

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

Report 3

**International Comparison of
Challenges in and Solutions
for Supplying
Pharmaceuticals after Natural Disasters
First Edition**

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The Federation of
Japan Pharmaceutical Wholesalers Association

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1. Report Objectives

Wholesalers industry have gone through phases of competition and consolidation, as well as diversification, as they have seen changes take place in consumer needs and the retail industry, and have experienced innovations in information technology. Pharmaceutical wholesalers are no exception, and play an important role in pharmaceutical distribution all over the world. Pharmaceutical wholesalers operate by buying medical pharmaceuticals, which are products related to life itself, from drug manufacturers, and selling them to medical institutions and pharmacies.

However, the basic functions of these pharmaceutical wholesalers vary depending on the features of the societies and institutions that exist in different countries. The International Committee has examined the differences in pharmaceutical wholesalers in Japan, the US, and Europe in its 1st report, “International Comparison of Pharmaceutical Wholesalers’ Function-Specific Costs” (December 2010) and the 2nd report, “International Comparison of Pharmaceutical Distribution Practices and the Functions of Pharmaceutical Wholesalers” (October 2013). The results of these examinations showed that the number of deliveries and the number of cost negotiation partners of pharmaceutical wholesalers in Japan are considerably higher than in the US and Europe, but that in spite of this, the selling, general, and administrative expenses, particularly the costs related to distribution, have been kept extremely low in Japan. The results also confirmed that while pharmaceutical wholesalers in Japan perform virtually all of their own negotiations with and deliveries to medical institutions and pharmacies, in addition to their inventory functions at distribution centers, in the US and Europe, pharmaceutical wholesalers typically specialize in receiving and placing orders, inventory management, and certain delivery functions. The comprehensive provision of services through in-house functions is unique to Japan. The results also suggest that the comprehensive functions of Japanese pharmaceutical wholesalers not only provide direct access to information, such as information on demand for pharmaceuticals in various regions, but that they prevent the entry of counterfeit pharmaceuticals or degraded products into the domestic distribution stream, and ensure the safety and quality of pharmaceuticals in distribution in Japan.

Fig. 1: Basic functions of pharmaceutical wholesalers



On the other hand, all countries experience emergency situations such as natural disasters, new flu outbreaks, and other pandemics, and pharmaceutical wholesalers operate within these contexts. This is what is known as “crisis management distribution.” The Great East Japan Earthquake that struck Japan in March 2011 resulted in unprecedented damage caused by both the earthquake and subsequent tsunami. Recovery efforts from that disaster are still underway. From the time the disaster struck, pharmaceutical wholesalers were praised for playing an irreplaceable role, but there is not all that much recognition of the various roles they play among the general public. Compared with other countries, there is certainly room for improvement in terms of the role played by pharmaceutical wholesalers and in the way they maintain connections with other organizations and groups. Therefore, the International Committee decided that the theme of the 3rd report should be the crisis management distribution of pharmaceuticals. We established the following goals, focusing on those natural disasters for which Japan is at particularly high risk.

- **Renew awareness of the natural disaster risks in Japan.**
- **Evaluate activities and identify challenges faced by pharmaceutical wholesalers during the Great East Japan Earthquake.**
- **Understand the preparations for and solutions to crisis management distribution among pharmaceutical wholesalers and related organizations and groups overseas.**
- **Make suggestions regarding the role of pharmaceutical wholesalers when disasters strike in Japan and regarding the connections between pharmaceutical wholesalers and related organizations and groups.**

2. Overview

Conducting an international comparison of Japan’s natural disaster risks from a statistical perspective once again highlighted just how vulnerable Japan is to disasters, especially earthquakes, as compared with other advanced nations.

In the Great East Japan Earthquake, pharmaceutical wholesalers were generally able to meet demand because they had already collected information on regional pharmaceutical demands through the deliveries and price negotiations their employees engaged in over the regular course of conducting business. They overcame facility destruction and inventory shortages through cooperation across companies. As a result, the general assessment was that wholesale channels will be more effective than other channels for supplying pharmaceuticals in future disasters. Based on these disaster lessons, all of the pharmaceutical wholesalers’ disaster response facilities have been developed, and at the prefectural level, work is being done to construct systems for connecting disaster-ready pharmaceutical supply systems.

To study the crisis management distribution of pharmaceuticals overseas, we focused on the US, which has a relatively high risk of natural disasters and where we could review the measures taken in response to the hurricane disasters of 2005 and 2012 as well as later efforts. We conducted interviews among pharmaceutical distributors and were able to identify several notable features of the disaster response measures taken by Japanese and US pharmaceutical wholesalers, as well as lessons that Japan can learn from the examples in the US.

- The experience of pharmaceutical suppliers after Hurricane Katrina in 2005 exhibits similarity to what Japan experienced during the Great East Japan Earthquake, including difficulties with vehicle traffic, issues with pharmaceutical supply routes, and challenges in the handling of donated pharmaceuticals.
- Some of the differences, however, included problems with security and state regulations in the US. In Japan, meanwhile, it is very difficult to respond to unpredictable disasters such as tsunamis and earthquakes, and the impacts of disasters on the entire country are extensive due to the country's small geographic area.
- In the US, pharmaceutical distributors played a central role in setting up the nonprofit organization Rx Response (now known as Healthcare Ready) as a consequence of issues arising after Hurricane Katrina. That organization works on solving problems related to the pharmaceutical supply, which are highlighted by disaster situations, and the effects of its efforts were evident when Hurricane Sandy struck.

Through this study, we identified the following issues with regard to pharmaceutical distribution during natural disasters in Japan.

- The development of concrete policies should be contemplated based on the lessons learned from the Great East Japan Earthquake, such as the rationalization of systems for supplying pharmaceuticals from pharmaceutical wholesalers to first-aid stations and evacuation shelters.
- We need to disperse the risks and develop possible alternatives from all angles with regard to moving pharmaceuticals from drug manufacturers to pharmaceutical wholesalers.
- In a disaster that affects a large region, collaboration with the national government and multiple local governments will be essential. Therefore, in the future, we need to create systems for comprehensive disaster response that is not limited to individual industries or local governments.

We hope that this report will help stimulate discussions regarding efforts to provide medical treatment and supply pharmaceuticals in times of disaster.

