

Report on the 3rd Survey about Counterfeit Medicines

(English translation is for convenience purpose only. The Japanese original supersedes this translation.)

June 20, 2018

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

[Background]

Threats of counterfeit medicines are increasing. Not only damaging effects of private imports via the Internet but also counterfeit medicines for treatment of type C hepatitis were found at chain pharmacies in Japan last January. The Japan Pharmaceutical Manufacturers Association (JPMA) has conducted the third questionnaire survey on counterfeit medicines among its member companies in order to better understand the latest countermeasures including the comparison with the results of the past surveys.

We obtained valuable and insightful information on strengthening organizational structures and specific activities in individual companies, recognition of the current impact of counterfeit medicines, awareness of information activities, and change in awareness of the problem of counterfeit medicines.

We will share the results of analyses with the member companies of the JPMA. In addition, through further collaboration with the JPMA committees and stakeholders involving 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 actual damaging effects among member companies of the JPMA, to prepare an action plan for the future, and to use the results for benchmark for future activities on counterfeit medicines in individual companies.

Survey subjects: Member companies of JPMA

Survey method: Internet survey

Survey period: January 26 to February 23, 2018

Number of valid responses: 49 /72 companies (68.1%)

Survey organization: Macromill Carenet, Inc. and Macromill Inc.

[Remarks]

The questionnaire on counterfeit medicines were conducted. According to the WHO definition, counterfeit medicines were defined as medical products that deliberately and fraudulently misrepresent their identity, composition or source, and we asked the member companies to respond to the questionnaire. Substandard medicines that fail to meet the quality standards due to low technical level (substandard) and illegal diversion of authorized medicines (diversion) were not included.

[Executive Summary]

1. Organizational structure for planning actions against counterfeit medicines

-More companies are tackling with the problems of counterfeit medicines-

The percentage of “domestic capital” companies that reported to currently tackle with the problems of counterfeit medicines in Japan increased from approximately 35% in the 1st survey (2013) and approximately 46% in the 2nd survey (2015) to approximately 62% in this survey. As division for activities on counterfeit medicines, “Production/Quality related division” including Quality Assurance Division, Reliability Assurance Division, and Production Division, were common as well as Business Division, Pharmaceutical Affairs Division, and Legal Division among the member companies.

Many companies responded that the leading division for activities on counterfeit medicines was “Production/Quality related divisions” for the domestic and global sectors, or “Security related division” including global and product security.

Many “foreign capital” companies had “Security related division.” Since counterfeit medicines in multiple fields are frequently found in the global sector in many countries/regions, it is assumed that “Security related division” is established to collaborate between health organizations/law enforcement, and to take cross-sectional actions for criminal trials and other purposes.

2. Status of counterfeit medicines confirmed (over the past 2 years)

-Counterfeit medicines in Japan are not only drugs for improvement of sexual performance-

This questionnaire survey found counterfeit medicines of oral contraceptives for the first time in Japan. Counterfeit medicines of drugs for improvement of sexual performance were found in the 1st (2013) and the 2nd surveys (2015), while those of antifungal drugs were also found in the 2nd surveys (2015). These results reveal that counterfeit medicines are continuously present.

As counterfeit medicines of multiple anti-cancer drugs, antipsychotics, antibiotics, antihypertensives, and antidiabetic drugs were found in the global sector, suggesting that fields in top sales ranking are likely to be the target of counterfeit medicines. For companies who deal with or plan to launch major products, preventive measures (product countermeasures: e.g., prevention of counterfeiting, evaluation/introduction of identification methods, and supply chain security) is a challenge.

Most of the confirmed cases of counterfeit medicines were drugs for improvement of sexual performance regardless of domestic or global sector. In Japan, private imports are frequently observed via agents for private imports because of its characteristics (including non-insurance coverage and hesitation to visit a specialist), slipping counterfeit medicines into such cases via unauthorized route, and boarder crackdowns (import suspension measure) of such counterfeit medicines at customs office in Japan are plausible factors.

3. Health damage due to counterfeit medicines

-Serious adverse reactions have been reported-

In Japan, 3 of 4 companies reporting counterfeit medicines in “drugs for improvement of sexual performance” confirmed “there were reactions that were considered insignificant.” For the

global sector, “there were reactions that were considered significant” was found in counterfeit medicines of “antidiabetic drugs.” “There were no critical reactions, but reactions were not insignificant” was found in counterfeit medicines of “antidiabetic drugs” and “drugs for improvement of sexual performance,” while “there were reactions that were considered insignificant” was found in counterfeit medicines of “antacids.” These results suggest that counterfeit medicines continue to be a serious threat to patient health.

4. Countermeasures against counterfeit medicines

“Improvement of internal system” and “coordination with public institutions/industry groups” are strengthening-

The companies who confirmed counterfeit medicines take actions and measures, including import injunction requests to customs office, purchase/analysis of samples of counterfeit drugs (identification of true/false), detection in cooperation with health organizations and police, and collaboration with sales companies.

The responses to the questions for all member companies found that many companies strengthened <improvements of internal system> (“clarification of responsible and relevant divisions,” “clarification of incident reporting/information sharing process about falsified medicine” and “establishment/awareness of internal procedure manual (including group companies)” in Japan. These results suggest the impact of the issue of counterfeit medicines for type C hepatitis occurred in 2017. Many companies reported “product countermeasures” are taken in both domestic and global sectors, but about 18% of the companies reported “getting stronger” and “getting slightly stronger” that was significantly lower than in the global sector (30%). Similar to the 2nd survey (2015), many companies received information on counterfeit medicines from organizations, including the Federation of Pharmaceutical Manufacturers’ Associations of Japan (EPMAJ), JPMA, International Pharmaceutical Manufacturers & Associations (IFPMA), Pharmaceutical Security Institute (PSI), suggesting the importance of the role of industry organizations. Some companies take active measures, including information sharing and collaboration with MHLW, police, and customs office, press seminars, purchase investigation, and collaboration with universities.

Although few companies confirmed counterfeit medicines in Japan, it is important for a majority of the member companies to keep information collection regarding counterfeit medicines in collaboration with pharmaceutical companies/industry groups, in addition to continuous preventative measures for own products and <improvements of internal system> with reference to their own and global efforts.

