</b>	<b>8</b>	<b>5</b>	<b>2</b>
	%	100.0	70.0	60.0	70.0	40.0	80.0	50.0	20.0

<Observations>

Counterfeit medicines were found in many areas of Japan, and regional differences were not prominent. This is considered to be due to personal purchase through non-official routes.

In the global sphere, counterfeit medicines were often found. In some regions, due to poor development of the health insurance and medical systems, access to medical treatment is limited and medicines cannot be obtained through formal routes. As a result, there is a certain risk of counterfeit medicines being supplied.

○Impact of counterfeit medicines

**Q9** Please tell us more about the fields for which you answered that the existence of counterfeit medicine has been confirmed by your company (including your parent company) in Japan over the past two years.

Please select all choices that apply to the extent of harm suffered by your patients.

**Q10** Please tell us more about the fields for which you answered that the existence of counterfeit medicine has been confirmed by your company (including your parent company) on a Global basis over the past two years.

Please select all choices that apply to the extent of harm suffered by your patients.

<Domestic>

2 out of 4 companies that recognized counterfeit drugs for improvement of sexual performance answered “reactions that were considered critical” had occurred.

\*Based on companies that have recognized the existence of counterfeit

	Total	There were deaths	There were reactions that were considered critical	There were no critical reactions, but reactions were not insignificant	There were reactions that were considered insignificant	Does not apply
Unit: # of company						
Drugs for improvement of sexual performance	4	0	2	1	2	1
Other	1	0	0	0	0	1
<b>total</b>	4	0	2	1	2	2
	%	0.0	50.0	25.0	50.0	50.0



<Global>

Among companies that recognized counterfeit medicines, the answer “There were reactions that were considered critical” was selected for “Antibiotics,” “Lipid-lowering drugs,” and “Atopic dermatitis drugs.”

\*Based on companies that have recognized the existence of counterfeit

Unit: # of company	Total	There were deaths	There were reactions that were considered critical	There were no critical reactions, but reactions were not insignificant	There were reactions that were considered insignificant	Does not apply
Antibiotics	3	0	1	0	0	2
Antiviral drugs	2	0	0	0	0	2
Drugs for improvement of sexual performance	3	0	0	2	0	1
Oral contraceptives	2	0	0	0	1	1
Alopecia drugs	1	0	0	1	0	0
Anti-obesity drugs	1	0	0	0	1	0
Anticancer drugs	6	0	0	1	0	5
Antipsychotic drugs	3	0	0	1	0	2
Antidepressants	2	0	0	1	0	1
Dementia drugs	1	0	0	0	0	1
Antihypertensives	4	0	0	0	0	4
Lipid-lowering drugs	3	0	1	0	0	2
External preparations	2	0	0	0	0	2
Atopic dermatitis drugs	1	0	1	0	0	0
Antidiabetic drugs	5	0	0	1	1	3
Anti-Inflammatory Analgesic	3	0	0	2	0	1
Other	9	0	1	0	0	9
<b>total</b>	<b>13</b>	<b>0</b>	<b>1</b>	<b>3</b>	<b>2</b>	<b>11</b>
	<b>%</b>	<b>0.0</b>	<b>7.7</b>	<b>23.1</b>	<b>15.4</b>	<b>84.6</b>

<Observations>

Companies that recognized counterfeit medicines, either domestically or globally, reported that “There were reactions that were considered critical.” Accordingly, counterfeit medicines are a significant threat to the health of patients. Moreover, there are cases in which adverse event reports were made without knowing that the drug was counterfeit. Thus, counterfeit medicines may cause damage to a company’s reputation.

○Countermeasures and actions plans against counterfeit medicines

**Q11 Please tell us more about the fields for which you answered that the existence of counterfeit medicine has been confirmed by your company (including your parent company) in Japan over the past two years. Please indicate in detail the efforts/measures your company took in response to cases that were actually confirmed.**

**\* Any reply is fine. Replies could include efforts/measures taken within your company, or coordination with outside organizations.**

**Q12 Please tell us more about the fields for which you answered that the existence of counterfeit medicine has been confirmed by your company (including your parent company) on a Global basis over the past two years. Please indicate in detail the efforts/measures your company took in response to cases that were actually confirmed.**

**\* Any reply is fine. Replies could include efforts/measures taken within your company, or coordination with outside organizations.**

<Domestic>

Companies conducted product countermeasures in order to prevent counterfeit products cooperation/information sharing with relevant organizations (the MHLW, Police, Customs and FPMAJ), and awareness activities on the web. Companies selling “drugs for the improvement of sexual performance” are engaged in cooperation with the MHLW and Police and Customs, as well as being involved in PR activities. Specifically, these companies are involved in changes to drug packaging, enforcing import bans by Customs, purchase of samples of counterfeit drugs, overseas investigations, and filing of cases with the Police.