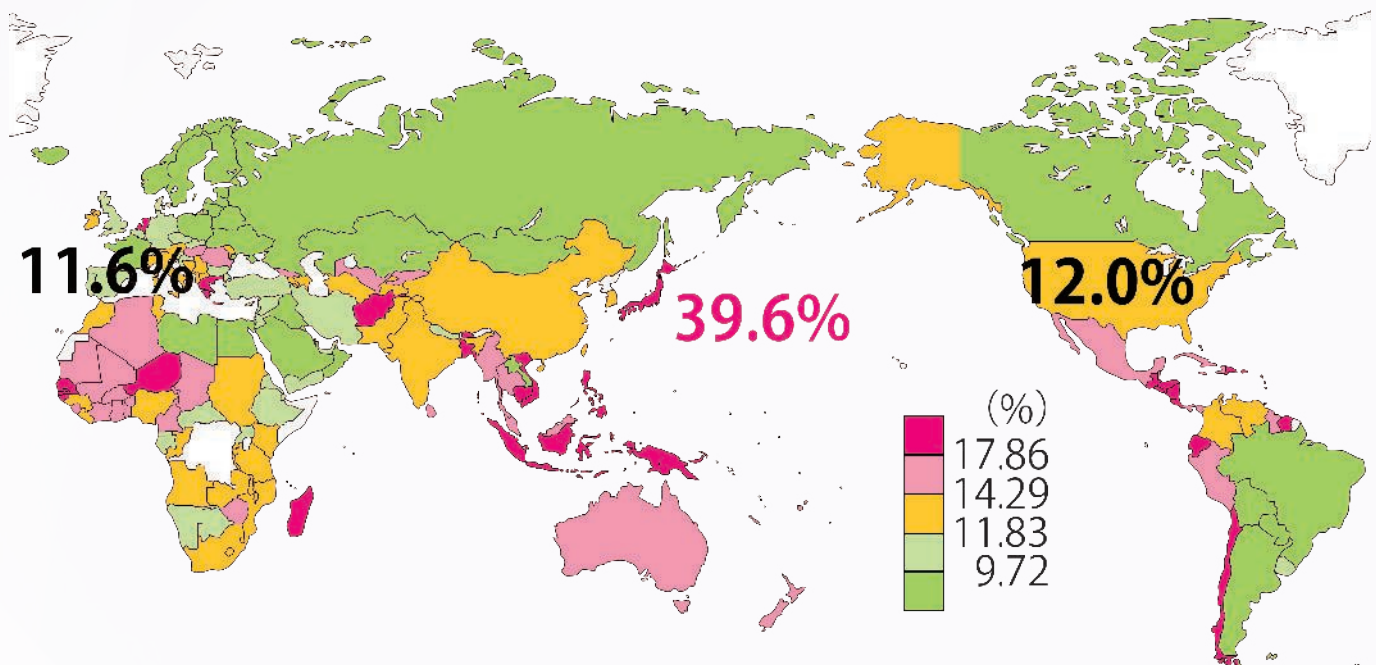
International Comparison of Natural Disasters

The Great East Japan Earthquake helped raise awareness of the importance of being prepared for emergencies on a regular basis. While four years have passed since this disaster, we need to once again highlight the magnitude of the natural disaster risks Japan faces.

1. World Risk Report Risk Estimates

Fig. 2 shows the disaster exposure facing countries around the world in five different levels. Here, disaster exposure is estimated from disaster data from 1970 to 2005. These estimates are based on the potential number of victims from earthquakes, typhoons, floods, and drought in one year and the total number of people each year estimated to be impacted by a one meter sea level rise due to warming by the year 2100. According to this report, natural disaster exposure is **39.6% in Japan**, **12.0% in the US**, and **11.6% in the UK**, showing that Japan's disaster exposure is far and away higher than that of other developed nations.

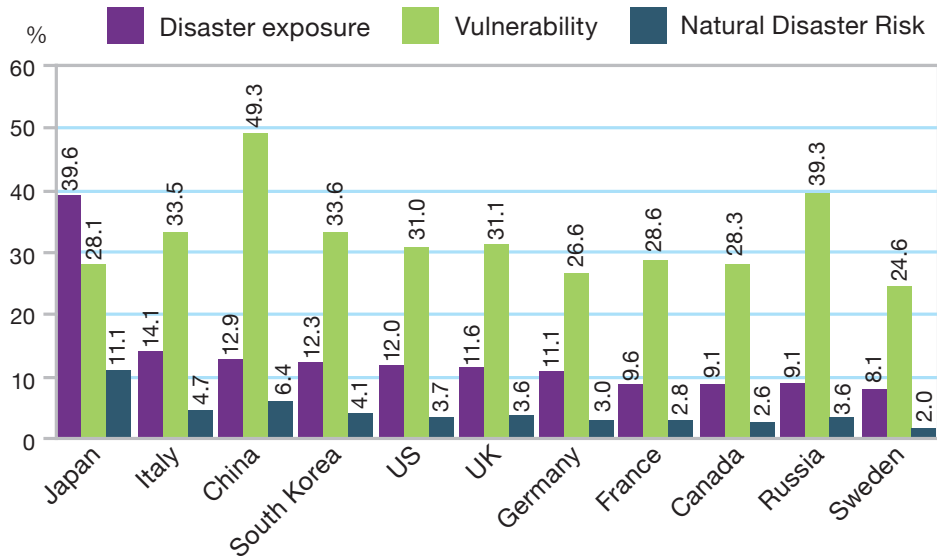
Fig. 2: World Disaster Exposure



Source: United Nations University, World Risk Report 2011

We multiplied the disaster exposure levels shown in **Fig. 2** by the index of natural disaster vulnerability, to determine “natural disaster risk,” and then compared that risk across the developed nations as shown in **Fig. 3**. Japan has about the same level of vulnerability to natural disasters as other nations, but because its disaster exposure is so much higher, its natural disaster risk is much higher than in other countries.

Fig. 3: World Natural Disaster Risk



*Nations listed in order of greatest disaster exposure
Source: United Nations University, World Risk Report 2011

2. Breakdown of Natural Disaster Damage over the Past 30 Years in Japan, the US, and Europe

We classified natural disasters into typhoons, floods, abnormal temperatures, earthquakes/tsunamis, and other disasters, and calculated the number of disaster-specific deaths and economic damage resulting from disasters over the past 30 years (1985–2014) in Japan, the US, the UK, Germany, and France. **Fig. 4-1**, showing the breakdown in the number of fatalities, reveals that many fatalities are caused by earthquakes/tsunamis in Japan, by typhoons in the US, and by abnormal temperatures in Europe and the US. **Fig. 4-2** shows that economic damages are particularly severe in Japan and the US. Much damage is accounted for by earthquakes/tsunamis in Japan and by flooding in the US.

Fig. 4-1: Disaster-Specific Fatalities over the Past 30 Years in Japan, the US, and the UK

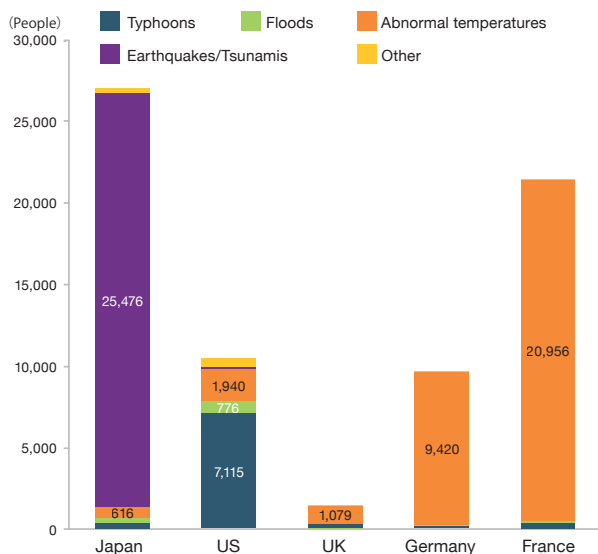
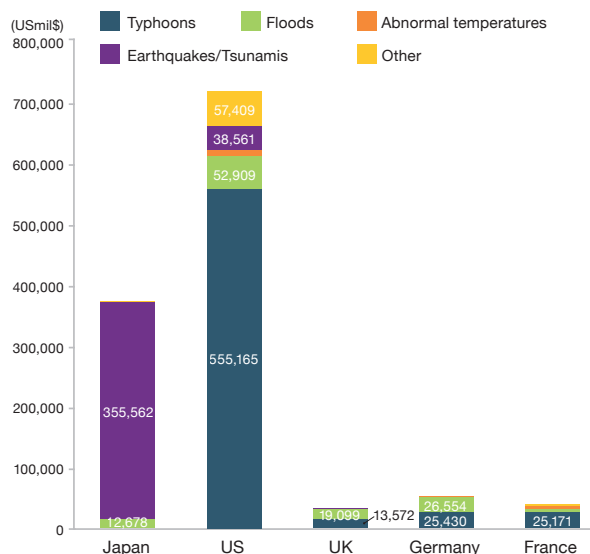


