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To date, non-prescription (over-the-counter) drugs have only been handled by pharmacists without distinction. The Law for Partial Amendment to the Pharmaceutical Affairs Law that was put into force in June 2009 classified these drugs into three groups according to the risk involved. This amendment aims to build a sales structure in which licensed persons at multiple levels are involved according to the magnitude of the associated risk.

Based on the revised law, drugs that are considered to have relatively low risk are now sold at supermarkets and convenience stores. For the drug store industry, this deregulation has meant the emergence of competitors coming from different lines of business, and has brought about a major change in the competitive environment where they operate.

What is considered necessary for drug stores to survive is to pursue the improvement of their technical knowledge and skills to a greater extent than in the past, rather than simply expanding the scale of their business activities. Drug stores must remind themselves of the significance of being "home pharmacies" and must strengthen their technical abilities to build consumer trust.

Suggested approaches to strengthen the technical abilities of drug stores include providing information to consumers based on reliable clinical research data (evidence), developing tools enabling the provision of appropriate counseling to customers and considering alliances and/or functional integration with dispensing pharmacies to equip drug stores with functions to fill prescriptions.

I Amendment to Japan's Pharmaceutical Affairs Law

In June 2006, the Law for Partial Amendment to the Pharmaceutical Affairs Law (Law No. 69, 2006) was announced and was put into force in June 2009.

The revision of the sales structure for non-prescription drugs was the first in 46 years since the enactment of the Pharmaceutical Affairs Law in 1960.

1 Major Changes Addressed by the Revised Law

The amendment intends to achieve the following matters in the sales of non-prescription drugs known as over-the-counter (OTC) drugs:

- Assessing and classifying OTC drugs according to the magnitude of risk involved
- Requiring licensed individuals (pharmacists or registered salespersons) to be involved depending on the magnitude of risk of the pertinent OTC drug
- Establishing an environment such as for providing appropriate information

Risks are classified into three categories, i.e., Types 1, 2 and 3, based on side effects and interactions. According to these categories, a person who is engaged in sales, furnishes information or provides consulting services is explicitly defined (Table 1).

A registered salesperson refers to a person newly licensed to engage in the sales of OTC drugs. In order to obtain this license, candidates must pass an examination that tests their ability to provide appropriate information to purchasers. The qualifications of candidacy for the examination include that the person has completed a course in the department of pharmacy at a university, etc. or at least has one year's relevant work experience (Table 2).

The revised law requires the following actions to establish the environment to provide appropriate information:

- Posting notices indicating the types of drugs sold at the drug store
- Displaying signs on outer packages of products that help purchasers readily understand the degree of risk involved in the pertinent drug
- Wearing ID badges to identify pharmacists, registered salespersons and other employees

2 Background Factors that Led to Amendment

This section examines why the sales structure that remained unchanged for such a long time was revised. The following five factors are considered to constitute the background behind the amendment.

(1) In academic year 2006, the curriculum of the department of pharmacy at universities was changed from a four-year program to a six-year program. This change is expected to cause a projected shortage of graduates from the departments for academic years 2010 and 2011. Accordingly,

Table 1. Risk Classification of Non-Prescription Drugs (OTC Drugs) and Qualification Required of Salespersons

Risk Category	Example product	Qualification required of salespersons	Furnishing information	Providing consultation
Type 1 (Risk is especially high)	Gaster 10 (stomach antacid)	Pharmacists	Required (in writing)	Required
Type 2 (Risk is relatively high)	Bufferin (pain reliever and fever reducer)	Pharmacists or registered salespersons	Obligation to make effort	Required
Type 3 (Risk is relatively low)	Chocola BB (vitamin compound)	Pharmacists or registered salespersons	Not required	Required

Source: Compiled based on material published on the website of the Ministry of Health, Labour and Welfare regarding the sales structure for OTC drugs, etc.