<Global>

Companies conducted product countermeasures in order to prevent the use of counterfeit products, investigations, raids, sample analysis, cooperation/information sharing with (the FDA, Police, Customs, PSI, etc.). Furthermore, the following activities were conducted: distribution of information, legal actions, complaints about criminal activity, and activities to increase awareness through internal communication. Actions were taken in many medical fields, including actions for anticancer drugs and antidiabetic drugs. In addition to cooperation with administrative officers and the Police and Customs, international law enforcement agencies such as Interpol and international organizations such as PSI (Pharmaceutical Security Institute) are also involved. Specific actions include anti-counterfeit packages, investigations, raids, import bans, purchase of samples of counterfeit drugs, sample analysis (judgment of authenticity), improvement of internal communication / awareness, and filing criminal complaints, etc.

<Observations>

Domestically, the majority of actions are taken with regard to “drugs for improving sexual performance”. Compared with the global sphere, activities are relatively limited. Globally, actions are not limited to “drugs for improvement of sexual performance” and many areas are affected. Global activities included spreading information about counterfeits, information gathering, reporting to administrative officers,

sample analysis, and filing criminal charges. Inside the company, improved governance and communication are major activities.

○ **Inquiries about counterfeit medicines and the number of such inquiries**

**Q13 Has your company received any inquiries regarding counterfeit medicine?**

**Please check off who has made inquiries over the last year in Japan, and write the number of inquiries (approximately) that you received during the year.**

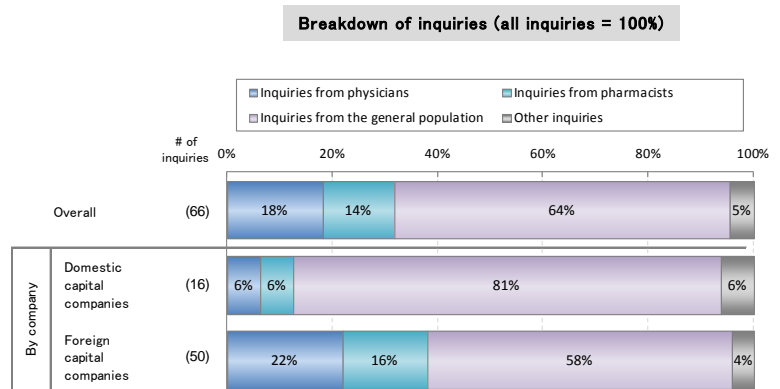
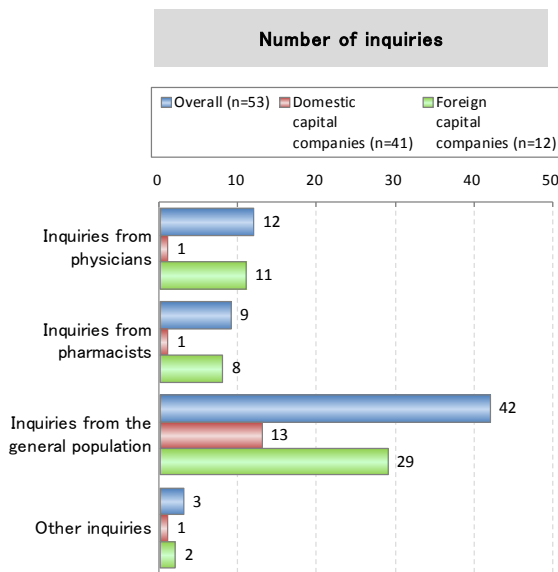
**\* Please also include inquiries related to authentication of pharmaceuticals.**

<Domestic>

In the past 1 year, a total of 66 inquiries were related to counterfeit medicines. Among them, 42 inquiries (64%) were from the general population. Inquiries from healthcare professionals comprised 12 (18%) from physicians and 9 (14%) from pharmacists.

<Observations>

Domestically, inquiries related to counterfeit medicines were mostly from ordinary people, while about one third were from healthcare professionals.



○Countermeasures against counterfeit medicines

**Q14 Please tell us how efforts against counterfeit medicine have been progressing in your company (including your parent company) in Japan over the last two years, for each item below.**

**If your company is taking new efforts not listed below, please list them in as much detail as possible in the "Other" section.**