5. Awareness about events and change to regulations

- About 80% of the companies changed their awareness of the issue by the domestic distribution of counterfeit medicines -

About 80% of the companies reported “issue awareness increased” of “counterfeit medicines for

type C hepatitis” occurred in 2017. Their awareness of the issue was influenced by the relevant “Discussion board for prevention of falsified medicine distribution in Japan organized by the Ministry of Health, Labour and Welfare (MHLW),” and “the Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical devices, ministerial order to partially revise the enforcement regulations (Establishment of new regulations for pharmacies, wholesalers, store sellers, and household distributors in order to prevent from falsified medicine distribution)”. The detection of counterfeit medicines in the domestic distribution channel gave a great impact on patients and medical product industry, and this issue was widely covered by media such as TV and national newspapers. The results of this questionnaire survey confirmed a significant impact on the member companies.

[Summary]

Counterfeit medicines are prevalent in multiple therapeutic fields, and patients have developed health problems due to such medicines. Hopefully, this will be a good opportunity for the member companies to learn from actions of proactive companies and global measures and to review measures to prevent health damage and counterplan for the event of health damage. Future tendencies deserve continued attention, and joint efforts of the member companies and relevant parties are necessary to share information and actions to prevent the expansion and eradicate counterfeit medicines.

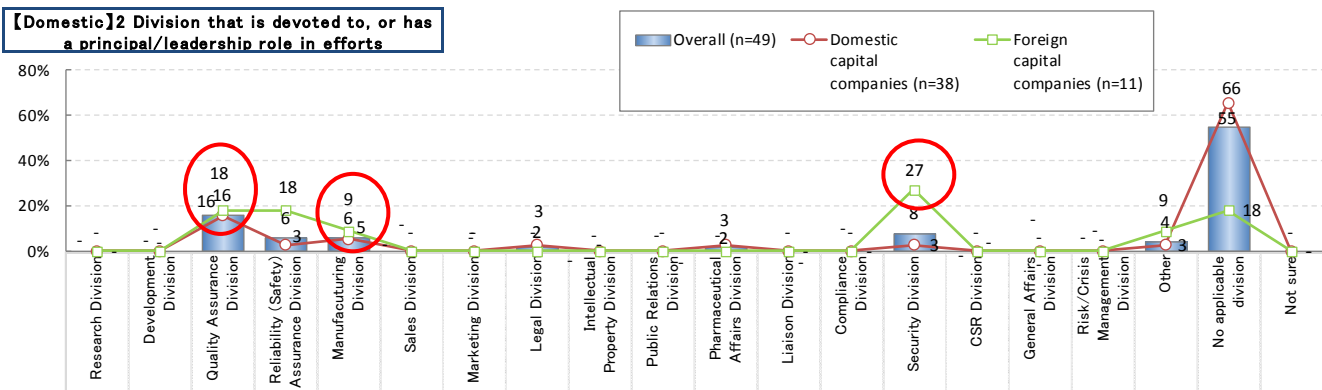
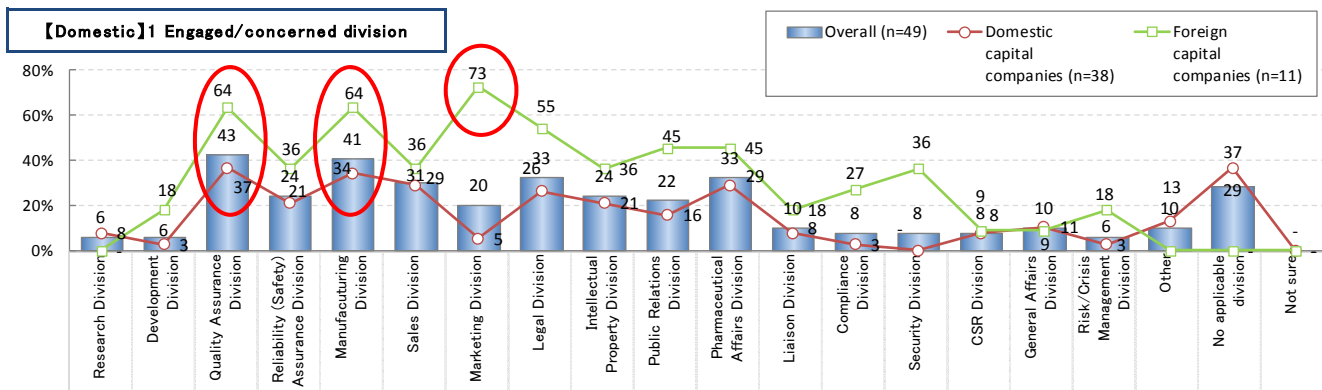
[Results and discussion for each question]

○Division in charge of counterfeit medicines

Q2 Does your company (including your parent company) have a division that is taking measures against counterfeit medicine, in Japan and Global?

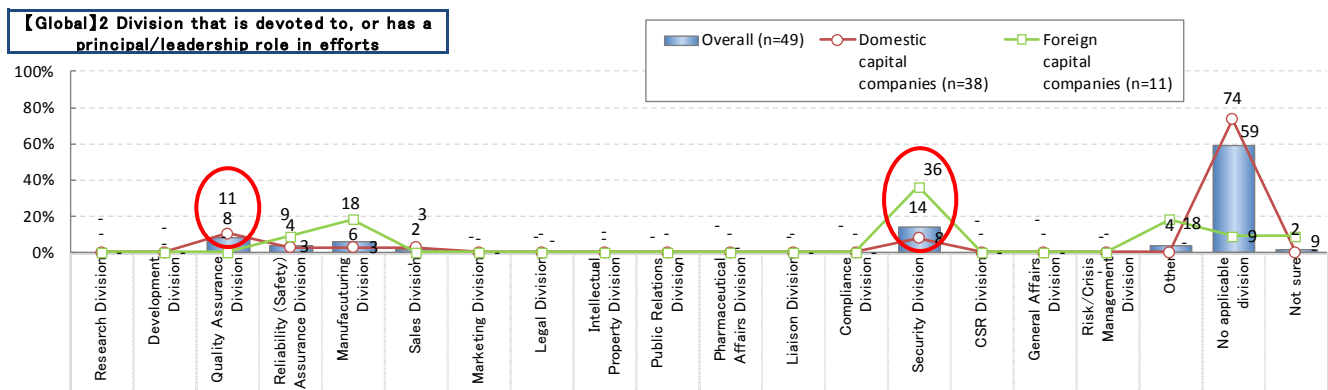
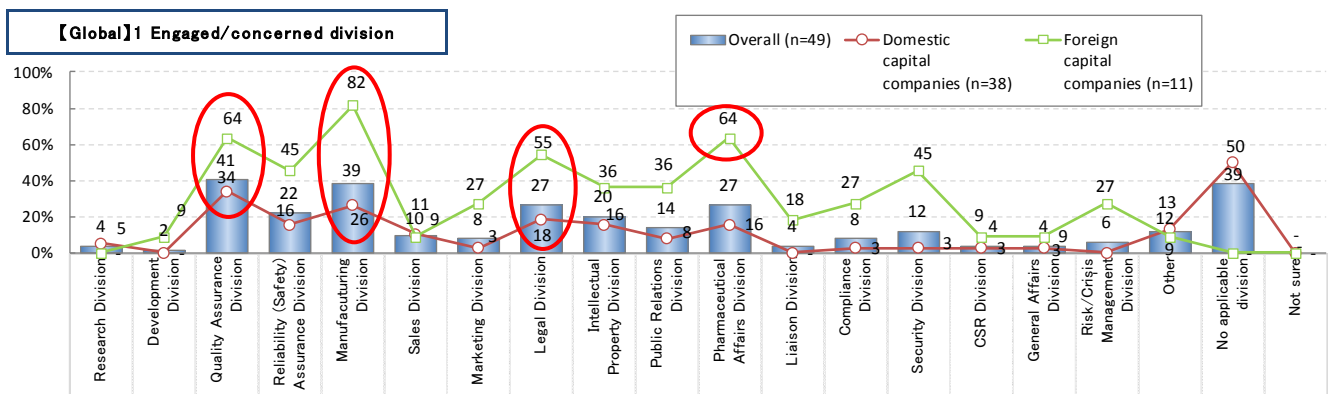
<Domestic>