Fig. 4-2: Disaster-Specific Economic Damage over the Past 30 Years in Japan, the US, and the UK



Source: The International Disaster Database

3. Average Annual Number of Earthquakes (Japan Meteorological Agency Calculations)

Table 1 provides information on the frequency of earthquakes, which are particularly problematic among the natural disasters that Japan faces, as compiled for the world and Japan by the Japan Meteorological Agency. About 10% of the world's earthquakes occur in or around Japan. It is important to note that earthquakes measuring 8.0 or higher on the Richter scale occur in or around Japan at a frequency of about once every five years.

**Table 1: Number of Earthquakes Around the World and in or Around Japan
(Annual Average)**

Magnitude	World Since 1900	In or Around Japan	
		2001-2010	2011
M8.0 or higher	1	0.2 (once in 5 years)	1
M7.0-7.9	17	3	8
M6.0-6.9	134	17	107
M5.0-5.9	1,319	140	665
M4.0-4.9	13,000	approx. 900	N/A
M3.0-3.9	130,000	approx. 3,800	N/A

Source: Japan Meteorological Agency

These data show that Japan must be extremely vigilant about the damage caused by natural disasters, particularly earthquakes. Even as compared with other countries, the scope of both human suffering and economic damage due to these disasters is quite large. For Japan to use the lessons learned from its disasters to build highly disaster-resistant systems, it is important that it stimulate a crisis consciousness with regard to disasters.

Evaluation of Pharmaceutical Wholesalers in Supplying Pharmaceuticals after Natural Disasters (Experiences from the Great East Japan Earthquake)

1. Ministry of Health, Labour and Welfare (MHLW) Response to the Great East Japan Earthquake (MHLW)

The Great East Japan Earthquake that struck on March 11, 2011 was a disaster of unprecedented proportions for Japan due to both the widespread damage caused along the Pacific coast by the subsequent tsunami and due to the dispersal of radioactive particles. Even the pharmaceutical wholesalers operating business within the disaster zone sustained damage in the form of structural damage, flooding, and power outages at their business offices and distribution centers. Road damage and gasoline shortages also temporarily hindered their ability to supply pharmaceuticals. As a result, some media broadcasted that there were shortages of pharmaceuticals in the disaster zone in the early stages immediately after the earthquake.

In reality, however, the supply of medical pharmaceuticals was virtually fully restored by March 14, just three days after the quake. There were two types of pharmaceutical supply routes in the disaster zone. One was the ordinary supply route of medical pharmaceuticals to medical institutions and pharmacies. The other was a supply route for getting medical and general pharmaceuticals to evacuation shelters. Impediments to the pharmaceutical supply caused by confusion resulting from delays in the sorting of donated pharmaceuticals that arrived in mass quantities occurred in the latter of these two routes. The former operated pretty much as usual with virtually no shortages.

A report by MHLW on the “Response to the Great East Japan Earthquake (MHLW) (July 2012)” stated in a section on the “Delivery of Necessary Pharmaceuticals and Medical Supplies to Evacuation Shelters and Evacuees” that one of the four lessons learned was that “although supply systems were quickly developed by local wholesalers, the fact that a large quantity of pharmaceuticals was supplied through national industry organizations and shipments to the disaster zone were delayed resulted in a surplus of pharmaceuticals.” (See “Donated Pharmaceuticals.”)

Response measures were therefore adopted as follows: “Because there are shortages of medical pharmaceuticals in the early stages immediately following a disaster but surpluses after the supply systems have been developed, national and prefectural governments shall take measures to provide needed support after using wholesalers to quickly ascertain the supply-and-demand status of medical pharmaceuticals needed in the disaster zone and assessing the wholesalers’ supply capabilities.”

2. Great East Japan Earthquake Activity Report (Japan Pharmaceutical Association)

The Japan Pharmaceutical Association (JPA) established a Disaster Management Headquarters immediately after the Great East Japan Earthquake and sent pharmacists to pharmaceutical stockyards that served as centers of for pharmaceutical supply efforts and to first-aid stations established at evacuation shelters. The Great East Japan Earthquake Activity Report (March 2012), which recorded these support activities, proposed that based on the experience of pharmaceutical shortages at first-aid stations, it might be efficient that pharmaceutical wholesalers supply pharmaceuticals not only to medical institutions and pharmacies, but also to evacuation shelters through their ordinary routes.

3. Approaches to Systems of Disaster Medicine (Tokyo Disaster Medicine Council)

After holding many discussions aimed at ensuring seamless medical services when large-scale disasters strike in the Tokyo metropolitan area, the Tokyo Disaster Medicine Council compiled the results of its investigations in a report entitled “Approaches to Systems of Disaster Medicine (Tokyo Disaster Medicine Council Report)” in September 2012. This report stipulates that “when procuring pharmaceuticals, medical supplies, sanitation materials, and dental pharmaceuticals (hereafter, ‘pharmaceuticals’), medical institutions shall basically purchase goods from the wholesalers they ordinarily use” and that “for this reason, the metropolitan government must provide support to ensure that those wholesalers can recover as quickly as possible.”

When it came to donated supplies (free pharmaceuticals supplied by drug manufacturer organizations), “the vast majority were not used effectively, and storage and sorting activities proved to be a huge burden for the government and pharmaceutical industry personnel during the Great East Japan Earthquake.” Recognizing this, “the pharmaceuticals used in disasters generally shall be purchased from wholesalers, with donated supplies relegated to complementary use only.”

All of these reports presented the opinion that the supply of pharmaceuticals during a disaster should be handled, to the extent possible, using the ordinary distribution functions of pharmaceutical wholesalers. When it comes to the supply of pharmaceuticals during an emergency, wholesalers:

- **Have nationwide networks of distribution centers and other facilities.**
- **Have cooperative relationships with local pharmaceutical wholesalers.**
- **Have established systems for pharmaceutical distribution and communications.**
- **Adhere to the principle of having a one-half month’s distribution inventory on hand.**
- **Are very familiar with pharmaceutical demand, including the number of patients served by local medical institutions.**

For all these reasons, they should be viewed as a more effective option than any other supply methods.

In this way, pharmaceutical wholesalers need to have a level of resilience that allows them to maintain their ordinary roles even when a disaster strikes, or, in other words, to be able to quickly recovery from a disaster. To fulfill this mission, it is essential that pharmaceutical wholesalers develop disaster management policies and make relevant investments on a regular basis, and they need to maintain and strengthen these efforts over time.

Special Note: Donated Pharmaceuticals

Pharmaceuticals, unlike food and clothing, are unique in that they are difficult for disaster victims to select and use themselves. Therefore, it is not enough just to deliver the items; effective support is also needed. Medical professionals must ascertain what is needed, select medicines that meet that need, and then deliver medicines to patients. In other words, pharmaceutical supplies can be vital only when relevant information is attached. When the Great East Japan Earthquake struck, many donated pharmaceuticals were sent to the disaster zone. However, since it was only the goods that were delivered, many were not able to be put to effective use in helping people. In addition, it required tremendous work loads just to store and sort everything that was received.