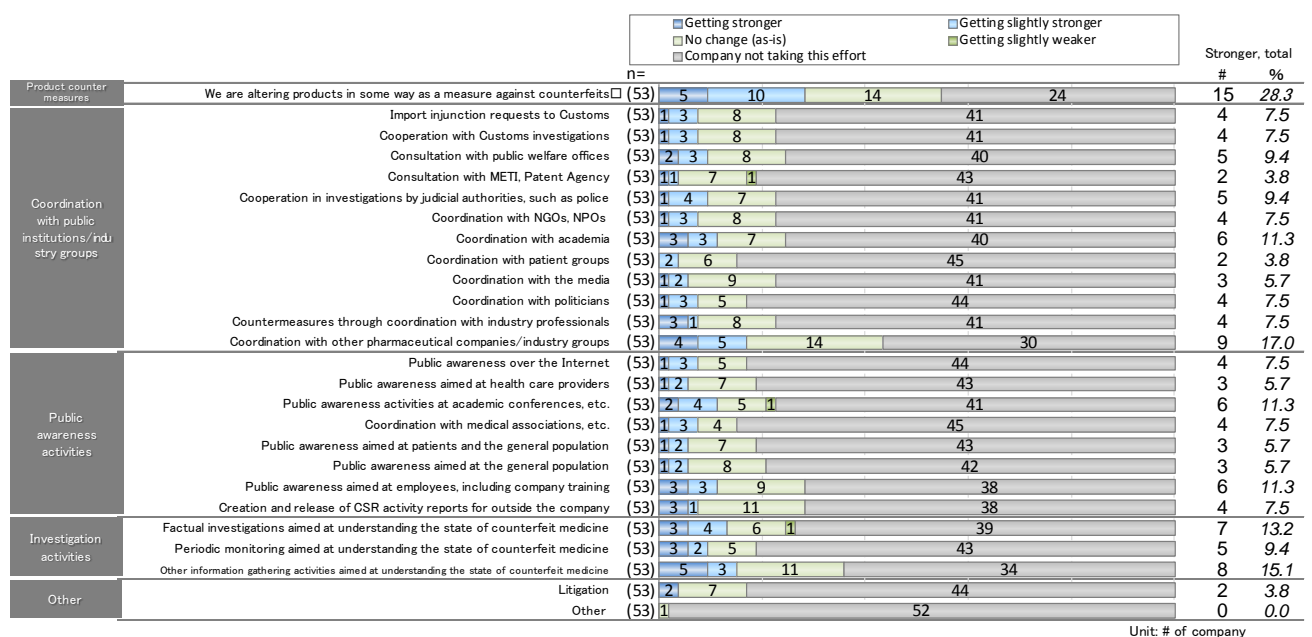
**Q15 Please tell us how efforts against counterfeit medicine have been progressing in your company (including your parent company) on a Global basis over the last two years, for each item below.**

**If your company is taking new efforts not listed below, please list them in as much detail as possible in the "Other" section.**

<Domestic>

Concerning the attitude to countermeasures, 15 out of 53 companies answered that it was “Getting stronger” or “Getting slightly stronger” in the case of <Product countermeasures>, 14 companies answered “No change (as-is)”, and 24 companies answered “Company not making this effort.”

On the other hand, with regard to most of sub-activities in such as <Coordination with public institutions/industry groups>, <Public awareness activities>, and <Investigations and other activities>,.less than 5 companies answered “Getting stronger” and “Getting slightly stronger”. About 40 companies answered “Company not making this effort.” Concerning ”Coordination with other pharmaceutical companies/industry groups” and “Other information gathering activities aimed at understanding the state of counterfeit medicine”, 9 and 8 companies answered “Getting stronger” and “Getting slightly stronger,” respectively. When “No change (as-is)” was included, these numbers increased to 23 and 19, respectively.



Unit: # of company

<Global>

Among <Product countermeasures>, 20 out of 53 companies answered “Getting stronger” or “Getting slightly stronger” for “We are altering our products (including packaging) in some way as a measure against counterfeits”, while 7 companies answered “No change (as-is)” and 26 companies answered “Company not taking this effort.”

With regard to <Coordination with public institutions/industry groups>, <Public awareness activities>, and <Investigations and other activities>, the number of companies that answered “Getting stronger” or “Getting slightly stronger” was larger than in Japan. Especially, with regard to “Cooperation in investigations by judicial authorities (Interpol), such as police” and “Countermeasures through coordination with industry professionals,” 10 and 8 companies answered “Getting stronger” or “Getting slightly stronger,” respectively. When “No change (as-is)” was included, these numbers became 19 and 20, respectively. Thus, these are considered to be unique global activities.

		<div style="display: flex; justify-content: space-between; font-size: small;"> <span>■ Getting stronger</span> <span>■ Getting slightly stronger</span> </div> <div style="display: flex; justify-content: space-between; font-size: small;"> <span>■ No change (as-is)</span> <span>■ Getting slightly weaker</span> </div>				Stronger, total			
		n=				#	%		
Product countermeasures	We are altering products in some way as a measure against counterfeits	(53)	11	9	7	26	20	37.7	
	Import injunction requests to Customs	(53)	2	4	11	36	6	11.3	
Coordination with public institutions/industry groups	Cooperation with Customs investigations	(53)	4	3	11	35	7	13.2	
	Consultation with public welfare offices	(53)	4	2	13	34	6	11.3	
	Consultation with METI, Patent Agency	(53)	3	1	14	35	4	7.5	
	Cooperation in investigations by judicial authorities, such as police	(53)	6	4	9	34	10	18.9	
	Coordination with NGOs, NPOs	(53)	3	3	13	34	6	11.3	
	Coordination with academia	(53)	2	4	10	36	6	11.3	
	Coordination with patient groups	(53)	1	4	10	38	5	9.4	
	Coordination with the media	(53)	3	4	10	36	7	13.2	
	Coordination with politicians	(53)	2	2	12	37	4	7.5	
	Countermeasures through coordination with industry professionals	(53)	6	2	12	33	8	15.1	
	Coordination with other pharmaceutical companies/industry groups	(53)	7	4	11	31	11	20.8	
	Public awareness activities	Public awareness over the Internet	(53)	2	4	9	38	6	11.3
		Public awareness aimed at health care providers	(53)	3	2	10	38	5	9.4
		Public awareness activities at academic conferences, etc.	(53)	2	1	12	38	3	5.7
Coordination with medical associations, etc.		(53)	2	1	12	38	3	5.7	
Public awareness aimed at patients and the general population		(53)	3	2	10	38	5	9.4	
Public awareness aimed at the general population		(53)	2	1	12	38	3	5.7	
Public awareness aimed at employees, including company training		(53)	5	5	8	35	10	18.9	
Creation and release of CSR activity reports for outside the company	(53)	3	1	14	35	4	7.5		
Investigation activities	Factual investigations aimed at understanding the state of counterfeit medicine	(53)	6	2	12	33	8	15.1	
	Periodic monitoring aimed at understanding the state of counterfeit medicine	(53)	6	2	10	35	8	15.1	
	Other information gathering activities aimed at understanding the state of counterfeit medicine	(53)	7	3	11	32	10	18.9	
Other	Litigation	(53)	3	2	12	36	5	9.4	
	Other	(53)	2			51	0	0.0	