Table 2. Qualifications Required of Registered Salespersons

(1) Qualification for candidacy for examination
• Persons who have completed a course in the department of pharmacy at a university, etc. • High school graduates with at least one year's relevant work experience (junior high school graduates need at least four year's relevant work experience)
(2) Examination items (total of 120 questions; 240 minutes)
• Common characteristics and basic knowledge of medicines • How the human body functions and relevant medicines • Principal medicines and their actions • Laws, regulations and systems related to pharmaceutical affairs • Proper use of and safety measures for the use of medicines

Source: "Guidelines on the Preparation of Examination Questions" published by the Ministry of Health, Labour and Welfare in August 2007.

the likelihood of a great shortage of pharmacists at pharmacies and drug stores is predicted.

(2) While the law required the involvement of pharmacists in the sales of medicines, it was not an uncommon situation where no pharmacists were present in drug stores.

(3) In cases such as sales of traditional household medicines (drugs distributed to each household by house-to-house salespersons) and exceptional drug sales (e.g., drugs sold at railway platform kiosks), salespersons have not been required to pass an examination, or there have been no applicable provisions covering such businesses in the Pharmaceutical Affairs Law. Accordingly, there was a need to resolve these contradictory situations.

(4) With the increasing use of the Internet, there were not a few cases where online sales of inappropriate medicines led to adverse drug reactions, which required the building of an appropriate method of sales.

(5) Medicines were continuously ranked high among the products that consumers want to be able to buy in convenience stores. As such, there were increasing needs among consumers for a greater number of stores where medicines are sold.

II Responses of Drug Stores to the Amended Pharmaceutical Affairs Law

As explained in Chapter I, what was recently amended was related to the method of selling medicines. Accordingly, the amendment had its greatest influence on the retail sector of the pharmaceutical industry. While changes occurring in the retail sector inevitably affect other sectors (pharmaceutical manufacturers and wholesalers), the focus of the discussion in this paper is chiefly on the retail sector in order to highlight the theme.

1 Shift of Sales from Drug Stores to Supermarkets and Convenience Stores

What moves will occur in the retail sector for the sales of Type-2 and Type-3 medicines that are now permitted to be sold by registered salespersons under the amendment? In other words, will the shift of sales from drug stores to supermarkets and convenience stores be substantial?

The trends in the sales of health drinks and antacids after deregulation took place in 1999 and 2004 can serve as an indicator.

With respect to health drinks and liquid antacids, nearly half of the total sales shifted from drug stores to supermarkets, convenience stores, etc. (Figure 1). However, no similar shift has been observed for general stomach medicines and digestive medicines for stomach and bowels (Figure 2).

The difference between these consumer responses can be assumed to stem from behaviors in which consumers select stores to buy medicines depending on their purposes and/or expected effects. It is reasonable to assume that while consumers buy medicines that are "to be taken on the spot," "for single use only" and "urgent relief" at convenience stores, they buy medicines for which "they expect long-term effect" and/or that are considered "household medicines" at drug stores. It is likely that these consumer behaviors are reflected in the difference in the shift of sales.

When deregulation took place in 1999 and 2004, some products that had been regarded as drugs in the past were reclassified as quasi-drugs. The sales of these products rapidly expanded at supermarkets and convenience stores. However, the recent amendment permits only stores where registered salespersons are on hand to sell Type-2 and Type-3 medicines. At the initial stage, the number of supermarkets and convenience stores where registered salespersons are on the premises would be limited. Accordingly, it is unlikely that the rapid shift of sales experienced in 1999 and 2004 would occur even for products such as aspirin for which urgent demands are expected to be high in emergency situations.

Nonetheless, drug stores should not underestimate the influence that the amendment would have on their business performance. This is because the amendment would lead to a reduction, even partial, in the sales of products with a high gross profit margin. From a long-term perspective, the sales share of supermarkets and convenience stores is projected to expand as they will add a greater number of registered salespersons.

