The Research Committee for International Pharmaceutical Distribution The Federation of Japan Pharmaceutical Wholesalers Association

Report 2

International Comparison of Pharmaceutical Business Practices and Functions of Pharmaceutical Wholesalers

November 2013



The Federation of Japan Pharmaceutical Wholesalers Association



What it means "to wholesale" prescription drugs varies significantly from country to country. Differences in the meaning of wholesaling are caused by differences in society, culture, health care systems, and pharmaceutical industries, and also by the accumulated drug trade practices that spring from each of these factors. Therefore, it is clear that the functions of pharmaceutical wholesalers have varied and will continue to vary by country. On the other hand, balancing restraints on government medical and drug spending, and guaranteed patient access to medical services is a challenge in every developed country. It is also clear that, while differences in circumstances have to be taken into consideration, there are features of drug wholesaling in other countries that Japan can learn from.

The pharmaceutical distribution that took place after the Great East Japan Earthquake of March 2011 made it clear that the role of Japan's pharmaceutical wholesalers, called "*Oroshi*", is different than that of the wholesalers of other countries. The trained sales reps, called marketing specialists (MS), of the pharmaceutical *Oroshi* showed a sense of duty that compelled them to deliver drugs to dispensers and provide information to prescribers. Thanks to these MS, pharmaceutical *Oroshi* were able to quickly fulfill their roles as distributors, collect information about local supply & demand situations, and convey the information. In Japan, where earthquakes and other disasters occur regularly, society at large now understands that the continuation of appropriate investment into pharmaceutical *Oroshi* infrastructure is an important responsibility.

In Report 1 of the Research Committee for International Pharmaceutical Distribution of the Federation of Japan Pharmaceutical Wholesalers Association (hereinafter referred to as "the committee"), which is titled *International Comparison of Pharmaceutical Wholesalers' Function-Specific Costs* (December 2010), qualitative and quantitative comparisons were made of the various functions and costs of the pharmaceutical wholesalers of Japan, the US, and Europe. The objective of the report was to give all concerned parties a clear understanding of how the types and quantities of functions being fulfilled by Japanese pharmaceutical *Oroshi* differ from those fulfilled by the pharmaceutical wholesalers of other countries. The report has been recognized as a success in that capacity.

In order to gain more understanding about *Oroshi*, the unique functions that are being fulfilled by pharmaceutical *Oroshi* and the differences in the systems and trade practices of Japan, the US, and Europe, the committee has carried out an international survey in which the pharmaceutical wholesalers of Japan, the US, and Europe were interviewed. The survey was conducted for the markets of Japan, the US, the UK, France, and Germany.

This survey has confirmed that the functions of pharmaceutical *Oroshi* in Japan clearly differ from those of the wholesalers in other countries in the following ways.

- The percentage of *Oroshi* that train and employ their own delivery staff is high, excluding that in the UK.
- **2** Oroshi engage in price negotiations with all medical institutions & pharmacies.
- The approximately 18,000 MS located throughout Japan gain an understanding of local supply & demand situations by visiting drug dispensers and prescribers.
- Oroshi provide drug information on behalf of pharmaceutical companies and have a degree of influence on drug selection, primarily in clinics.

It is our hope that this report will contribute to the development of a clear discussion of the functions and costs of *Oroshi* among parties concerned with medical services and drugs in Japan.

International Comparison of Pharmaceutical Business Practices

Before we look at an international comparison of pharmaceutical business practices, let us first examine health insurance and reimbursement price systems. As was mentioned in the first report, and as is clear from Table 1, these systems vary significantly by country.^(Reference 1)

In Japan, under the drug pricing system, the reimbursement price (drug price) is revised once every two years on the basis of the actual market price (the price at which the drug is sold to medical institutions & pharmacies). To determine the actual market price, drug price surveys are conducted in the year before a drug price is revised. Due to the facts that reimbursed drug costs are paid for with public funds and that the pharmaceutical industry is intimately connected with the health of the Japanese people, this system must be managed sustainably in a form that can be explained to the Japanese people.