Fig. 5: Donated pharmaceuticals during the Great East Japan Earthquake



The Miyagi Prefecture Government Affairs Training Center.

Challenges in and Solutions for Supplying Pharmaceuticals after Natural Disasters

Based on disaster lessons learned and given the reevaluation of the position of pharmaceutical wholesalers in the development of post-disaster management systems discussed in the last chapter, pharmaceutical wholesalers have made major revisions to their business continuity plans (BCPs) and disaster response manuals, and have made necessary adjustments. After the last quake, many prefectures updated pharmaceutical supply manuals intended for use in disasters, to rebuild their everyday and disaster response systems for relevant institutions, including government agencies and pharmaceutical wholesalers. The challenges faced in supplying pharmaceuticals during natural disasters, which were highlighted during the Great East Japan Earthquake, and the response measures taken by the pharmaceutical wholesalers are presented in **Table 2**. This shows that pharmaceutical wholesalers, along with the prefectural governments, have made the most of the lessons learned from the earthquake and have taken a wide range of response measures that are within the control of individual corporate organizations or governments.

Table 2: Challenges in Supplying Pharmaceuticals During Natural Disasters and Responses Measures Needed by Pharmaceutical Wholesalers

Pharmaceutical supply challenges during natural disasters, as highlighted by the Great East Japan Earthquake		Measures by pharmaceutical wholesalers (including those already implemented)
1 Securing means of communication	Several problems occurred, as digital channels were inoperable due to power outages and satellite phones cannot be used indoors.	Secure multiple modes of communication (satellite phones, analog phone lines, priority disaster phones, mobile phones, etc.)
2 Solutions to power outages		Ensure access to emergency power (home generators, etc.). Prepare data back up systems to ensure access to information regarding demand in disaster zones and nearby areas.
3 Solutions to vehicle traffic (issuance of emergency vehicle permits)	It took time to circulate procedures for issuing emergency vehicle permits (FAX machines were inoperable).	Confirm the emergency vehicles to be used and report vehicle replacements promptly to the prefecture. (Prefectures should gather info on all the emergency vehicles of pharmaceutical wholesalers and request the permits to the prefecture's public safety committee)
4 Access to gasoline	In the early stages after the disaster, emergency vehicles were given priority access to gasoline, as shortages had impacted their ability to transport pharmaceuticals.	Same as above, but since it is possible that the appropriate response may differ depending on the disaster, discussions should be held with relevant agencies for different disasters.
5 Supplying pharmaceuticals to evacuation centers	Large quantities of pharmaceuticals were provided from all over the country, but sorting them required a great deal of work and there was a significant mismatch in the supply versus demand. This resulted in a surplus of pharmaceuticals.	Matters related to the supply of disaster pharmaceuticals (everyday reserves, pharmaceutical supply routes during disasters, handling of support pharmaceuticals, establishment of stockpiles, etc.) were handled in accordance with various prefectural manuals and contracts.
6 Collection and storage of donated pharmaceuticals	There was no designated collection site; it took time to sort the items.	
7 Communication with relevant organizations	It took time to confirm the contact information for various partners.	Create communication networks with prefectures and relevant organizations, establish communication systems within companies, and update these regularly.
8 Cultivation of human resources that can be mobilized in a disaster	Pharmaceutical storage management, medication counseling, and sanitation management played important roles at evacuation centers.	Actively contribute to the cultivation of disaster medicine coordinators at the prefectural level.
9 Disaster exercises	The importance of communication between relevant organizations and nearby facilities was highlighted.	Hold disaster exercises within companies and at the community level.

Created by the International Committee from the disaster manuals of various pharmaceutical wholesalers and from manuals on supplying pharmaceuticals during disasters that have been compiled by individual prefectures.

However, as we learned from the last quake, damage often extends beyond those areas in which preparations have actually been made. As will be discussed in the next chapter, the International Committee conducted interviews among pharmaceutical suppliers in the US to obtain new perspectives on the crisis management distribution of pharmaceuticals.

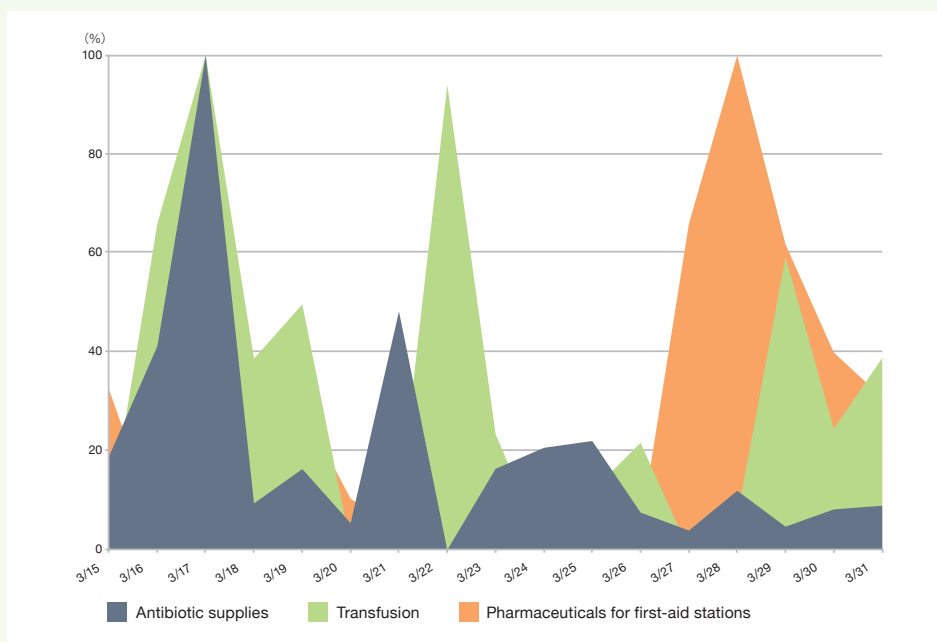
Special Note: Everyday Pharmaceutical Reserves

Manuals on everyday pharmaceutical reserves vary by prefecture. Although they have inconsistencies, they tend to be similar in the following respects.

- **Medical facilities, particularly disaster base hospitals, maintain three days worth of supplies.**
- **Separate from these, pharmaceutical wholesalers maintain reserves that serve as their distribution inventory based on agreements they have with the prefectural governments. These agreements cover products (about 80 product types), quantities, and reserve locations.**

Fig. 6 shows the number of pharmaceuticals supplied immediately after the Great East Japan Earthquake in Miyagi Prefecture, with the number supplied on the peak supply day in March 2011 set at 100%. The pharmaceuticals whose demand spiked most immediately after the earthquake were antibiotics and transfusion preparations for treating acute conditions. All medical institutions should maintain a certain reserve of these products to address all kinds of conditions. On the other hand, since the demand at first-aid stations for pharmaceuticals including those for chronic conditions such as antihypertension drugs, oral anti-diabetics, and anti-depressants, rose after the initial period, it is possible to supply these pharmaceuticals through the early recovery of pharmaceutical wholesalers' supply routes or through wholesale inventories in adjacent regions. In this way, it is important to set aside reserves by making distinctions between immediate needs and later needs following a disaster.