2 Movement in Three Directions Observed among Drug Stores

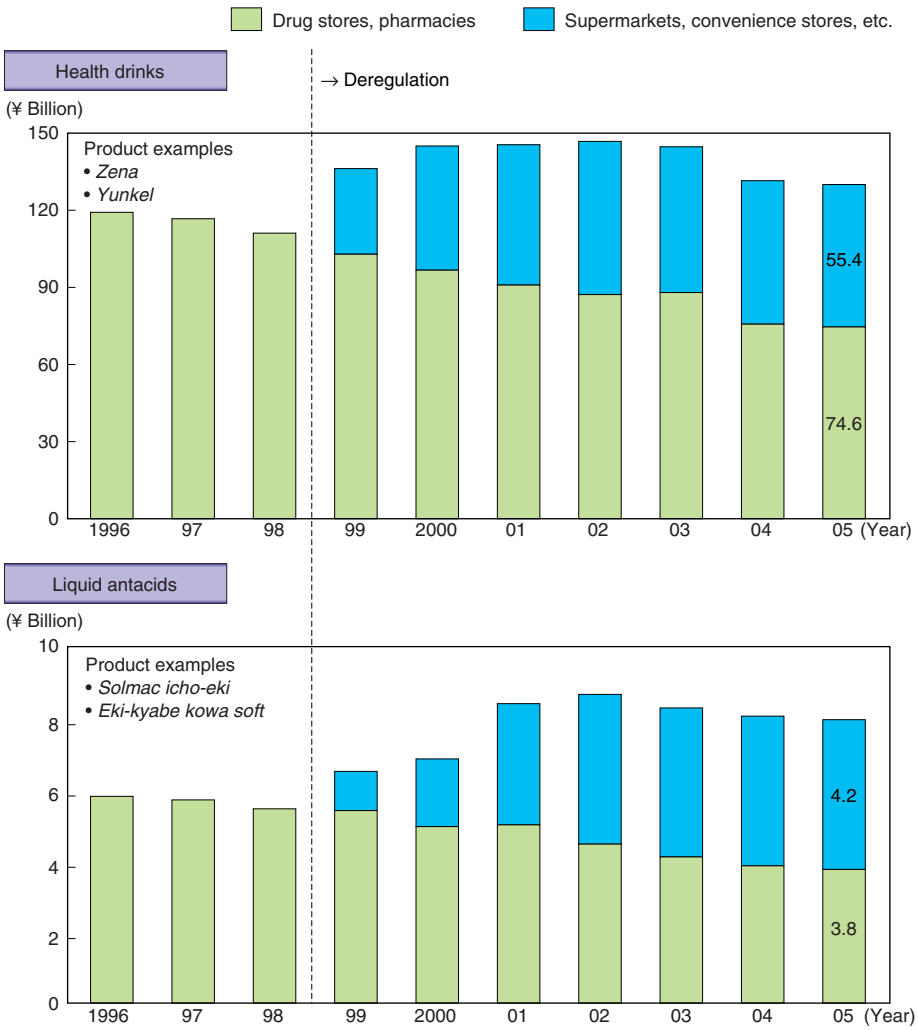
Drug stores, which are projected to be affected to the greatest extent by the revised law among the retail sector, have grown relatively smoothly to date (Figure 3).

The following sections outline the ongoing movement of drug stores in response to the recently amended law.

The first direction of movement concerns the accelerated deployment of new stores by fully utilizing registered salespersons. It becomes possible for a company to open new stores even with the same number of pharmacists they currently have by opening new stores where Type-1 OTC drugs that require the involvement of pharmacists and cannot be handled by registered salespersons are not sold or where the hours of selling such drugs is limited.

For example, Matsumoto Kiyoshi, one of the leading drug store chains in Japan, started to open new stores

Figure 1. Changes in Sales Volume of Medicines by Sales Channel (1)



Source: Compiled based on *OTC Drug Data Book* published by Fuji Keizai.

within railway station premises where only registered salespersons are available. Welcia Kanto, which also operates drug chain stores, announced a plan to increase the number of its stores that stay open later at night. In addition, these two companies have announced tie-ups with convenience stores to jointly open new stores selling both daily necessities and OTC drugs.