In the US, there are no official national restrictions on the reimbursement price. In Germany and France, pharmaceutical companies are relatively free to set the price of unique patented drugs, but official prices are set for generic drugs. However, there is no system for revising reimbursement prices on the basis of actual market prices. In the UK, pharmaceutical companies can set the prices of patented drugs freely within a designated profit range, but the reimbursement prices of generic drugs are revised quarterly in accordance with actual market prices. As is clear from the above, Japan is the only country in which the actual market price is the basis for all reimbursement prices, including those of both patented and generic drugs.

| _ | Health | Reimbursement Price System | | | | | | | | |
|---------|---------------------------------|---|--|--|--|--|--|--|--|--|
| | System | Patented | Generic | | | | | | | |
| Japan | Public insurance | Determined through negotiations with the Ministry of Health, Labour and Welfare when a drug is launched on the market After a drug is launched on the market, its price is revised on the basis of actual market prices once every two years. Prices of specific types of medicines and items may be lowered. | When a drug is launched on the market, in principle, its price is set to 70% of the price of the original drug. After a drug is launched on the market, its price is revised on the basis of actual market prices once every two years. | | | | | | | |
| | Private insurance | Unregulated: Decided through negotiations between ph | armaceutical companies and respective payers | | | | | | | |
| 03 | Public insurance | Unregulated: Prices are set by federal and state govern | ments, considering actual market prices. | | | | | | | |
| UK | Public healthcare service | Pharmaceutical companies may set prices freely within a designated profit range. Prices may be reduced across-the-board through agreement with the government. The National Institute for Health and Care Excellence (NICE) provides prescription restriction guidance. | When a drug is launched on the market, its price may be set freely as long as it is lower than that of the original drug. After a drug is launched on the market, its price may be revised on the basis of the actual market price (every quarter). | | | | | | | |
| Germany | Public insurance | Pharmaceutical companies set prices freely. When a drug is not found to be significantly effective, it is put into a reference price group. | A maximum price (reference price) paid by insurance is set for each reference price group. Prices are revised once a year (on April 1). | | | | | | | |
| France | Public insurance | The government sets the retail price (maximum sales price) of drugs through negotiations with pharmaceutical companies. In principle, prices are revised every five years. Prices may be revised on the basis of actual market prices. Prices are reduced when patents expire. | After the patent expires, the official price is set based on the value of 40% of the ex-factory price of the original drug. After 18 months, the price is reduced by 4%. | | | | | | | |
| | | If the switch to the generic product is not proceeding after | er the patent expires, a reference price system is applied. | | | | | | | |

Table 1: Comparison of Health Insurance and Reimbursement Price Systems

(Source: Medical and Drug Price Systems: Research on Drug Usage, etc., March 2011, Institute for Health Economics and Policy)

Therefore, in Japan, when provisional deliveries of prescription drugs are made before the wholesale price has been determined through negotiations between pharmaceutical *Oroshi* and medical institutions & pharmacies, and when total value transactions (bulk buying) are made in which the prices of individual items are not set, the actual market price as determined by the drug price survey cannot be said to correctly reflect the value of a pharmaceutical product. This fact may undermine the reliability of the drug price survey. In addition, for a pharmaceutical *Oroshi* to present a price to medical institutions that reflects the value of a product, negotiations on individual ex-factory prices must be made between the pharmaceutical company and the pharmaceutical *Oroshi*. With the purpose of addressing these issues, the Committee for Improvement of the Prescription Drug Business Practices, which serves as a means for the Director of the Health Policy Bureau of the Ministry of Health, Labour and Welfare to gather opinions, published Urgent Proposal for Improvement of the Prescription Drug Business Practices in September 2007. Let us examine the trade practices of Europe and the US that the survey indicates Japan might learn from in its attempt to improve business practices with regard to these issues.

(1) Margin Caps, Principle Negotiators, and Trade Practices in Transactions between Pharmaceutical Wholesalers and Medical Institutions & Pharmacies

The conditions under which transactions are made between pharmaceutical wholesalers and medical institutions & pharmacies vary significantly by country. The differences in margin limits, principle negotiators, and trade practices revealed by the committee's interviews of pharmaceutical wholesalers in Japan, the US, and Europe are summarized in Table 2.