- (1) Eleven out of 11 (100%) foreign capital companies and 24 out of 38 (63%) domestic capital companies answered that there is a division in charge of countermeasures against counterfeit medicines (excluding companies reporting “no applicable division” and “don’t know”). “Production/Quality Division” including Quality Assurance Division, Reliability Assurance Division, and Production Division, were common as well as Pharmaceutical Affairs Division, Business Division, and Legal Division among domestic capital companies. In foreign capital companies, “Marketing Division” (73%; 8 out of 11), “Production/Quality related division,” Legal Division and Public Relations Division were common.
- (2) Nine out of 11 (82%) foreign capital companies and 13 out of 38 (34%) domestic capital companies had a division as specialized in counterfeit medicines or with leadership. “Production/Quality Division” including Quality Assurance Division, Reliability Assurance Division, and Production Division were common in both domestic and foreign capital companies, while “Security related division” including global and product security was also common among foreign capital companies.



<Global>

- (1) Eleven out of 11 (100%) foreign capital companies and 19 out of 38 (50%) domestic capital companies had a dedicated division for countermeasures against counterfeit medicines (excluding companies reporting “no applicable division” and “don’t know”). “Production/Quality related division” including Quality Assurance Division, Reliability Assurance Division, and Production Division were common as well as Pharmaceutical Affairs Division and Legal Division in both domestic and foreign capital companies.
- (2) Nine out of 11 (82%) foreign capital companies and 10 out of 38 (26%) domestic capital companies had had a division as specialized in counterfeit medicines or with leadership. “Production/Quality related division” or “Security related division” including global and product security in both domestic and foreign capital companies, but “Security related division” was also common in foreign capital companies.



<Discussion>

The percentage of “domestic capital” companies that reported to currently tackle with the problems of counterfeit medicines in Japan increased from approximately 35% in the 1st survey (2013) and approximately 46% in the 2nd survey (2015) to approximately 62% in this survey. Although the fields and distribution channels of counterfeit medicines in Japan were limited, domestic distribution of counterfeit medicines, and environmental changes such as increased opportunities to share the information on counterfeit medicines in multiple fields in the global

sector affected organizational efforts to take actions for counterfeit medicines.

The number of “domestic capital companies” reporting that they have a division as specialized in counterfeit medicines for the global sector also increased. It is suggested that the “domestic capital companies” who have security division as a division as specialized in counterfeit medicines for the global sector are those who develop business in many international markets.

○ **Organizations and meeting structure in charge of countermeasures against counterfeit medicines**

Q3 Please answer the following about organizations, meeting structure, and others related to measures against counterfeit medicine concerning your products in your company (including your parent company), in Japan and Global.

< Domestic >

- (1) “Production/Quality related division” including Quality Assurance Division and Reliability Assurance Division or “Security related division” including global and product security were common as a division responsible for planning and managing the budget for countermeasures against counterfeit medicines.
- (2) “Production/Quality related division” and “Security related division” were common as a division responsible for managing meeting structure about counterfeit medicines among the member companies.
- (3) The responsible person for countermeasures against counterfeit medicines was generally the manager of the responsible division. Some companies reported that board members were responsible. General managers in production/sales, and quality assurance were also listed among the responses.
- (4) A broad range of divisions participate in meeting structure about counterfeit medicines as well as those that take measures against/are involved in counterfeit medicine in Q2. Many companies add supply chain division to the above.

< Global >

- (1) “Security related division” including global and product security were common as a division responsible for planning and managing the budget for countermeasures against counterfeit medicines.
- (2) Similarly, the main division responsible for countermeasures is often “Security related division.”
- (3) The responsible person for countermeasures against counterfeit medicines was generally the manager of the responsible division.
- (4) A broad range of divisions participate in meeting structure about counterfeit medicines as well as those that take measures against/are involved in counterfeit medicine in Q2. Many companies added supply chain division to the above.

〈Discussion〉

In Japan, the division responsible for planning and managing the budget for countermeasures against counterfeit medicines was often the “Production/Quality related division” including Quality Assurance and Reliability Assurance Division. Those divisions are also responsible for internal meeting structure about counterfeit medicines. On the other hand, “Security related division” including global and product security was common in the global sector. This is considered to be due to the fact that few domestic capital companies have encountered counterfeit medicines and focused on preventive measures (product countermeasures: e.g., prevention of counterfeiting, evaluation / introduction of identification methods, and supply chain security). In the global sector, counterfeit medicines were found in many fields in many countries/regions. It is assumed that “Security related division” serves as the key division for managing cross-functional activities such as sample analysis, collaboration between health organizations and law enforcement, 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 and to Global.