Unit: # of company

<Observations>

Regarding the current situation in Japan, counterfeit medicines are mostly found in a very small number of disease fields. Accordingly, most of our member companies have first taken action for their own products. In addition, through cooperation with pharmaceutical companies / industry associations, information related to counterfeit medicines is being gathered.

Globally, similar to the Domestic situation, high ranking items in the list of action plans include “Product countermeasures,” “Coordination with other pharmaceutical companies/industry groups,” and “Other information gathering activities aimed at understanding the state of counterfeit medicine.” On the other hand, unlike in Japan, many companies perform activities leading to criminal charges such as “Cooperation in investigations by judicial authorities (Interpol), such as police,” “Countermeasures through coordination with industry professionals,” “Cooperation with Customs investigations” and “Import injunction requests to Customs.”

○Effectiveness of countermeasures against counterfeit medicines

**Q16 Please tell us the results of efforts against counterfeit medicine in your company (including your parent company) in Japan over the last two years, for each item below.**

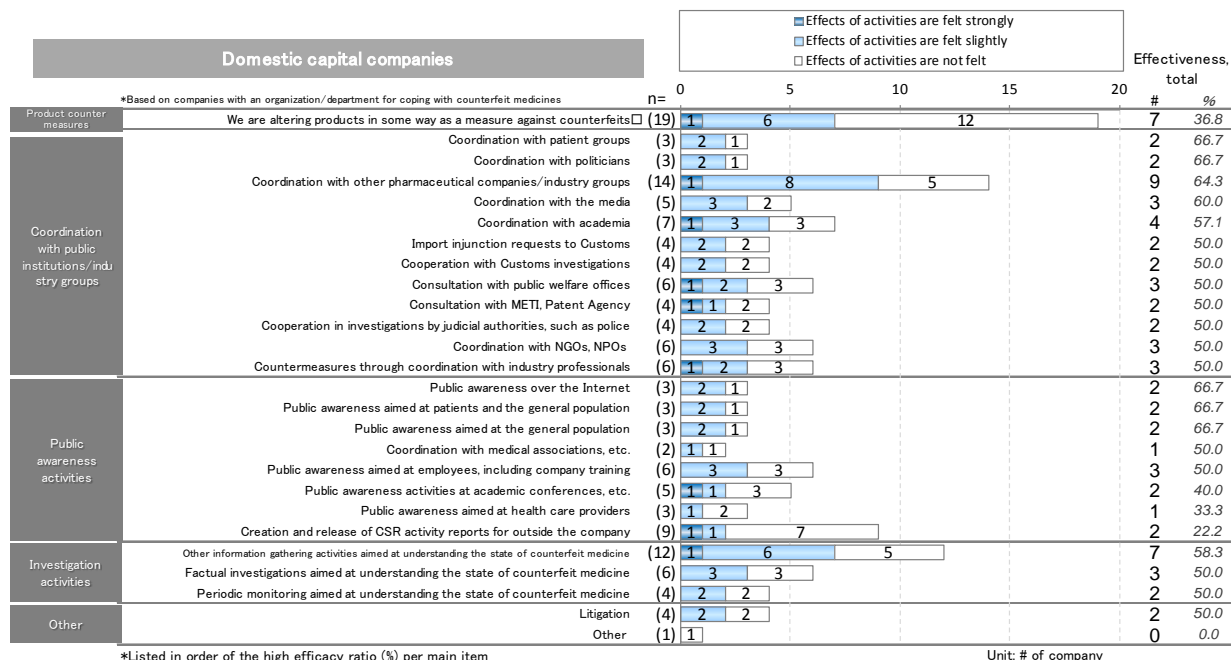
**Q17 Please tell us the results of Global efforts against counterfeit medicine in your company (including your parent company) over the last two years, for each item below.**