Fig. 6: Trends in the Number of Pharmaceuticals Supplied Immediately after the Great East Japan Earthquake (Using the number of pharmaceuticals supplied on the peak day of supply in March 2011 as 100).



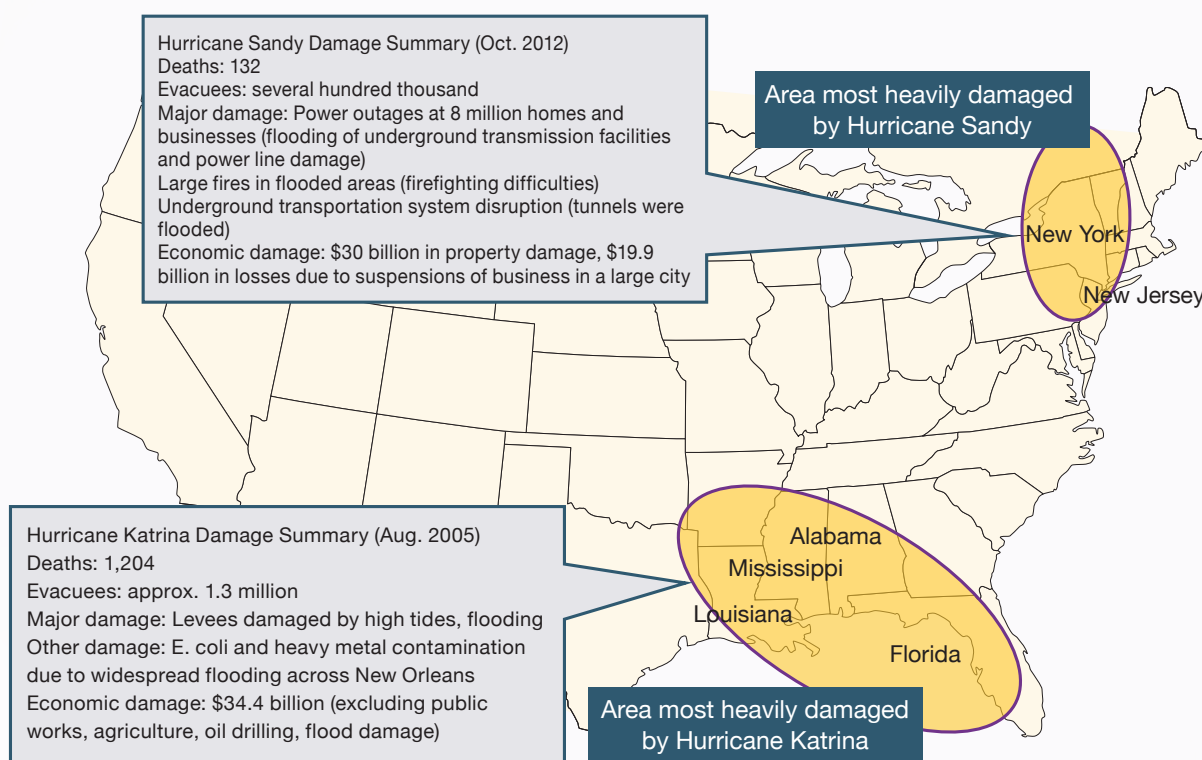
Source: Actual supply data in Miyagi Prefecture.
(Actual supplies of antibiotics and transfusion preparations to Miyagi prefectural coastal hospitals)

Results of Survey on Responses to Natural Disasters in the US

As was shown in Chapter 2, natural disaster damage poses a serious social issue in both the US and Japan. During both Hurricane Katrina in August 2005 and Hurricane Sandy in October 2012 (**Fig. 7**) pharmaceutical supplies were thought to be severely affected. The way pharmaceutical supplies were handled in the US during these situations, as well as the lessons learned by US pharmaceutical suppliers, surely include lessons that can also be of use to Japan. Because Japanese pharmaceutical wholesalers regularly function in within the framework of the universal health insurance system, which is the public social security system in Japan, there are no major obstacles to having them play a public role in emergency situations. In the US, how does the public-private partnership between pharmaceutical wholesalers and the national government function in times of disaster?

To clarify the above-mentioned points, the International Committee interviewed the Healthcare Distribution Management Association (HDMA), a pharmaceutical wholesaler (AmerisourceBergen), an international shipping service provider (UPS), a chain pharmacy (Walgreens), and a non-profit organization that was established to centralize pharmaceutical supply information during disasters (Rx Response*). These interviews revealed the following.

Fig. 7: Overview of Damage Caused by Hurricanes Katrina and Sandy



Source: Ministry of Land, Infrastructure, Transport and Tourism.

1.The Concept of Emergency Management in the US

Because the US is so geographically expansive, regional natural disasters such as tornadoes and snowstorms occur frequently. There is a strong crisis consciousness not only with regard to natural disasters, but also to terrorism. Because of this, institutions specializing in emergency management in the US often exist at both the federal and state level.

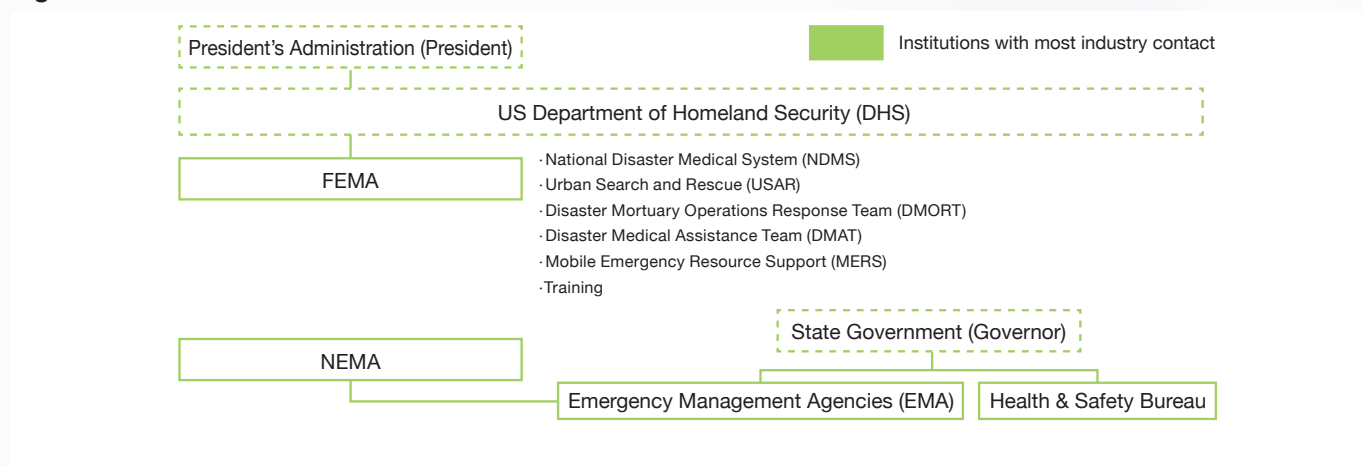
The Federal Emergency Management Agency (FEMA) is the organization that operates at the federal level to help coordinate the activities of federal institutions, state governments, and local institutions not only in response to natural disasters like floods, hurricanes, and earthquakes, but also to terrorist threats and pandemics. Emergency management

*Rx Response was renamed Healthcare Ready in August 2015.

agencies (EMA) are also established by each state government, with the National Emergency Management Association (NEMA) acting as the national coordinating body for those associations. The organizations contacted by the pharmaceutical industry during a disaster are FEMA and NEMA, as well as the emergency management agencies and health and safety bureaus in place at the state level (**Fig. 8**).