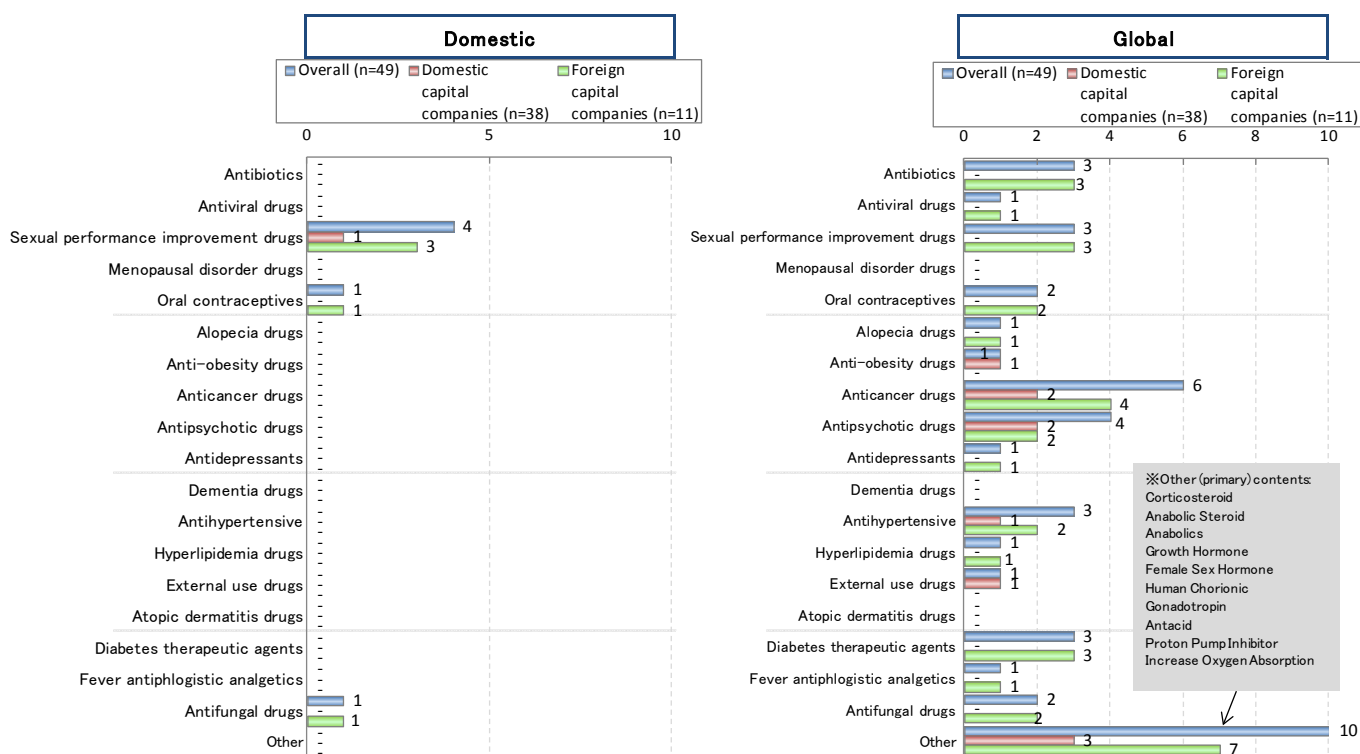
<Domestic >

Domestically, 4 companies (1 domestic capital and 3 foreign capital) had encountered counterfeit antifungal drugs and 1 company (foreign capital) confirmed a counterfeit of oral contraceptive.

<Global >

Globally, both domestic and foreign capital companies had encountered counterfeit medicines in many fields. Specifically, counterfeit medicines of anticancer drug were confirmed in 6 foreign capital companies, followed by antipsychotics (4 companies), antibiotics (3 companies), drugs for improvement of sexual performance (3 companies), antihypertensives (3 companies), and antidiabetic drugs (3 companies).

Two companies confirmed counterfeit medicines of oral contraceptives, antifungal drugs, anabolic steroids, antacids/proton pump inhibitors.



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.

Looking the number of confirmed cases of counterfeit medicines over the past two years in Japan, a majority of the confirmed cases was “drugs for improvement of sexual performance” of “foreign capital” companies. In Japan, 4 companies confirmed counterfeit medicines, including only 1 out of 38 domestic capital companies and 3 out of 11 foreign capital companies. Domestically, there were 1,246 cases of counterfeit medicines of drugs for improvement of sexual performance, 12 for antifungal drugs, and 1 for oral contraceptive.

	Overall		Domestic capital		Foreign capital	
	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)
Sexual performance impr	4	1,246	1	10	3	1,236
Oral contraceptives	1	1	0	0	1	1
Antifungal drugs	1	12	0	0	1	12
total	4	1,259	1	10	3	1249

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) Global (regions/countries out of Japan) over the past two years. If your company has confirmed the existence of counterfeit medicine, please indicate the number of confirmed cases.

In the global sector, 4 of 38 domestic capital companies and 6 out of 11 foreign capital companies confirmed counterfeit medicines. The results suggest that multiple domestic capital companies were affected by counterfeit medicines in the global sector, although they were not confirmed in Japan. Drugs for improvement of sexual performance accounted for majority of counterfeit medicines also in the global sector (573 cases; 3 foreign capital companies). Other confirmed counterfeit medicines included 113 antidiabetic drugs (3 foreign capital companies), 46 anti-cancer drugs (2 domestic and 4 foreign capital companies), and 34 oral contraceptives (2 foreign capital companies).

	Overall		Domestic capital		Foreign capital	
	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	17	0	0	3	17
Antiviral drugs	1	11	0	0	1	11
Sexual performance improvement drugs	3	573	0	0	3	573
Oral contraceptives	2	34	0	0	2	34
Alopecia drugs	1	2	0	0	1	2
Anti-obesity drugs	1	25	1	25	0	0
Anticancer drugs	6	46	2	24	4	22
Antipsychotic drugs	4	13	2	4	2	9
Antidepressants	1	1	0	0	1	1
Antihypertensive	3	17	1	2	2	15
Hyperlipidemia drugs	1	20	0	0	1	20
External use drugs	1	2	1	2	0	0
Diabetes therapeutic agents	3	113	0	0	3	113
Fever antiphlogistic analgetics	1	28	0	0	1	28
Antifungal drugs	2	11	0	0	2	11
Other	10	164	3	8	7	156
total	10	1077	4	65	6	1012

〈Discussion〉

In this questionnaire survey, counterfeit medicines for oral contraceptives were confirmed in Japan for the first time. Counterfeit medicines for the improvement of sexual performance were confirmed both in the first (2013) and the second (2015) surveys, while antifungal drugs were also

confirmed in the second survey (2015), suggesting continuous presence of counterfeit medicines.