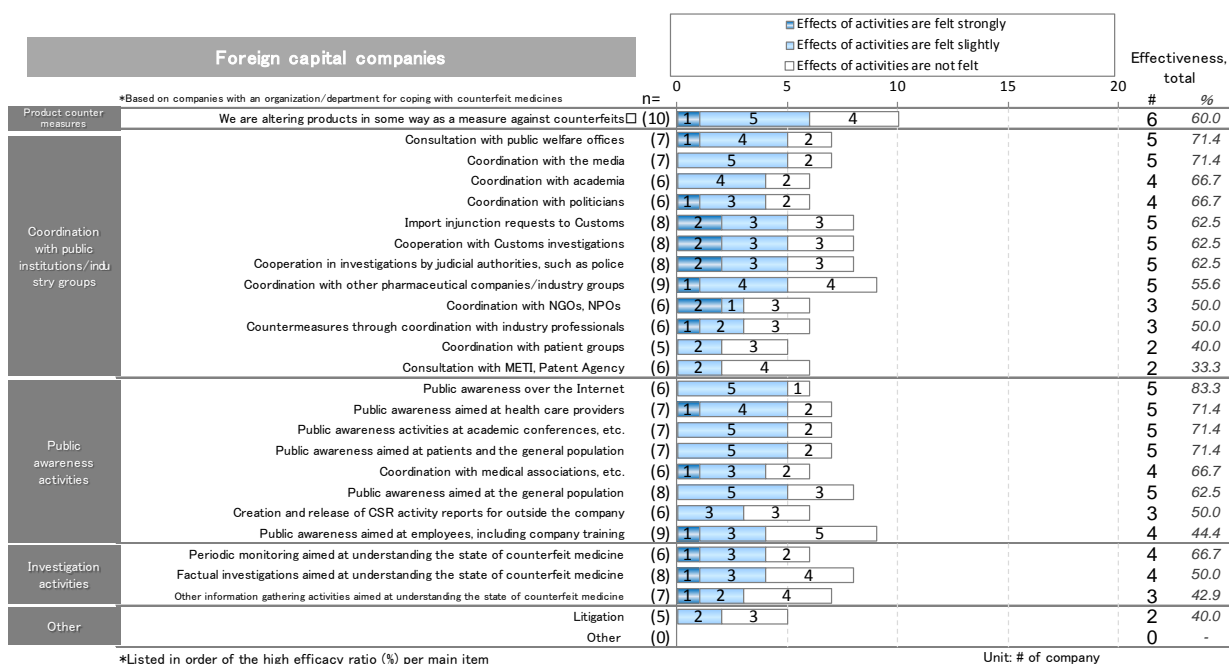
<Domestic>

The actions against counterfeit medicines that many companies felt effective in Japan were “Product countermeasures” and “Coordination with other pharmaceutical companies/industry groups.” On the other hand, higher rates of effectiveness were observed with “Public awareness over the Internet,” “Public awareness aimed at patients and the general population,” and “Coordination with the media / politicians.”

The action that domestically owned capital companies considered to be less effective was “Product countermeasures.” Despite more companies taking actions, the difference versus Foreign capital companies is still large.

Among Foreign capital companies, all actions showed a high level of effectiveness. Among them, 5 out of 6 companies (83%) mentioned “Public awareness over the Internet.”