In addition, they have a qualification called a Certificate of Emergency Management, ensuring that specialists with shared knowledge are available to control emergency situations.

Fig. 8: Overview of FEMA and NEMA



2. Differences in the Everyday Roles Played by Pharmaceutical Wholesalers and Pharmacies

It is important to point out that the roles played by pharmaceutical wholesalers and pharmacies in the US and Japan differ significantly during non-emergency situations in the following two ways.

First, as was shown in Edition 2 of the Committee's report, pharmaceutical wholesalers in the US do not hire their own shipping employees. That is, during both non-emergency and emergency situations, shipments are handled by a shipping company such as UPS or FedEx.

Second, the roles played by pharmacies in community healthcare are different. Because medical and dispensary practices are completely separated in the US, the entire inventory of pharmaceuticals regularly needed by citizens is held by pharmacies. Individual access to medical institutions is often limited by the health insurance to which they are subscribed, and pharmacies function as health consultants that are more easily accessible to the individual. Because of these characteristics, access to pharmacies is particularly important both for citizens living in evacuation shelters as well as for shipping companies.

3. Similarities and Differences in Problems Faced During Disasters

(1) Similarities

Although there are differences in their everyday roles, the experiences of pharmaceutical suppliers during Hurricane Katrina in 2005 were in many ways similar to Japan's experience during the Great East Japan Earthquake.

a) Vehicle traffic and access to gasoline

In both the US and Japan, vehicle traffic permits and access to gasoline became major problems. Because the US is a collection of states, there are different traffic regulations implemented by each state government as well as each local government. Handling these problems was therefore extremely difficult, and even now, more than 10 years since that disaster, there has been no significant progress in this area. In Japan, on the other hand, pharmaceutical transport vehicles were designated as emergency transport vehicles the day after the earthquake, and gasoline and diesel fueling restrictions for those vehicles were waived on March 19. Public-private cooperation went relatively smoothly as a result of these and other measures, but given the severity of the gasoline shortages, it was still very difficult to find fuel.

b) Challenges with pharmaceutical supply routes

When a disaster struck in the US, FEMA tried to create pharmaceutical supply routes for use in cases of emergency, separate from existing distribution routes. However, these were suspended when the Chain Drugstore Association and the HDMA stressed that it made more sense to make use of ordinary distribution channels. There was also a movement among some medical institutions in Japan to require pharmaceutical wholesalers to purchase pharmaceuticals through special emergency supply routes, but making purchases through pharmaceutical wholesalers was ultimately proven to be the most effective approach.

c) Collection and storage of donated pharmaceuticals

Large quantities of donated pharmaceuticals were collected largely from drug manufacturers, but the shipment, allocation, and handling of those items proved to be quite difficult. Related tasks were ultimately handled by AmeriCares, an NGO. Likewise in Japan, the sorting of pharmaceuticals collected at a collection site took a vast amount of labor and time.

d) Supplying pharmaceuticals to evacuation shelters

Stadiums and other evacuation shelters were set up under FEMA's guidance, and many evacuees gathered in these locations. The pharmaceutical wholesalers ended up making decisions about the pharmaceutical demands of victims, but there were significant difficulties in sharing information with FEMA. Likewise in Japan, challenges remain with regard to supplying pharmaceuticals to evacuation shelters, particularly in the areas of ascertaining demand and responding quickly.

In the several days immediately following these disasters, the need was greatest for pharmaceuticals for acute medical needs (such as antibiotics). In the subsequent days, there was an increased need for pharmaceuticals for chronic medical conditions (such as diabetes and hypertension drugs). A need was also identified for mental health pharmaceuticals to prevent PTSD, and problems involving dialysis patients also arose. These were issues the US had in common with Japan (see Chapter 4, Special Note: Everyday Pharmaceutical Reserves).

e) Pharmaceutical costs

The costs of pharmaceuticals for disaster victims in the US were covered by payments from the federal government to pharmacies. After the Great East Japan Earthquake, victim health care was exempted from out-of-pocket-payment requirements.

f) Determining victims' prescriptions

When the records of hospitals and clinics were lost, it became extremely difficult to determine which medications had been prescribed to disaster victims. It was pointed out after the disaster that a "Medication Notebook" would be useful in Japan, but in the US, Obamacare has made it possible for prescription information to be stored in the cloud. The US sees this as major progress.

g) Securing means of communication and adapting to power outages

Power outages made it difficult to use regular phone lines. Satellite phones were used to communicate with medical institutions.

Also, although not specifically related to the hurricanes, the following experiences are similar to those faced by Japan.

h) Issues with media exposure

When a pandemic strikes in the US, a one-day delay in the arrival of anti-viral drugs to a remote island is reported as though there has been a shortage in pharmaceuticals. As a result, efforts had to be made to persuade medical institutions not to engage in panic-buying of pharmaceuticals. However, pharmaceutical wholesalers were focused on delivering pharmaceuticals to patients who actually needed them, rather than increasing sales, and could be fair in the ways they took action. Both the US and Japan struggle with issues related to media reports.

i) Weak everyday disaster consciousness

Governments and citizens strive to improve policies immediately after a disaster, but as time passes there is a strong tendency for the sense of urgency to decrease. This is common in both the US and Japan.

(2) Differences

The following differences can be found between the US and Japan. First, we will list three of the most distinctive features of the US.

a) Security issues

During disasters, the issue American pharmaceutical wholesalers have to address first is the safety of their shipments. Because there is concern that shipments might be looted, shipments will not be made if it is not possible to ensure the safety of the region prior to shipment. It takes time to guarantee safety.

b) Regulations vary by state

As discussed in similarity (a), the fact that traffic regulations vary by state in the US is a major hindrance to distribution efforts during emergency situations. Although the state-by-state variance in regulations around prescriptions makes it difficult to ship prescription drugs across state borders under normal conditions, saving lives will be given priority during emergencies.

c) Multiple regional disaster plans

Cities, states, and the federal government all have disaster plans, but they do not share information effectively. Even within FEMA, there is inadequate sharing of information between the areas that were affected by Hurricane Katrina (the states of Louisiana, Mississippi, and Texas) and those affected by Hurricane Sandy (the states of New York and New Jersey). In Japan, disaster plans are often created under the leadership of the prefectural government, and contain stipulations specifying the roles of the municipal governments and the private sector.

Next we will list three differences that pose particularly significant challenges for Japan.

d) Potential for disaster forecasts

Before a hurricane makes landfall, there is time to prepare for its arrival, making it possible to increase reserves by increasing orders of supplies and to investigate pharmacy openings. Earthquakes, however, cannot be predicted. This is the most crucial difference between an earthquake and a hurricane.

e) Magnitude of damage on the entire country

Because the US covers such an expansive area, damage caused by a natural disaster is regionally limited, making it relatively easy to seek alternate modes of operation.

f) Concentration of drug manufacturer distribution centers and factories

This is related to item (e) above, but because the US is so spread out, issues related to the geographical concentration of drug manufacturing facilities are not very serious. As will be discussed in Chapter 6, this is a very serious problem in Japan.