Both domestically and globally, the majority of confirmed cases of counterfeit medicines was drugs for improvement of sexual performance. Especially in Japan, private imports are frequently observed via agents for private imports because of its characteristics (including non-insurance coverage and hesitation to visit a specialist), slipping counterfeit medicines into such cases via unauthorized route, and boarder crackdowns (import suspension measure) of such counterfeit medicines at customs office in Japan are plausible factors.

As the above, the tendency has not been changed that the confirmed cases of counterfeit medicines of drugs for improvement of sexual performance stand out, however, the items of counterfeit medicines have increased since 2013, when the questionnaire survey started. Despite it was the company who did not participate in this survey, the issue of counterfeit medicines for type C hepatitis occurred in 2017. Future tendencies deserve continued attention, and joint efforts of the member companies and relevant parties are necessary to share information and actions to prevent the expansion and eradicate counterfeit medicines.

Globally, various counterfeit medicines were recognized, including anti-cancer drugs, drugs for lifestyle-related common diseases, and hormone drugs. According to the Political Research News Office of Pharmaceutical Industry Research¹⁾, of 100 items in the top sales medical products in the IMS World Review Analyst 2017, anti-cancer drugs/immunomodulators (29 items) were the most common, followed by systemic anti-infectious drugs (14 items), drugs for gastrointestinal organs and metabolic medicines (12 items), and neurological drugs (12 items). Counterfeit medicines were found in multiple anti-cancer drugs, antipsychotics, antibiotics, antihypertensives, and antidiabetic drugs, suggesting that top sales fields are likely to be targets of counterfeit medicines. For companies who deal with or plan to launch major products, preventive measures (product countermeasures: e.g., prevention of counterfeiting, evaluation/introduction of identification methods, and supply chain security) is a challenge. The impact of the global problems on Japan needs to be predicted.

- 1) Political Research News No.52, November 2017: Nationality of manufacturers of top global sales medical products — trends in 2016 —

○Region with counterfeiting medicines

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 Global (regions/countries out of Japan) over the past two years. Please select all applicable regions where counterfeit medicines were confirmed.

Counterfeit medicines were confirmed in “Latin America region” in 8 out of 10 companies, “Asia region” and “Europe region” in 7 out of 10 companies. In “Europe region,” 4 companies confirmed counterfeit medicines of “anti-cancer drugs.” Counterfeit medicines of “drugs for improvement of

sexual performance,” “drugs for obesity,” “anti-cancer drugs,” and “antidiabetic drugs” were confirmed in all global regions.

*Based on companies that have recognized the existence of counterfeit

	T o t a l	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 (antibacterial agents for infectious diseases)	3	3	0	1	1	0	1	0	0
Antiviral drugs	1	0	0	1	0	0	0	1	0
Sexual performance improvement drugs	3	3	3	3	3	2	2	1	0
Menopausal disorder drugs	0	0	0	0	0	0	0	0	0
Oral contraceptives	2	2	0	1	0	0	0	0	0
Alopecia drugs	1	0	1	0	0	0	0	0	0
Anti-obesity drugs	1	1	1	1	1	1	1	1	0
Anticancer drugs	6	4	1	2	4	1	1	1	0
Antipsychotic drugs	4	2	2	1	2	1	0	0	0
Antidepressants	1	1	0	0	0	0	0	0	0
Dementia drugs	0	0	0	0	0	0	0	0	0
Antihypertensives	3	2	0	1	0	0	0	0	0
Hyperlipidemia drugs	1	1	0	0	0	0	0	0	0
External use drugs	1	1	0	0	1	0	0	0	0
Atopic dermatitis drugs	0	0	0	0	0	0	0	0	0
Diabetes therapeutic agents	3	3	0	0	1	0	0	0	0
Fever antiphlogistic analgetics	1	1	0	1	0	0	0	0	0
Antifungal drugs	2	1	0	1	0	0	0	0	0
Other	10	4	1	3	4	0	3	1	0
total	10	7	6	8	7	3	5	4	0
	%	70.0	60.0	80.0	70.0	30.0	50.0	40.0	0.0

〈Discussion〉

Counterfeit medicines were confirmed in the all global areas. Among 10 companies who confirmed counterfeit medicines in each region, there were 8 companies in “Latin America region,” 7 in “Asian region,” and 7 in “European region.”

In the total number of companies who confirmed counterfeit medicines in “each region,” “Asian region” was the highest. This trend has not been changed since the results of the 2nd survey (2015). The results suggest that many companies are still at risk of counterfeit medicines in “Asian region.” Although a definite conclusion cannot be drawn from the results based on the number of companies, it is suggested that there is a large number of types of counterfeit medicines distributed in “Asian region.”

Fewer drugs were reported in the “African region,” but it is likely that companies are not so aware of the situation in that region. In such region, access to care is low because of the poor health care system, suggesting that the difficulty of obtaining medical products from the official channel increases a risk of counterfeit medicines.

○Damaging effects of counterfeit medicines

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) in Japan over the past two years. Please select all choices that apply to the extent of harm suffered by your patients.

Three of 4 companies reporting counterfeit medicines in “drugs for improvement of sexual performance” confirmed “there were reactions that were considered insignificant.”

*Based on companies that have recognized the existence of counterfeit

	T o t a l	There were deaths	There were reactions that were consider ed critical	There were no critical reactions, but reactions were not insignific ant	There were reactions that were consider ed insignific ant	Does not apply
Unit: # of company						
Sexual performance improvement drugs	4	0	0	0	3	1
Oral contraceptives	1	0	0	0	0	1
Antifungal drugs	1	0	0	0	0	1
total	4	0	0	0	3	2
	%	0.0	0.0	0.0	75.0	50.0

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 Global (regions/countries out of Japan) over the past two years. Please select all choices that apply to the extent of harm suffered by your patients.

“There were reactions that were considered critical” was found in counterfeit medicines of “antidiabetic drugs.” “There were no critical reactions, but reactions were not insignificant” was found in counterfeit medicines of “antidiabetic drugs” and “drugs for improvement of sexual performance,” while “there were reactions that were considered insignificant” was found in counterfeit medicines of “antacids.”