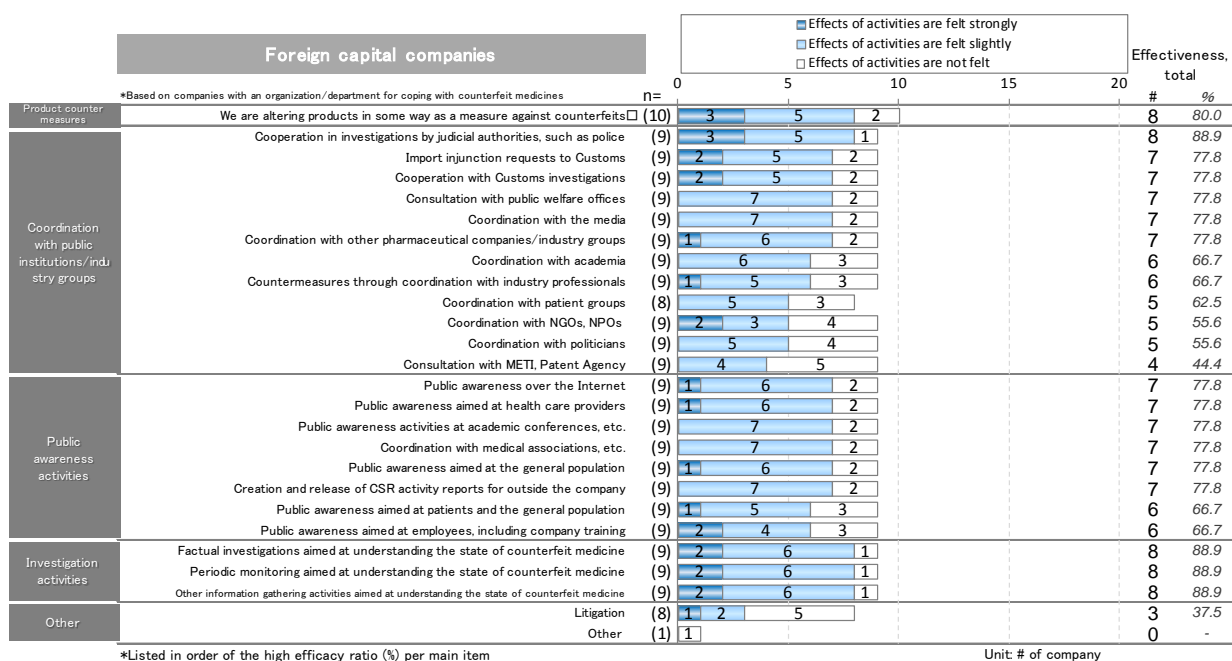
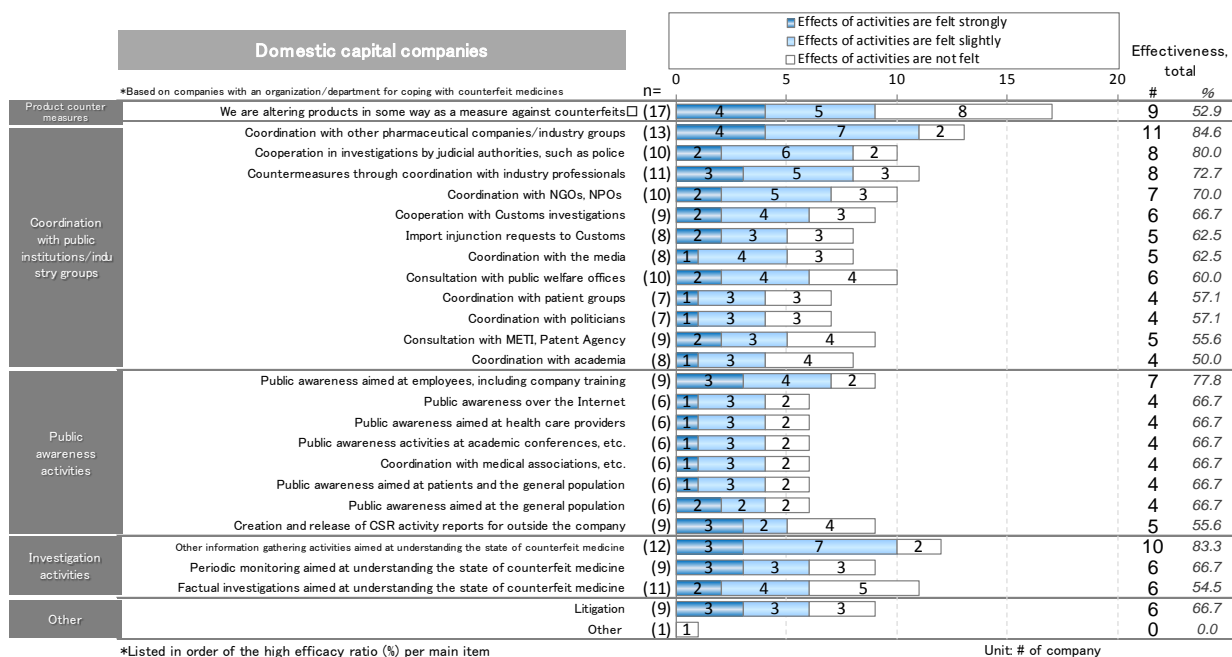
<Global>

Globally, the effectiveness of countermeasures against counterfeit medicines was rated more highly compared with the measures taken in Japan (60% to 80% range). Specifically, the following actions were rated over 80%: “Other information gathering activities aimed at understanding the state of counterfeit medicine,” “Cooperation in investigations by judicial authorities (Interpol), such as police,” and “Coordination with other pharmaceutical companies/industry groups.”

Among global affiliates of Domestic capital companies, actions showed higher effectiveness compared to within Japan. Specifically, “Coordination with other pharmaceutical companies/industry groups” was higher in the global sphere.

Foreign capital companies tended to give higher effectiveness ratings for all items. 7 or more companies noted that 16 out of 26 items were effective. Especially, “Product countermeasures” and “Cooperation in investigations by judicial authorities (Interpol), such as police” were strongly felt to be effective by 3 companies.





<Observations>

Both in Japan and globally, the rate of effectiveness was high for “Coordination with other pharmaceutical companies/industry groups.” Since counterfeit medicines are an issue in all regions of the world, it is necessary to conduct activities on a global basis through stronger cooperation among industry members.

Globally, many companies considered the following activity to be very effective: “Cooperation in investigations by judicial authorities, such as police or Interpol,” that may result in raids. However, domestically, the number of companies that have detected counterfeit medicines is still small and the therapeutic fields affected are limited, so fewer companies considered it to be effective. Although many of our member companies have not yet encountered counterfeit medicines, in order to take quick and effective actions once counterfeit medicines are discovered, it would be better to strengthen cooperation with public institutions in advance and to prepare other action plans.