| _ | | | Japan | | US | | UK | | Germany | | France | |
|--------------------|--|------------|------------------------|---------|-----------------------|--------------------------|--------------|------------|---|------------|---|---------|
| | | | Patented | Generic | Patented | Generic | Patented | Generic | Patented | Generic | Patented | Generic |
| Margin | Wholesaler margin o | caps | No | No | No | No | Vee* | No | Yes | Yes | Yes | Yes |
| caps | Hospital and pharmacy margin caps | | No | No | No | No | res | No | Yes | Yes | Yes | Yes |
| Principal | Hospitals | | Oroshi | Oroshi | Pharma | Wholesaler | Pharma | Pharma | Pharma | Pharma | Pharma | Pharma |
| negotiator | Pharmacies | | Oroshi | Oroshi | Pharma** | Wholesaler | Wholesaler | Wholesaler | Wholesaler | Wholesaler | Wholesaler | Pharma |
| | Transaction guarantee (contract) | | No | | Ye | es | Yes | | Yes | | Yes | |
| | Average period of contract validity | | | | З ує | ears | 1 to 3 years | | 1 to 2 years | | Depends on transaction | |
| | Unit pricing/bucket pricing | | Both | | Unit p | oricing | Unit pricing | | Unit pricing | | Unit pricing | |
| | Provisional delivery before agreement | | Yes | | Occurs brie transa | efly for some actions | No | | Occurs briefly for some transactions | | Occurs briefly for some transactions | |
| | Stipulation of transaction conditions | | Depends on transaction | | Ye | es | Yes | | Depends on transaction | | Yes | |
| Trade practices | Effects of delivery conditions, etc., on price | | No | | Ye | es | No | | Yes | | No | |
| | Additional fees resulting from delivery conditions, etc. | | No | | Ye | es | Yes | | Yes | | No | |
| | Price adjustments resulting from amount of consumption | | Yes | | Ye | es No | | Yes | Yes | | No | |
| | Acceptance of returns | | Yes | | Yes*** | | Yes | | Yes*** | | Yes*** | |
| | Existence of group | Hospitals | No | | Ye | es | Yes | | No | | Yes | |
| | purchasing organizations (GPOs) | Pharmacies | Yes | | Ye | es | Yes | | Yes | | Yes | |

Table 2: Distribution Circumstances Regarding Pharmaceutical Wholesalers and Medical Institutions & Pharmacies

* The total margin rate for wholesalers and pharmacies is 12.5% or less of the reimbursement price.

*** There are exceptions in the US depending on expiration dates and damage conditions. In Germany and France, exceptions are made for specialty products.

⁽Source: Results of an interview survey conducted by the Research Committee for International Pharmaceutical Distribution)

^{**} Pharmaceutical wholesalers serve as the principal negotiators for individual pharmacies and other smaller customers.

First, there are no margin caps in Japan and the US, but there are margin caps in the UK, Germany, and France. In the UK, the total margin for patented drugs for both pharmaceutical wholesalers and pharmacies is customarily restricted to be 12.5% or less, which is separated between wholesalers and pharmacies by negotiation and free competition within this limit is permitted. There is no margin cap for generic drugs. However, there is a clawback provision* that limits the drug profits of pharmacies and thereby prevents pharmacies from receiving excessive discounts. Also, the Direct to Pharmacy (DTP) model, in which pharmaceutical companies sell medical drugs directly to pharmacies by utilizing wholesalers, has expanded in recent years. Germany and France impose significant restrictions on margins. In Germany, the margins of pharmaceutical wholesalers and pharmacies are strictly regulated for each package unit, and it is difficult for free competition to arise. France recognizes official margins and official permitted discounts for both pharmaceutical wholesalers and pharmacies, but there are upper limits on both. In other words, there is room for free competition in France, but because this competition occurs under conditions in which a designated profit is secured and because there are limits on margins, excessive discounts do not occur.^(Reference 1)

Next, let us examine who the principle negotiators are. In Japan, pharmaceutical *Oroshi* handle price negotiations with all delivery destinations—that is, hospitals, clinics, and pharmacies—except in cases where generic drugs are purchased directly, which account for approximately 3% of the market size.^(Reference 2) On the other hand, in the US, 96–98% of the price negotiations with hospitals throughout the country are handled by pharmaceutical companies through a group purchasing organization (GPO).^(Reference 3) In most cases, pharmaceutical companies pay the management fees for GPOs, which are necessary for listing prescription drugs on formularies. In addition, in most countries in Europe, sales to hospitals are made directly by pharmaceutical companies, and thus there are no price negotiations by pharmaceutical wholesalers. Therefore, in Europe and the US, most wholesaler price negotiations consist of negotiations with pharmacies.