*Based on companies that have recognized the existence of counterfeit

	T o t a l	There were deaths	There were reactions that were consider ed critical	There were no critical reactions, but reactions were not insignific ant	There were reactions that were consider ed insignific ant	Does not apply
Unit: # of company						
Antibiotics (antibacterial agents for infectious diseases)	3	0	0	0	0	3
Antiviral drugs	1	0	0	0	0	1
Sexual performance improvement drugs	3	0	0	1	0	2
Oral contraceptives	2	0	0	0	0	2
Alopecia drugs	1	0	0	0	0	1
Anti-obesity drugs	1	0	0	0	0	1
Anticancer drugs	6	0	0	0	0	6
Antipsychotic drugs	4	0	0	0	0	4
Antidepressants	1	0	0	0	0	1
Antihypertensives	3	0	0	0	0	3
Hyperlipidemia drugs	1	0	0	0	0	1
External use drugs	1	0	0	0	0	1
Diabetes therapeutic agents	3	0	1	1	0	2
Fever antiphlogistic analgetics	1	0	0	0	0	1
Antifungal drugs	2	0	0	0	0	2
Other	10	0	0	0	1	9
total	10	0	1	2	1	10
	%	0.0	10.0	20.0	10.0	100.0

〈Discussion〉

Although “there were reactions that were considered critical” was not confirmed in Japan in this questionnaire survey, “there were reactions that were considered critical” was confirmed in Japan in the 2nd survey (2015). It is reasonable to say that a threat of counterfeit medicines to patient health does not subside but continues. Furthermore, since the adverse reaction was reported without proof of relation with counterfeit medicines in the past, the issue of counterfeit medicines may lose the credibility of authentic medicines and pharmaceutical companies.

○Countermeasures, action plans and others against counterfeit medicines

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) in Japan over the past two years. Please indicate specific the efforts/measures your company took in response to cases that were actually confirmed.

Actions and measures are taken, including import injunction requests to customs office, purchase/analysis of samples of counterfeit drugs (identification of true/false), public awareness activities such as press seminars, detection in cooperation with police and customs office, and submission of a request on prevention of distribution of counterfeit medicines for Internet registrar.

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 Global (regions/countries out of Japan) over the past two years. Please indicate specific efforts/measures your company took in response to cases that were actually confirmed.

Actions and measures are taken, including import injunction requests to customs office, purchase/analysis of samples of counterfeit drugs (identification of true/false), detection in cooperation with health organizations and police, and collaboration with sales companies.

〈Discussion〉

In Japan, actions and measures similar to the global activities were observed. These actions and measures, however, are taken by companies who confirmed counterfeit medicines such as drugs for improvement of sexual performance. JPMA should take an important role to make an environment that is required for other member companies to use these findings on an ongoing basis.

Although global counterfeit medicines are not only drugs for improvement of sexual performance but has a wide variety, there are not big differences in actions/measures between the fields. International collaboration among WHO, INTERPOL, and World Customs Organization is ongoing.

○Countermeasures against counterfeit medicines/collaboration with stakeholders

Q12 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.

The percentage of companies reporting that they take <product countermeasures> (excluding “not making this effort”) was about 76%. About 18% of the companies reported “getting stronger” or “getting slightly stronger,” while about 57% of the companies answered that it was “no change (as is).” Regarding <improvements of internal system>, nearly 70% of the companies take actions about “clarification of responsible and relevant divisions,” “clarification of incident reporting/information sharing process about falsified medicine” and “establishment/awareness of internal procedure manual (including group companies),” and about 40% of the companies reported “getting stronger” or “getting slightly stronger.” On the other hand, more than 60% of the companies reported “not making this effort” in all categories other than the above. Among these, focusing on the responses of “getting stronger” or “getting slightly stronger,” “public awareness for employees including inhouse training” (about 18%), coordination with other pharmaceutical companies/industry groups (e.g., IFPMA, PhRMA, EFPIA) (about 10%), and periodic monitoring to understand the state of falsified medicine (about 10%) were rated higher.

Product countermeasures	n=	Response				Stronger, total		
		Getting stronger	Getting slightly stronger	No change (as-is)	Company not taking this effort	#	%	
Anti-counterfeiting measures for products (including packaging) (e.g. Hologram, anti-counterfeiting printing ink, two-dimensional bar code)	(49)	6	12	57	24	9	18.4	
Coordination with other pharmaceutical companies/industry groups (for example, IFPMA, PhRMA, EFPIA)	(49)	4	6	35	2	53	5	10.2
Countermeasures through coordination with industry professionals	(49)	4	4	27	2	63	4	8.2
Consultation with MHLW	(49)	6	27			67	3	6.1
Coordination with NGOs, NPOs (for example, PSI, PSM)	(49)	4	2	27	2	65	3	6.1
Coordination with academia	(49)	4	2	29	2	63	3	6.1
Cooperation in investigations by judicial authorities (Interpol), such as police	(49)	4	31	2		63	2	4.1
Import injunction requests to Customs (Custom recordal)	(49)	2	33			65	1	2.0
Cooperation with Customs investigations	(49)	2	31			67	1	2.0
Coordination with patient groups	(49)	2	22	2		73	1	2.0
Consultation with METI, Patent Agency	(49)		31			69	0	0.0
Coordination with the media	(49)		29	2		69	0	0.0
Coordination with politicians	(49)		24			76	0	0.0
Public awareness aimed at employees, including company training	(49)	2	16	14	4	63	9	18.4
Public awareness activities at academic conferences, etc.	(49)	2	4	20	2	71	3	6.1
Public awareness over the Internet	(49)	2	4	24		69	3	6.1
Creation and release of CSR activity reports for outside the company (for example, annual reports)	(49)	2	2	22		73	2	4.1
Public awareness aimed at the general population	(49)	2	2	22		73	2	4.1
Public awareness aimed at patients and the general population	(49)	2	2	24		71	2	4.1
Coordination with medical associations, etc.	(49)	4	24			71	2	4.1
Public awareness aimed at health care providers	(49)	2	2	27		69	2	4.1
Establish/awareness of internal procedure manual (including subsidiary/group company)	(49)	10	35	20		35	22	44.9
Clarification of incident reporting/escalation/information sharing process about falsified medicine	(49)	14	27	29		31	20	40.8
Clarification of the division that are devoted or have a primary leadership role and divisions contributing to /concerned with measures	(49)	12	22	35		31	17	34.7
Implementation of simulation training	(49)	2	24			73	1	2.0
Periodic monitoring aimed at understanding the state of falsified medicine	(49)	4	6	29		61	5	10.2
Factual investigations aimed at understanding the state of falsified medicine	(49)	4	4	31		61	4	8.2
Other information gathering activities aimed at understanding the state of falsified medicine	(49)	4	4	33		59	4	8.2
Litigation	(49)		27			73	0	0.0
Other	(49)	2	8			90	1	2.0

※Descending sort by category based on the score of “stronger total (companies)”

Q13 Please tell us how efforts against counterfeit medicine have been progressing in your company (including your parent company) in Global (regions/countries out of 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.