○Countermeasures against counterfeit medicines: Cooperation with stakeholders

**Q18 You indicated that your company (including your parent company) is taking the following measures against counterfeit medicine. Please explain in detail successful cases (for example, specific examples where "effects of activities are felt strongly") or failure cases (for example, specific examples where "Effects of activities are getting worse") that you can share for "product countermeasures," "coordination with public institutions/industry groups," "public awareness activities," and "investigation activities" that include governments, etc. in Japan and on a Global basis.**

<Domestic>

Many companies (12 companies) are working on actions at a product level with several different approaches. 6 companies are mainly focused on "Sealing" to prevent falsification and replacement. Only 6 companies are mainly focused on countermeasures against counterfeit medicines.

Many companies receive information related to counterfeit medicines from industry groups (JPMA, PSI, etc.), although passive, this highlights the importance of the role of industry associations.

Only 5 companies conduct active measures such as seminars at Customs offices, purchase investigations, and cooperation with universities. However, the number is increased to 7 by including companies that are engaged in "Visualization actions" such as distribution of information outside the company (Annual report, Internet page, etc.).

<Global>

Globally, many companies are actively introducing specific counterfeit prevention technology compared with the situation in Japan. Most respondents (13 companies) have introduced some kind of anti-counterfeit technology.

There are also many companies that emphasize cooperation with industry groups, such as IFPMA and PSI. It was suggested that more specific countermeasures against counterfeit medicines could be instituted through cooperation with government organizations and law enforcement agencies.

<Observations>

Domestically, it was shown that companies are carrying out limited activities, apart from 4 companies that have encountered counterfeit drugs for improvement of sexual performance. However, responses to other questions indicate that their awareness of this matter has been increased and it was suggested that sharing information is important.

Companies in the global field are taking multiple actions, especially cooperation with law enforcement agencies and Customs as well as sharing information with other companies, which are considered to be effective measures.

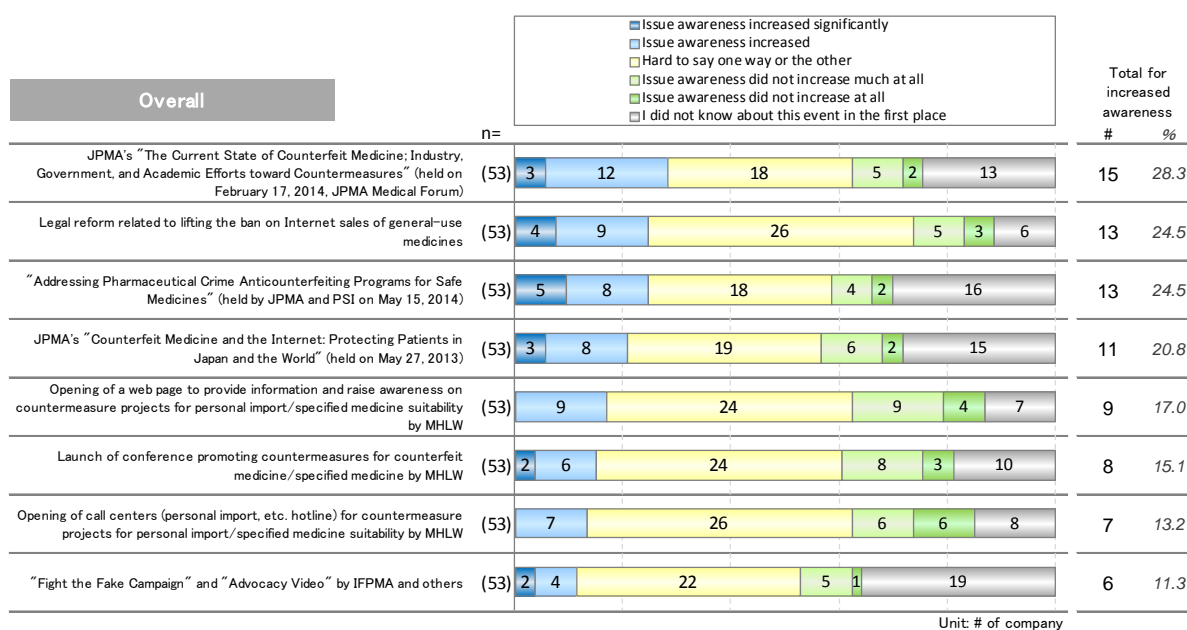
○Awareness of events and changes to the regulations

**Q19 How did awareness of the issue of counterfeit medicine change as a result of the following events or institutional revisions, in your company (including your parent company)?**

**Please select the single most applicable answer for each.**

<Overall>

Concerning the effectiveness of improving awareness through events/seminars and the effect of changes to regulations, many companies felt that domestic events organized by industry groups such as JPMA and PSI were effective. Regarding changes to the regulations, events extensively covered by the mass media significantly contributed to increasing awareness (higher recognition rate), including “Legal reform related to lifting the ban on Internet sales of general-use medicines” and “Launch of a conference promoting countermeasures for counterfeit medicines/specified medicines”.



<Domestic capital companies >

Compared with the Overall situation, although there were some differences of the numbers, a similar trend was demonstrated.