4. Establishment of Rx Response (now known as Healthcare Ready)

US pharmaceutical suppliers supply pharmaceuticals under private authority during emergency situations just as during non-emergency situations and will not wait for instructions from government agencies such as FEMA. However, there are some operations that require some coordination with the federal government, such as the provision of pharmaceuticals to evacuation shelters set up by FEMA and applications for regulatory exemptions. Hurricane Katrina taught many lessons to the pharmaceutical supply chain in the US regarding the lack of government awareness of private sector pharmaceutical supply functions, the complicated nature of the procedures needed to implement regulatory exemptions in different states, and the shipment of large quantities of donated pharmaceuticals. It resulted in a particularly increased awareness of the massive confusion caused by an inadequate sharing of information and information disarray. Solving these problems cannot be achieved by a single organization alone. It has been determined that “connecting the industries” of all of the pharmaceutical suppliers and enabling them to “speak with one voice” is essential.

Rx Response is a nonprofit organization that was established in 2006 as a result of these efforts. With its creation, responsibilities relating to the emergency management functions of the US Healthcare Distribution Management Association (HDMA) were shifted to this organization. Rx Response was a federation comprised of eight member organizations including three drug manufacturer organizations including Pharmaceutical Research and Manufacturers of America (PhRMA), the HDMA, three health care provider organizations, and the American Red Cross (as of March 2015; see footnote). This organization was renamed “Healthcare Ready” in August 2015.

(1) Disaster Response Activities of Rx Response

By 2015, Rx Response had conducted activities during 55 disasters. Of these, 42% were hurricanes and 15% were floods (Fig. 9).

a) Centralization of information

- To prevent the concentration of inquiries in the event of a disaster and the subsequent information disarray, this organization collects necessary information from 50 emergency managers at FEMA and NEMA, creates reports, and provides that information to member companies via email and its website.
- It functions as a portal for inquiries from the national government, state governments, corporations, and individuals.

b) Provision of information on pharmacy openings

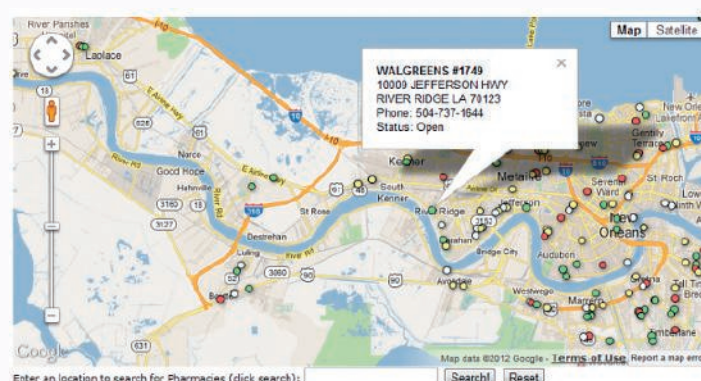
- The organization is creating a system for showing the status of pharmacy openings, only following disasters, using Google (Rx Open, see Fig. 10). Open information is automatically obtained from insurance claim status. During Hurricane Sandy, information was provided on 10,000 pharmacies across 11 states. This information is used not only by citizens, but also by the federal government and pharmaceutical wholesalers. Because this system makes it possible for disaster victims to go to a pharmacy and get the drugs they need, it eliminates the need for pharmaceutical donations.

Fig. 9: Activities of Rx Response



Source: www.rxresponse.org

Fig. 10: Rx Open (sample screen)



Pharmacies in disaster zones are color coded depending on their open status on a Google map. Users can click to view information on a particular pharmacy.

Source: www.rxresponse.org

Rx Response member organizations: Pharmaceutical Research and Manufacturers of America (PhRMA), Generic Pharmaceutical Association (GPhA), Biotechnology Industry Organization (BIO), Healthcare Distribution Management Association (HDMA), National Association of Chain Drug Stores (NACDS), National Community Pharmacists Association (NCPA), American Hospital Association (AHA), and the American Red Cross (ARC). (As of March 2015.)

Rx Response has a headquarters that is housed within PhRMA, and employs three full-time staff. That number is increased when a disaster strikes.

(2) Everyday Role

a) Education and outreach activities

- During everyday life, the organization promotes a framework by which citizens can go to pharmacies that are open in times of disaster, get their medications, and have those medications paid for by the national government. By engaging in these outreach activities and providing information on pharmacies that are open during disaster situations, this organization significantly helped solve the problems of donated pharmaceuticals during Hurricane Sandy.
- The organization created a system on its website whereby individuals could regularly record information on their own doctors, pharmacies, and prescriptions (drug names, dosages, and administration instructions) and carry it with them (Rx on the Run, see Fig. 11).

b) Exercise

- It is critical to recognize that disaster awareness is important all the time, particularly between one disaster and the next. This organization provides advice on the creation of federal and state level crisis management plans and also plans and participates in disaster exercises.

c) Participation in conferences

- Recognizing the need to spread awareness of the functions and importance of pharmaceutical supply efforts during disasters, this organization sends individuals to attend conferences on pharmaceutical risk management policies and disaster management policies (organized or sponsored by hospital organizations such as the AHA or ARC), and to engage in exchanges of ideas.

d) Contact with government disaster managers

- They are regularly in touch with disaster managers so that they can quickly make contact with the most appropriate government officials when a disaster strikes.

Fig. 11: Rx on the Run prescription information card

The image shows a screenshot of the Rx on the Run website. The top section is titled 'PERSONAL INFORMATION' and includes fields for Name, Address, Phone, Age, Height, Weight, and Sex. Below this is a 'PHYSICIAN INFORMATION' section with fields for Name, Address, Phone, and Email. To the right of these sections is a 'DOCTOR CONTACTS' section with fields for Name, Address, Phone, and Email. Below the 'DOCTOR CONTACTS' section is a 'PHARMACY INFORMATION' section with fields for Name, Address, Phone, and Email. The bottom section is titled 'PRESCRIPTION INFORMATION' and includes a table for recording prescriptions. The table has columns for Name, Dosage, Frequency, and Instructions. The table is currently empty.

This system lets you enter necessary information online, then print out that information on a passport-sized card for easy mobility.
Source: www.rxresponse.org.

5. Distinctive disaster response measures in the US

- UPS, the largest shipper in the US, has a control center where it collects disaster information and predictions from around the US and the world. This is the most reliable information available to local pharmaceutical wholesalers. In the event of a hurricane, measures are taken in advance to secure the best delivery routes. Agreements have been concluded regarding deliveries during a disaster, such that pharmaceuticals are given priority shipment status as long as the drivers can maintain their own safety in an emergency. Incentives are also offered to make this happen.
- Walgreens, a drug store chain, uses its excellent inventory control system to enable its headquarters to control the pharmaceuticals of all of its stores. It will increase its safety inventories and send necessary pharmaceuticals to stores in advance of a disaster.
- When Walgreens cannot open one of its stores, it will use trailers as temporary stores and send supplies to the disaster zone. To secure trailers in emergencies, the company has contracts set up with suppliers in advance. Deliveries are handled by pharmaceutical wholesalers (shipments are outsourced to specialized companies) and stores are set up in parking lots in front of or nearby the damaged stores. Since it can take a while to obtain a state license to run a temporary store, it is important even in these situations to secure a power supply and communicate with state agencies.