The percentage of companies reporting that they take <product countermeasures> (excluding “not making this effort”) was about 63%. About 30% of the companies reported “getting stronger” or “getting slightly stronger,” while about 33% of the companies answered that it was “No change (as is).”

Regarding <improvements of internal system>, about 50% of the companies take actions about “clarification of responsible and relevant divisions,” “clarification of incident reporting/information sharing process about falsified medicine,” and “establishment/awareness of internal procedure manual (including group companies),” and about 20% of the companies reported “getting stronger” or “getting slightly stronger.” On the other hand, more than 60% of the companies reported “not making this effort” in all categories other than the above. Among these, focusing on the responses of “getting stronger” or “getting slightly stronger,” “public awareness for employees including inhouse training” (about 14%), coordination with other pharmaceutical companies/industry groups (e.g., IFPMA, PhRMA, EFPIA) (about 14%), “factual survey to understand the state of falsified medicine” (about 12%), “periodic monitoring to understand the state of falsified medicine” (about 12%), and “information gathering activities to understand the state of falsified medicine” (about 12%) were rated higher.

		<div style="display: flex; justify-content: space-between; font-size: small;"> ■ Getting stronger ■ Getting slightly stronger </div> <div style="display: flex; justify-content: space-between; font-size: x-small;"> ■ No change (as-is) ■ Getting slightly weaker </div> <div style="display: flex; justify-content: space-between; font-size: x-small;"> ■ Company not taking this effort </div>				Stronger, total				
		n=	#	%						
Product countermeasures	Anti-counterfeiting measures for products (including packaging) (e.g. Hologram, anti-counterfeiting printing ink, two-dimensional bar code)	(49)	20	10	33	37	15	30.6		
	Coordination with other pharmaceutical companies/industry groups (for example, IFPMA, PhRMA, EFPIA)	(49)	10	4	24	2	59	7	14.3	
Coordination with public institutions/industry groups	Coordination with NGOs, NPOs (for example, PSI, PSM)	(49)	6	2	22		69	4	8.2	
	Countermeasures through coordination with industry professionals	(49)	6	2	22	2	67	4	8.2	
	Cooperation with Customs investigations	(49)	4	2	27		67	3	6.1	
	Consultation with FDA	(49)	4	2	24		69	3	6.1	
	Import injunction requests to Customs (Custom recordal)	(49)	4		27	2	67	2	4.1	
	Cooperation in investigations by judicial authorities (Interpol), such as police	(49)	4		31		65	2	4.1	
	Coordination with academia	(49)	4		24		71	2	4.1	
	Coordination with politicians	(49)	4		22		73	2	4.1	
	Consultation with the Department of Treasury, Patent Agency	(49)	2		29		69	1	2.0	
	Coordination with patient groups	(49)	2		22		76	1	2.0	
	Coordination with the media	(49)	2		27		71	1	2.0	
	Public awareness activities	Public awareness aimed at employees, including company training	(49)	12	2	18		67	7	14.3
		Public awareness aimed at health care providers	(49)	4		22		73	2	4.1
Public awareness activities at academic conferences, etc.		(49)	4		22		73	2	4.1	
Coordination with medical associations, etc.		(49)	4		22		73	2	4.1	
Creation and release of CSR activity reports for outside the company (for example, annual reports)		(49)	2	2	22	2	71	2	4.1	
Public awareness over the Internet		(49)	2		22		76	1	2.0	
Public awareness aimed at patients and the general population		(49)	2		22		76	1	2.0	
Public awareness aimed at the general population		(49)	2		22		76	1	2.0	
Improvements of internal system	Clarification of incident reporting/escalation/information sharing process about falsified medicine	(49)	10	10	29		51	10	20.4	
	Clarification of the division that are devoted or have a primary leadership role and divisions contributing to /concerned with measures	(49)	12	6	33		49	9	18.4	
	Establish/awareness of internal procedure manual (including subsidiary/group company)	(49)	10	8	29		53	9	18.4	
	Implementation of simulation training	(49)	2	2	22		76	0	0.0	
Investigation activities	Factual investigations aimed at understanding the state of falsified medicine	(49)	8	4	22	2	63	6	12.2	
	Periodic monitoring aimed at understanding the state of falsified medicine	(49)	6	6	22	2	63	6	12.2	
	Other information gathering activities aimed at understanding the state of falsified medicine	(49)	6	6	29		59	6	12.2	
Other	Litigation	(49)	2		22		73	1	2.0	
	Other ()	(49)	2	10			88	1	2.0	

※Descending sort by category based on the score of “stronger total (companies)”

Q14 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 perceived 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," "improvement of internal system," and "investigation activities" that include governments and others in Japan and Global.

<Japan>

Specific examples of product countermeasures were given by many companies (19 companies). Most of them reported strengthening “packaging”/”sealing” mainly for prevention of falsification/replacement at distribution (e.g., special printing, hologram, bar code, closing seals, pillow packing, GS1 code corresponding).

Similar to the 2nd survey (2015), many companies receive information related to counterfeit medicines from industry organizations (e.g., EPMAJ, JPMA, IFPMA, PSI), suggesting the importance of the role of industry associations. Some companies take active measures, including information sharing and collaboration with MHLW, police, and customs office, press seminars, purchase investigation, and collaboration with universities.

<Global>

Globally, many companies are actively introducing specific counterfeit prevention technology compared with the situation in Japan. Most respondents (17 companies) have introduced some kinds of technology. Beside the above, creative tablets, adoption of serialization and introduction of traceability technology are under consideration.

In addition to collaboration with international organizations, including WHO, IFPMA, and PSI, specific actions/measures for counterfeit medicines are being progressed in coordination with public institutions such as health organizations, police, and customs office in the country concerned.

<Discussion>

In Japan, it was confirmed that “clarification of responsible and relevant divisions,” “clarification of incident reporting/information sharing process about falsified medicine” and “establishment/awareness of internal procedure manual (including group companies)” were strengthened as <improvements of internal system>. These results suggest the impact of the issue of counterfeit medicines for type C hepatitis occurred in 2017.

Both domestically and globally, many companies reported that they take <product countermeasures>, but about 18% of the companies reported “getting stronger” and “getting slightly stronger” that was significantly lower than in the global (30%). Currently, the risk of counterfeit medicines may be lower in Japan than that in the global sector, considering the recent situation, preventative measures such as introduction of monitoring with advanced technology to prevent counterfeiting are important.