Japan's trade practices are also different from those in Europe and the US, where pharmaceutical wholesalers enter into agreements with medical institutions & pharmacies before making transactions with them. In most cases, the agreements explicitly state that the medical institution or pharmacy will purchase drugs from the wholesaler for a designated period of time. We will refer to an agreement that guarantees transactions in this way as a "guarantee contract."

In Japan, pharmaceutical *Oroshi* usually enter into "basic transaction agreements" with medical institutions & pharmacies before making transactions with them, but these agreements only become valid after the medical institution or pharmacy actually purchases drugs from the *Oroshi*. Therefore, the agreements do not guarantee transactions in the way that guarantee contracts do.

In Europe and the US, there are cases in which even after a guarantee contract has been entered into, deliveries may be made before certain conditions (such as the wholesale price) have been agreed upon. However, the period of validity of guarantee contracts is relatively long—ranging from one to three years—and during this period, transactions between pharmaceutical wholesalers and medical institutions or pharmacies are guaranteed. During the period of validity, the medical institution and pharmacy cannot stop purchasing a drug because of sales conditions. In addition, in Europe and the US, wholesale prices are fixed, and there are no retroactive discounts in which the wholesale price of a delivered prescription drug is changed retroactively. There are cases in which prices are adjusted according to the amount of usage, but these changes only apply to transactions that occur after the changes have been made. Also, in Europe and the US, unit price transactions in which wholesale prices are set per product are the norm.

In Japan, where drug prices are revised on the basis of actual market prices, we must note that in the first place, the primary negotiator with medical institutions & pharmacies is different than in Europe and the US. We can conclude that it is necessary to promote contracts featuring guaranteed transactions and memorandums, etc., and incorporating the specification of wholesale prices and their periods of validity.

^{*} Clawback provision: A system by which a designated percentage is subtracted from the reimbursement price and returned to the National Health Service (NHS) when overall pharmacy retained earnings exceed a designated amount.

(2) Margin Caps and Trade Practices in Negotiations between Pharmaceutical Wholesalers and Pharmaceutical Companies

The conditions under which transactions are made between pharmaceutical wholesalers and pharmaceutical companies also vary by country. The differences in margin caps and trade practices have been summarized in Table 3.

| | | Japan | | US | | UK | | Germany | | France | |
|----------------|--|----------|---------|----------|---------|------------------------|---------|------------------------|---------|------------------------|---------|
| | | Patented | Generic | Patented | Generic | Patented | Generic | Patented | Generic | Patented | Generic |
| Margin caps | Ex-factory price caps | No | No | No | No | Yes | Yes* | Yes | Yes | Yes | Yes |
| | Contracts | Yes | | Yes | | Yes | | Yes | | No | |
| | Average period of contract validity | 2 years | | 3 years | | Depends on transaction | | Depends on transaction | | Depends on transaction | |
| | Stipulation of transaction conditions | Yes | | Ye | es | Yes | | Yes | | No | |
| | Effects of wholesaler functions on ex-factory prices | No | | Ye | es | No | Yes No | | 0 | No | |
| | Change in ex-factory price when a competing product enters the market | No** | | N | 0 | No | Yes | No | | No | |
| Trade | Rebates | Yes | | Yes | | No | Yes | No | | Yes | |
| practices | Changes resulting from wholesaler functions | No | | Ye | es | _ | – Yes | | _ | No | |
| | Changes resulting from wholesaler procurement amounts | Yes | | Ye | es | _ | – Yes – | | No | | |
| | Changes resulting from wholesaler sales amounts | Ye | es | Ye | es | _ | Yes | - | - | Ye | es. |
| | Allowance (payment to representatives that provide information about prescription drugs) | Yes | | N | 0 | N | No No | | No | | |

Table 3: Distribution Circumstances Regarding Pharmaceutical Wholesalers and Pharmaceutical Companies

(Source: Results of an interview survey conducted by the Research Committee for International Pharmaceutical Distribution)

* When a product enters the market, its price must be lower than the reimbursement price of the original product.

** Depending on the product, there are occasionally cases in which the ex-factory price is changed.

First, there are no caps on the ex-factory price in Japan and the US, but in the UK, Germany, and France, there are caps on the ex-factory price as a result of the fact that there are margin restrictions on pharmaceutical wholesalers and pharmacies.