< Foreign capital companies >

Compared with Domestic capital companies, many of the Foreign capital companies considered that events and changes to the regulations had increased their awareness. With regard to domestic events held by industry groups, the rate was high at more than 40%. Launching of a web page by the MHLW to provide information and opening of call centers received somewhat lower ratings compared with other events, but were still around 25-33%.

Domestic capital companies		<ul style="list-style-type: none"> <li>■ Issue awareness increased significantly</li> <li>■ Issue awareness increased</li> <li>■ Hard to say one way or the other</li> <li>■ Issue awareness did not increase much at all</li> <li>■ Issue awareness did not increase at all</li> <li>■ I did not know about this event in the first place</li> </ul>						Total for increased awareness	
		n=						#	%
JPMA's "The Current State of Counterfeit Medicine; Industry, Government, and Academic Efforts toward Countermeasures" (held on February 17, 2014, JPMA Medical Forum)	(41)	3	6	15	5	2	10	9	22.0
Legal reform related to lifting the ban on Internet sales of general-use medicines	(41)	2	6	21	4	3	5	8	19.5
"Addressing Pharmaceutical Crime Anticounterfeiting Programs for Safe Medicines" (held by JPMA and PSI on May 15, 2014)	(41)	5	2	15	4	2	13	7	17.1
JPMA's "Counterfeit Medicine and the Internet: Protecting Patients in Japan and the World" (held on May 27, 2013)	(41)	2	4	14	6	2	13	6	14.6
Opening of a web page to provide information and raise awareness on countermeasure projects for personal import/specified medicine suitability by MHLW	(41)	5		18	8	4	6	5	12.2
Opening of call centers (personal import, etc. hotline) for countermeasure projects for personal import/specified medicine suitability by MHLW	(41)	4		19	6	5	7	4	9.8
Launch of conference promoting countermeasures for counterfeit medicine/specified medicine by MHLW	(41)	2	2	18	7	3	9	4	9.8
"Fight the Fake Campaign" and "Advocacy Video" by IFPMA and others	(41)	1	2	16	5	1	16	3	7.3

Unit: # of company

Foreign capital companies		<ul style="list-style-type: none"> <li>■ Issue awareness increased significantly</li> <li>■ Issue awareness increased</li> <li>■ Hard to say one way or the other</li> <li>■ Issue awareness did not increase much at all</li> <li>■ Issue awareness did not increase at all</li> <li>■ I did not know about this event in the first place</li> </ul>						Total for increased awareness	
		n=						#	%
"Addressing Pharmaceutical Crime Anticounterfeiting Programs for Safe Medicines" (held by JPMA and PSI on May 15, 2014)	(12)		6	3			3	6	50.0
JPMA's "The Current State of Counterfeit Medicine; Industry, Government, and Academic Efforts toward Countermeasures" (held on February 17, 2014, JPMA Medical Forum)	(12)		6	3			3	6	50.0
Legal reform related to lifting the ban on Internet sales of general-use medicines	(12)	2	3	5	1	1		5	41.7
JPMA's "Counterfeit Medicine and the Internet: Protecting Patients in Japan and the World" (held on May 27, 2013)	(12)	1	4	5			2	5	41.7
Opening of a web page to provide information and raise awareness on countermeasure projects for personal import/specified medicine suitability by MHLW	(12)		4	6	1	1		4	33.3
Launch of conference promoting countermeasures for counterfeit medicine/specified medicine by MHLW	(12)		4	6	1	1		4	33.3
Opening of call centers (personal import, etc. hotline) for countermeasure projects for personal import/specified medicine suitability by MHLW	(12)		3	7	1	1		3	25.0
"Fight the Fake Campaign" and "Advocacy Video" by IFPMA and others	(12)	1	2	6			3	3	25.0

Unit: # of company

<Observations>

It was confirmed that domestic events held by industry groups were useful for improved understanding of issues and sharing information among the member companies of JPMA. It is necessary to continue information activities focusing on themes that satisfy the needs of our member companies. On the other hand, 20-30% of companies responded that they were unaware of these events. Accordingly, efforts to improve the profile of such events should be made in the future.

○ **Activities and countermeasures related to theft, illegal distribution, and trademark violations**

**Q20 Please tell us about your efforts, measures, and other activities for combating theft, inappropriate distribution, trademark infringement, etc. in Japan and on a Global basis.**

<Domestic>

Concerning distribution, security assessment of logistics companies, review of contracts, and increased control of suppliers are being performed. Compared with the global situation, many of these activities are done on a “Request basis.” There are not many specific activities imposed on logistics companies.

<Global>

Globally, the following specific activities are required: enforcement of security rules, control of freight, new regulations for better protection, procedural control, and control of logistics companies. These are more involved.

In developing countries, many companies have introduced or are considering a GPS function, serialization (display of the serial number), and introduction of barcode technology.

With regard to violation of intellectual property rights, more active actions are being taken at developing countries.

<Observations>

Considering the limited extent of the damage that has occurred so far, various specific activities are being performed at the global level and multiple measures are being taken against theft, illegal distribution, and trademark violations. In the future, in order to promote actions and countermeasures against counterfeit medications in Japan, global activities will prove to be a valuable source of information for reference.

(end)