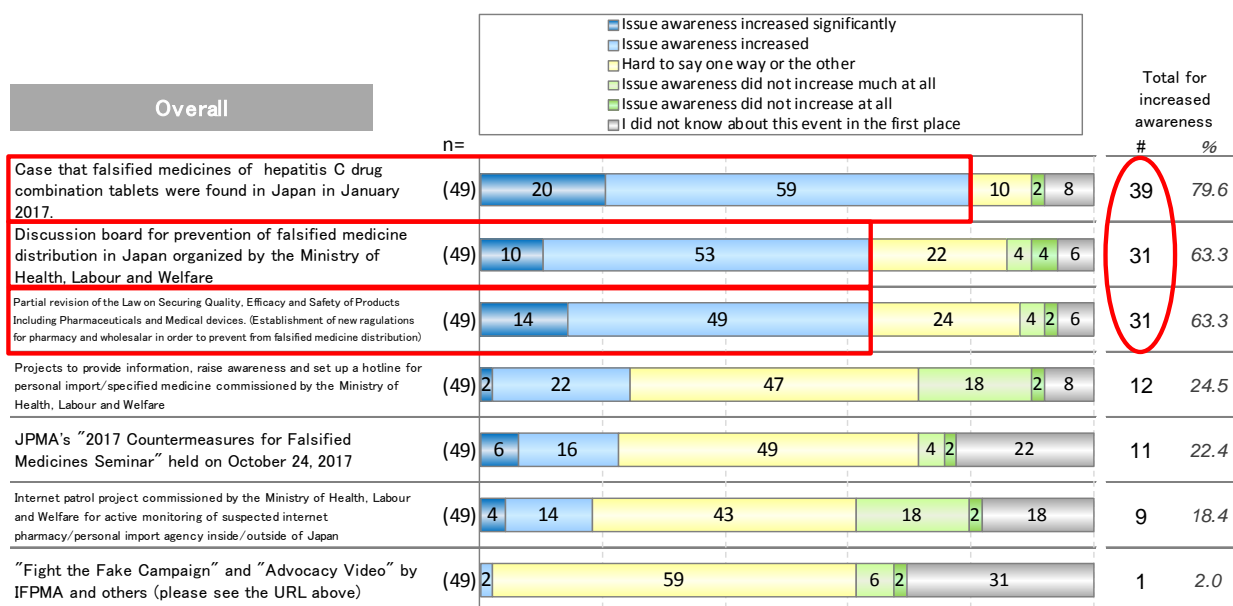
Although few companies confirmed counterfeit medicines in Japan, it is important for a majority of the member companies to keep information collection regarding counterfeit medicines

in collaboration with pharmaceutical companies/industry groups, in addition to continuous preventative measures for own products and improvements of internal system with reference to their own and global efforts.

○Awareness of events and changes to the regulations

Q15 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.

The percentage of the companies reporting “issue awareness increased significantly” or “issue awareness increased” of “counterfeit medicines for type C hepatitis” occurred in 2017 was about 80%, which was the highest response. Then, it was about 63% both in “Discussion board for prevention of falsified medicine distribution in Japan organized by the Ministry of Health, Labour and Welfare,” or “the Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical devices, ministerial order to partially revise the enforcement regulations (Establishment of new regulations for pharmacies, wholesalers, store sellers, and household distributors in order to prevent from falsified medicine distribution).”



〈Discussion〉

The top 3 responses were related to “the issue of counterfeit medicines for type C hepatitis.” The detection of counterfeit medicines in the domestic distribution channel gave a great impact on patients and medical product industry, and this issue was widely covered by media such as TV and national newspapers. The results of this questionnaire survey confirmed a significant impact on the

member companies.

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. On the other hand, about 20% 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**

Q16 Please tell us about your efforts, measures, and other activities for combating theft, inappropriate distribution, trademark infringement, and others in Japan and Global.

<Japan>

Against theft/illegal distribution, the following actions/measures are taken:

- (1) Individual agreements with importers (e.g., use of specialized delivery service, no dispatch over weeks, strict procedures for access, quality standards)
- (2) Strict stock management at storage warehouse/strengthening security system
- (3) Due diligence on contractors/implementation of inspection
- (4) Strengthening confirmation at delivery of medical products to distributors (e.g., product name/quantity/appearance/voucher/inspection) and conducting an investigation in case of abnormal order quantity
- (5) Response based on own GDP standards
- (6) Storage/management as a part of GMP management
- (7) Preparation of procedures/education and training/revamp system according to “Discussion board for prevention of falsified medicine distribution in Japan organized by the Ministry of Health, Labour and Welfare,” and “the Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical devices, ministerial order to partially revise the enforcement regulations-122”
- (8) Monitoring of dealing in the Internet and other.

Regarding trademark infringement, the following actions/measures are taken:

- (1) Register patent for active ingredient and a trademark for brand name and other
- (2) Application for import injunction requests to customs/lectures on customs
- (3) Monitoring for infringement of patent/trademark/other (e.g., online pharmacy)
- (4) Information activities on infringement of patent (e.g., notice)

<Global>

Against theft/illegal distribution, the following actions/measures are taken:

- (1) Improvement/assessment of procedure manuals/reporting procedures for carriers and supply chains
- (2) Change to a lock system/a form which is difficult to open to prevent falsification of delivery

packaging

- (3) Strick lock management of transport truck
- (4) Transport monitoring for value-added products
- (5) Due diligence on contractors/implementation of inspection
- (6) Assessment of security risks in countries related to business
- (7) Response based on own GDP standards or EU GDP
- (8) Storage/management as a part of GMP management

Regarding trademark infringement, the following actions/measures are taken:

- (5) Register patent for active ingredient and a trademark for brand name and other
- (6) Application for import injunction requests to customs/lectures on customs
- (7) Monitoring for infringement of patent/trademark/other (e.g., online pharmacy)
- (8) Information activities on infringement of patent (e.g., notice)

〈Discussion〉

More companies are likely to strengthen actions/measures against theft/illegal distribution in Japan from those in the 2nd survey. Regarding trademarks, application for import injunction requests to customs was reported as it was in the last time. Furthermore, multiple companies show an attitude to take decisive measures for infringement of intellectual properties. Regarding application for import injunction requests to customs, detailed information is given on the website of “customs actions against goods suspected of infringing intellectual property” of customs office, Ministry of Finance. Since the results of enforcement and acceptance information are released as well as outline/application procedure, please read them.

Various specific activities and measure are taken against theft, illegal distribution, and trademark violations at the global level. 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.

(end)