In addition, regarding trade practices, guarantee contracts are the norm in every country but France. The average period of validity of a guarantee contract is two years in Japan. This coincides with the frequency of drug price revisions. The average period in the US is three years. In other countries, the period of validity varies widely depending on the transaction. Furthermore, in almost every country, ex-factory price negotiations and price settings are made for individual drugs. The only exception to this is Germany (in which there are almost no negotiations for the prices of original drugs).

Moreover, in the US and UK, wholesalers play a clear role in influencing the ex-factory prices and rebates of generic drugs. This suggests that more rigorous functional evaluations are being carried out. In the US, this influence relates to the functions of wholesalers as distributors and providers of market information, and in the UK, the influence relates to the functions and purchase quantities of wholesalers.

In Japan, the MS of pharmaceutical *Oroshi* visit prescribers, mainly clinics, and provide information about prescription drugs on a daily basis. Pharmaceutical companies pay pharmaceutical *Oroshi* an allowance as compensation for these activities.

In Japan, it is common for the period between when a new reimbursement price is announced to when the price is applied to be less than a month, which is an extremely short period of time. As a result, the amount of time available for negotiations between pharmaceutical *Oroshi* and pharmaceutical companies regarding the ex-factory price of a drug is insufficient. It is worth considering improving processes so that ex-factory prices can be negotiated per product in a manner that takes the functions of *Oroshi* into consideration.

Given the above, we can list the following as matters that Japan might refer to when improving its trade practices regarding prescription drugs.

- In the US and Europe, the periods over which transactions between pharmaceutical wholesalers and medical institutions & pharmacies are contractually guaranteed are normally long, ranging from one to three years.
- In transactions between pharmaceutical wholesalers and medical institutions & pharmacies in the US and Europe, there is no custom of retroactive discounts in which the price of a past transaction is changed.

In transactions between pharmaceutical wholesalers and medical institutions & pharmacies in the US and Europe, most prices are negotiated per product.

International Comparison of the Functions of Pharmaceutical Wholesalers

When explaining pharmaceutical distribution in Japan, Japanese pharmaceutical *Oroshi* need to make it clear that the role they play is different than that played by pharmaceutical wholesalers in other countries. Japanese pharmaceutical *Oroshi* do not just function as gatherers of local supply & demand information and representatives who provide information on behalf of pharmaceutical companies, they also have unique basic functions (distribution and financial functions, for example) that set them apart from the pharmaceutical wholesalers of other countries.

(1) Distribution Function

One way in which the wholesalers of Japan, the US, and Europe are similar is that wholesalers in each region have their own distribution centers that their distribution networks are built around.

| | | Japan | US | UK | Germany | France |
|--|------------|------------|----------|------------|-----------|-----------|
| Number of destinations delivered to* | | 156,828 | 71,321* | 18,311 | 21,551 | 22,561 |
| Deliveries per | Hospitals | 1.6 | 1** | _ | _ | — |
| destination per day | Pharmacies | 2.3 | 1 | 2 | 3 | 2 |
| Degree to which delivery personnel belong to the company | | 80 to 100% | 0 to 20% | 40 to 100% | 40 to 80% | 40 to 80% |
| Lead time*** (hours) | | 1.4 | 6 to 10 | n/a | n/a | n/a |
| Inventory turnover rate p | ber year | 19.1 | 16.5 | n/a | n/a | n/a |
| | | | | | | |

Table 4: Comparison of Distribution Functions

(Source: Results of an interview survey conducted by the Research Committee for International Pharmaceutical Distribution)

* This is an estimate of the number of destinations to which deliveries are made on a daily basis and thus is different from the current total number of destinations.

(Reprinted from Report 1 of the International Committee, "International Comparison of Pharmaceutical Wholesalers' Function-specific Costs")

** For some hospitals, there are cases in which two deliveries are made in a single day.

*** Average lead time from the final shipping center of the pharmaceutical oroshi to the purchaser.

However, as is clear from Table 4, in Japan, a large percentage of deliveries from distribution centers are made by the employees of the wholesaler. In the US, almost all deliveries are outsourced, while in Europe except the UK, in-house and outsourced deliveries are mixed.