Conclusions and Remarks

In preparing this report, the International Committee conducted its first-ever survey on pharmaceutical supply services during disasters among pharmaceutical suppliers in the US. The results revealed that the US and Japan have a lot in common. This suggests that the pharmaceutical industry should pay attention to lessons and experiences from overseas in the future development of disaster management policies.

On the one hand, the US and Japan tended to be slightly different in terms of the way their public-private partnerships work. Japanese pharmaceutical wholesalers regularly function within the context of the national health insurance system, which is the public social security system in Japan, so they are highly aware of their connections with the national government when taking action after a disaster strikes. Manuals on pharmaceutical supply practices during disasters, which have been prepared by the prefectural governments, explicitly describe the role to be played by pharmaceutical wholesalers. On the other hand, the basic stance of pharmaceutical suppliers in the US is grounded in the idea that even in emergency situations, “private matters must be left to the private sector.” They operate on the fundamental principle that fully playing their own role in areas that intersect with the central government requires that they make the most of their private sector status, and also that and industry partners must work in unison to offer the best shortcuts.

Rx Response (now known as Healthcare Ready) was established within this context. To solve the problems that were highlighted by Hurricane Katrina, this organization functions as part of the crisis management system for pharmaceutical suppliers during both emergency and non-emergency situations. As a result of these activities, information centralization was achieved during Hurricane Sandy, and problems of information disarray were overcome. With regard to donated pharmaceuticals, through ongoing citizen outreach and the provision of information on pharmacy openings during disasters (Rx Open), Rx Response tried to solve problems by consolidating the need for donated pharmaceuticals. These kinds of trends in the US, by which disaster experiences were used to solve real problems between Hurricane Katrina and Hurricane Sandy, are of great interest, and present many lessons that are worthy of examination.

As was pointed out in Chapter 3, the actual experiences during the Great East Japan Earthquake exhibited that the supply of pharmaceuticals during emergency situations in Japan is most effectively achieved through wholesale routes than through any other supply methods. The reason for this is that pharmaceutical wholesalers, in addition to having well established systems for pharmaceutical distribution and communications, and having about a half-month’s worth of inventory on hand, are very familiar with the everyday needs of local medical institutions, including their addresses, departments, number of beds, number of outpatients, and normal product deliveries and quantities. During emergencies, as during everyday situations, pharmaceutical information in disaster zones is essential, and pharmaceutical wholesalers are the best positioned to have access to that information. Also, in disaster situations, pharmaceutical wholesalers do not just fill orders as usual, but work to make advanced judgments regarding specific distribution quantities and to allocate resources appropriately in order to prevent excessive concentrations of inventory. These efforts make it possible for distribution services to work more effectively. This suggests that the “comprehensive functions” of the pharmaceutical wholesalers are an essential component of the Japanese health care infrastructure.

In addition to a national health care system that is publicly run, Japan has a dual-faceted system that allows pharmaceutical wholesalers to engage in free competition just like companies in other industries during ordinary non-emergency times, but to provide a social and highly public service during emergency situations (disasters or pandemics). That is, pharmaceutical wholesalers are private companies that engage in highly public activities, and their business base is supported by their own activities under conditions of free competition. Pharmaceutical wholesalers will continue working on maintaining and strengthening their disaster preparations in the course of their everyday operations to fulfill their role in supplying pharmaceuticals during disasters and helping maintain the safety and health of the Japanese people.

This study has brought three issues into sharp relief in terms of preparing for pharmaceutical distributions during disaster situations in Japan.

First, further improvements that put to use the lessons learned during the Great East Japan Earthquake need to be implemented in the disaster pharmaceutical supply system. Since it has been shown that pharmaceutical wholesalers are most effective at supplying pharmaceuticals even during times of emergency, improvements have been made in the form of revisions to pharmaceutical supply manuals at the prefectural level. However, since current law requires pharmaceutical wholesalers to only supply their products to addresses that belong to medical institutions and pharmacies, those wholesalers cannot supply pharmaceuticals to first-aid stations or evacuation shelters. To address this, Miyagi Prefecture established a disaster medicine team called JMAT Miyagi together with not only the Miyagi Medical Association, but also with four other organizations (the Miyagi Dental Association, Miyagi Pharmaceutical Association, Miyagi Nursing Association, and the Miyagi Pharmaceutical Wholesalers Association). By doing this, they created an “all-Miyagi system” that made it possible for pharmaceutical wholesalers to supply pharmaceuticals directly to first-aid stations and evacuation shelters. The accumulation of these types of specific measures will help improve the reliability of pharmaceutical supply systems during disasters.

At the same time, to enable pharmaceutical wholesalers to supply pharmaceuticals during emergency situations, ongoing efforts must be made to enable those companies to maintain their wholesaling functions or to recover as quickly as possible when disaster strikes. The fact that pharmaceutical wholesalers are primarily responsible for pharmaceutical supplies during emergencies means there must be increased social demand for even greater measures to be taken during ordinary times to prepare for those situations. Pharmaceutical wholesalers must continue to make significant efforts to meet these expectations.

Second, improvements must be made in getting pharmaceuticals from drug manufacturers to pharmaceutical wholesalers during disasters. Pharmaceutical wholesalers typically have a half-month's worth of supply on hand, but if their supply of pharmaceuticals from the drug manufacturers is disrupted, measures must be taken to enable them to continue fulfilling their wholesale functions. During the Great East Japan Earthquake, supplies from some drug manufacturers were disrupted, and nationwide measures were taken to coordinate supply and demand or to secure substitute products. On the other hand, large quantities of donated pharmaceuticals ended up obstructing ordinary distribution services.

These types of supply issues can be fundamentally attributed to the concentration of manufacturing or distribution companies. Differences in the predictability of disasters and in the geographic size of the nation create increasingly serious challenges in Japan, more so than the US, and situations that are difficult to address. Disaster management policies must adequately address these issues and redundancies and substitution policies must be adopted to achieve risk diversification.

In manufacturing, for example, it is desirable for substitution policies to be established not only at the manufacturing plant, but also in the procurement of raw materials. In the distribution sector, where the use of outsourcing is increasing, it is well known that distribution centers are heavily concentrated around Misato in Saitama and around Konohana in Osaka. Policies that incorporate various modes of transportation are required to address this.

The inventory management and shipment functions performed by pharmaceutical wholesalers can be effective in handling distribution as well. Strategies that extend across industrial sectors are expected to be developed.

The issue of donated pharmaceuticals is also one that requires an investigation into strategies developed under non-emergency conditions with the central government and various sectors.

Third, we need to create comprehensive systems to address issues that cannot be adequately handled by individual sectors or local governments alone. For example, progress has been made on revising manuals at the prefectural level, but during widespread disasters, cooperation with other local governments is essential. If the development of manuals is not coordinated between local governments within a given region, this will hinder their ability to work together. When it comes to supplying pharmaceuticals, disaster management policies need to be implemented throughout the

supply chain from manufacturing to shipment to sales. In this sense, Rx Response, the American disaster management organization that connects manufacturing, shipment, and sales provides an example that offers many suggestions for how things might be done better. Also, the functions of Rx Response, a cross-sectoral organization that cooperates with government institutions in charge of crisis management on an everyday basis, do not exist in Japan. This organization should thus be positioned as a model for how to engage in disaster management on an everyday basis.

We hope that this report will help stimulate discussions regarding efforts to provide medical treatment and supply pharmaceuticals in times of disaster, and will foster collaboration and information sharing between relevant organizations.



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for Supplying
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