Despite the fact that the people who choose the products (prescribers) and the ones who buy the products (delivery destinations) are usually different in the industry, Japanese pharmaceutical *Oroshi* were able to maintain precise and wide-reaching delivery even after the Great East Japan Earthquake. This was thanks to their highly developed drug distribution and communication systems, the fact that they maintained a certain amount of distribution inventory (during the disaster, the distribution inventory was about half a month), and the fact that they maintained detailed knowledge on a daily basis of conditions such as the locations of local medical institutions and the departments at the institutions, the number of beds, number of out-patients, and the number and type of drugs that were normally delivered to the institutions. In addition, they also trained their own delivery staff and instilled a strong sense in them of the role that distribution plays in contributing to medicine.^(Reference 8)

(2) Financial Function (Account Management Function)

It is important to be aware of the following two points regarding the financial function of Japanese pharmaceutical Oroshi.

Japanese pharmaceutical Oroshi negotiate prices with all medical institutions & pharmacies.

As indicated in Table 2 in Chapter 2, Japanese pharmaceutical *Oroshi* negotiate prices with all medical institutions & pharmacies. In most cases, the principle negotiators of the prices for patented drugs in the US are pharmaceutical companies. In Europe, pharmaceutical companies negotiate prices with hospitals.

2 Responsibility for credit risks

According to the data obtained from the 17 Japanese wholesalers who participated in the interview, the average default rate in 2011 was 0.04% for independent pharmacies, 0.02% for clinics, 0.01% for hospitals (with 100 or more beds), and 0.01% for chain pharmacies (with 20 or more stores). The survey results for the US showed the same relationship between the default rates of the customers listed above. On average, less than 0.5% of credit is guaranteed. Insurance is procured for individual delivery destinations for which there are a large number of claims. In addition, the premium rates for this insurance can vary by as much as one to two orders of magnitude. On the other hand, Japanese pharmaceutical wholesalers do not insure their receivables. The same is true for Europe.

(3) Regional Supply & Demand Information Collection Function

In Japan, there are currently about 18,000 MS (total provided by the Federation of Japan Pharmaceutical Wholesalers Association in 2012) visiting medical institutions & pharmacies throughout the country.^(Reference 4) In addition, by visiting prescribers and pharmacies, MS are able to provide and gather information about drugs, such as their side effects. They are also able to keep track of the types and quantities of drugs being chosen by prescribers, and in some cases, they even participate in said selection. Through these MS activities, each pharmaceutical *Oroshi* is able to keep track of the supply & demand trends of an area on a daily basis. Japanese pharmaceutical *Oroshi* are the only type of organization that exhibits this function.

This function enables pharmaceutical *Oroshi* to cooperate with prefectural governments, local medical and pharmaceutical organizations, and others to make adjustments to ensure a stable supply of drugs and ensure that local drug distribution is not interrupted in emergency situations, such as during new influenza outbreaks and large earthquakes.

(4) Function as a Representative That Provides Information about Pharmaceutical Companies to Prescribers (Promotional Function)

The MS of Japanese pharmaceutical *Oroshi* visit medical institutions on a daily basis, and provide information about prescription drugs to physicians, primarily those at clinics, as well as to pharmacists at pharmacies. In this capacity, pharmaceutical wholesalers are recognized as representatives who provide information to prescribers on behalf of pharmaceutical companies.

To provide supplemental verification of this function of pharmaceutical *Oroshi* in Report 1, *International Comparison of Pharmaceutical Wholesalers' Function-Specific Costs*, Crecon Research & Consulting Inc. was hired by the Federation of Japan Pharmaceutical Wholesalers Association to conduct repeated surveys of 29,768 physicians working at medical institutions with less than 100 beds in 14-day cycles over the one-year period from April 1, 2012, to March 31, 2013.^(Reference 5) During the survey period, it was found that the surveyed physicians were visited by MS a total of 320,309 times. Of those visits, 165,443 were made to request the new prescription of a specific prescription drug. In the survey, when an MS was going to make a visit to request a new prescription, the physician was asked before the visit to report on an awareness of the product on a five-step scale. The lowest awareness level is "Did not know about it." The next awareness levels, in order of degree of interest, are "Knew about it," "Was interested in it," and "Wanted to use it." The level of awareness reported before a visit that is closest to the state of actually prescribing the drug is "Thought it was the best of all the possible choices."

Figure 1-1 shows the number of cases in which a recommended product was prescribed after a visit, broken down

according to the impression of the physician before the visit. The position of an element represents the awareness level, and the width of an element represents the number of cases in which it was actually prescribed. Of the visits made to request a new prescription, the number of visits after which a physician prescribed the drug being recommended by the MS was 14,239 (8.6% of the total number of visits to request a new prescription). Most physicians that prescribed a drug after a visit said that they "Wanted to use it" before the visit. However, there were cases in which new prescriptions of a drug were made by physicians who said that they "Did not know about it" or "Knew about it," that is, physicians whose level of interest in the drug was low.

Figure 1-2 shows the prescription trend after visits by MS to physicians who were already prescribing a specific prescription drug. MS visits have significant impact, primarily on the continuation of prescriptions and on their increase. The number of visits that were followed by an increased number of prescriptions was 26,617, which is 17.2% of the visits made to physicians who were already prescribing a drug. On the other hand, there were also 2,321 visits (1.5% of all visits to physicians who were already prescribing a drug) after which the amount of prescriptions declined. This implies that physicians may have switched to prescribing a different drug as a result of these MS visits.

Fig. 1-1: Number of visits by MS who acquired new prescriptions (organized by attitude level of the physician before the visit)

Visits in which new prescriptions were requested: 165,443 Of those visits, visits in which new prescriptions were acquired: 14,239



Fig. 1-2: Number of visits by MS who tried to increase prescriptions



Note: The width of each item is proportional to the number of visits.

(Source: Data from Crecon Research & Consulting Inc., April 2012 to March 2013)

(5) Value-added Services for Medical Institutions & Pharmacies

The range of value-added services offered by pharmaceutical wholesalers to medical institutions & pharmacies has been growing rapidly not only in the US and Europe, but in Japan as well. As Table 5 shows, value-added services include a wide range of activities that encompass inventory management systems, customer management systems, and safety information systems.

| | | | Japan | US | UK | Germany | France |
|--------------------------------------|------------------------------------|------------|---------|-----|-----|---------|--------|
| Inventory | Drovidod | Hospitals | Yes | Yes | No | No | No |
| system (inventories | Provided | Pharmacies | Yes | Yes | No | Yes | No |
| inventory | Foo boood | Hospitals | Yes Yes | | _ | _ | _ |
| functions, etc.) | ree-based | Pharmacies | Yes | Yes | _ | Yes | _ |
| | Ducy ideal | Hospitals | Yes | Yes | No | No | No |
| management | FIOVIDED | Pharmacies | Yes | Yes | No | No | No |
| care reservation | Fee beend | Hospitals | Yes | Yes | _ | _ | _ |
| system, etc.) | ree-baseu | Pharmacies | Yes* | Yes | _ | _ | _ |
| Information delivery | Drovidod | Hospitals | Yes | Yes | Yes | No | Yes |
| system (safety information delivery, | Frovided | Pharmacies | Yes | Yes | Yes | No | Yes |
| etc.) | Fees from pharmaceutical companies | | Yes | n/a | Yes | _ | Yes |

Table 5: Comparative Example of Value-added Services for Medical Institutions & Pharmacies

These results are limited to the companies that were interviewed (private information) and may differ with the actual service conditions in each country.

(Source: Results of an interview survey conducted by the Research Committee for International Pharmaceutical Distribution)

* Replies were only received from three or fewer of the 18 Japanese pharmaceutical Oroshi companies surveyed.

In addition, in the US, there are now more wholesale businesses that specialize in specialty drugs, exemplified by biologic medical products, for which transaction amounts are growing rapidly. Due to the fact that specialty drugs have temperature management requirements and other handling standards that are stricter than those of other drugs, there are many cases in which the realization of seamless distribution traceability is offered as a form of added value. Furthermore, in the US, due to the fact that there are countless forms of private and public insurance, and as it is complicated to verify patient ability to pay for drugs and to carry out reimbursement procedures, wholesalers offer services to assist with reimbursement procedures for patients and medical institutions (prescribers).

Given the above, as the functions of pharmaceutical *Oroshi* in Japan are clearly different from those of wholesalers in other countries, it is important to understand that *Oroshi* and wholesalers are not the same.

To conclude this report, we will discuss the future direction of Japan's pharmaceutical *Oroshi* in light of the results of the survey.

In the first report of the committee, cost analysis showed that Japan's pharmaceutical *Oroshi* are less expensive than the wholesalers of other countries on an individual drug cost basis. The analysis also showed that the costs of financial functions are appropriate. Japanese pharmaceutical *Oroshi* function as representatives who provide information to prescribers on behalf of pharmaceutical companies (promotional function). This function sets *Oroshi* apart from wholesalers in other countries. The first report proved that this function of *Oroshi* has a tangible effect on the prescription decisions of clinics.^(Reference 6)

How will the social significance of and the needs for the basic functions and other optional functions, including promotional function, of Japanese pharmaceutical *Oroshi* change in the future? Further, how should we perceive the distribution of function-specific costs?

This report has provided many clues to the answers to these questions. First, most pharmaceutical wholesalers in the US and Europe except the UK only have fixed costs that extend to their distribution centers, whereas shipping and other distribution costs beyond that point are variable. As a result, these wholesalers face increased costs as they add optional functions to their basic functions. However, these wholesalers succeed in their business by making the functions and values of their added costs clear and by receiving appropriate compensation for them. Most pharmaceutical wholesalers in the US and Europe provide optional functions by establishing separate companies.

However, Japan's pharmaceutical *Oroshi* handle everything up to delivery by their own workers, and the percentage of their costs that are fixed is therefore high. The advantage of this situation is that even if the functions of an *Oroshi* increase, they can be temporarily absorbed within fixed costs. In a unique distribution situation in which the people who choose products (prescribers) and the ones who buy the products (delivery destinations) are usually different, approximately 18,000 MS throughout Japan work together with every medical institution and pharmacy to sustain the supply of drugs to each area. In addition, it can be said that the fact that *Oroshi* engage in price negotiations with every medical institution and pharmacy leads to the sustenance, development, and streamlining of the overall medical system. Furthermore, the reason that there are no counterfeit drugs in Japan and that the distribution of defective drugs is kept to a minimum can be attributed to the role that pharmaceutical *Oroshi* play in maintaining order in the pharmaceutical market.

Thus, due to the fact that the range of functions covered by Japanese pharmaceutical *Oroshi* is different from that covered by pharmaceutical wholesalers in the US and Europe, simple comparisons of fixed costs are meaningless. Japan's pharmaceutical *Oroshi* can be thought of as functioning as critical social infrastructure.

Moreover, it has become clearer that, from the perspective of prescribers, through visits by approximately 18,000 MS to medical institutions & pharmacies, Japanese *Oroshi* not only fulfill the unique basic functions mentioned above, they also influence the drug selections made by prescribers, primarily at clinics. It can be said that this function also contributes to the streamlining of the overall medical community.

For Japanese pharmaceutical *Oroshi* to continue to fulfill appropriate roles under the drug pricing system, they must improve their trade practices together with medical institutions, pharmacies, and pharmaceutical companies. In the course of this improvement, the following facts that have been highlighted in this report pertaining to the US and Europe

must be taken into consideration: (1) There is a custom of entering into contracts that guarantee transactions with medical institutions & pharmacies; (2) there are no retroactive discounts in transactions with medical institutions & pharmacies; and (3) wholesalers negotiate purchase prices with pharmaceutical companies for individual drugs. In addition, it is necessary to verify appropriate prices and margins by promoting a managerial accounting system that includes the selling expenses of each handled product and that incorporates cost management that includes general and administrative expenses.

Further, with the goal of maintaining or improving the quality of local medical services, which are faced with tight budgets, and for maintaining or reducing the costs for such, it is necessary to develop the unique basic and optional functions of Japanese pharmaceutical *Oroshi* while taking local medical services into consideration so that these functions can be used more effectively.

Japanese pharmaceutical *Oroshi* are characterized by their ability to provide comprehensive distribution, financial, and information services to all medical institutions & pharmacies. The Federation of Japan Pharmaceutical Wholesalers Association will continue in its efforts to ensure that pharmaceutical *Oroshi* can function as robust critical social infrastructure, even in times of disaster, and to ensure that pharmaceutical *Oroshi* continue to contribute to the improved productivity of the medical and pharmaceutical industry as a whole.

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International Comparison of Pharmaceutical Business Practices and

Functions of Pharmaceutical Wholesalers November 2013

Issued by -

The Federation of Japan Pharmaceutical Wholesalers Association Yaesuguchi Kaikan 7-20, Yaesu 1-chome, Chuo-ku, Tokyo 103-0028 Japan

Edited by -

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