The second direction of movement relates to differentiation. This movement is ongoing in anticipation of the intensification of competition as triggered by the full-scale participation of supermarkets and convenience stores in selling medicines. What is most noticeable in their efforts to pursue differentiation is the strengthening of their prescription-filling business[1]. Because filling prescriptions requires a pharmacist, it is not easy for supermarkets and convenience stores to operate such a business.

For example, Sugi Pharmacy has set up dispensaries at all of its stores. Many companies are endeavoring to increase the number of stores where dispensaries are available.

The third direction of movement involves collaboration with companies that are about to start the sales of medicines. Specific actions include that drug stores supply products to supermarkets, home centers and large electrical appliance retail stores that plan to start the sales of medicines in the future, or that drug stores provide them with the necessary expertise by entering into a franchise chain (FC) contract. This strategy pursues alliances with competitors, rather than opening new stores on their own.

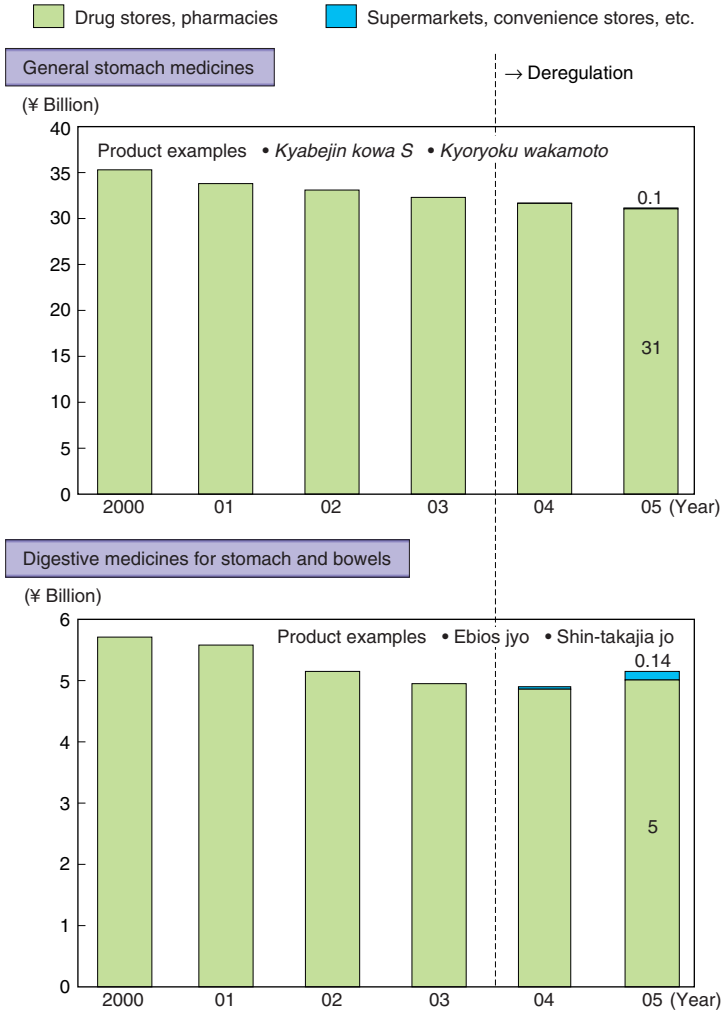
An example of this approach is Sundrug, which is making focused efforts to increase the number of FC member stores. The sales to FC stores for the fiscal term ending March 2009 showed a year-on-year growth of slightly less than 20 percent.

3 Structural Change of Drug Stores in the Retail Industry

Before the enforcement of the revised law, many drug stores worked to expand their business scale by forming groups among those companies in the same line of business.

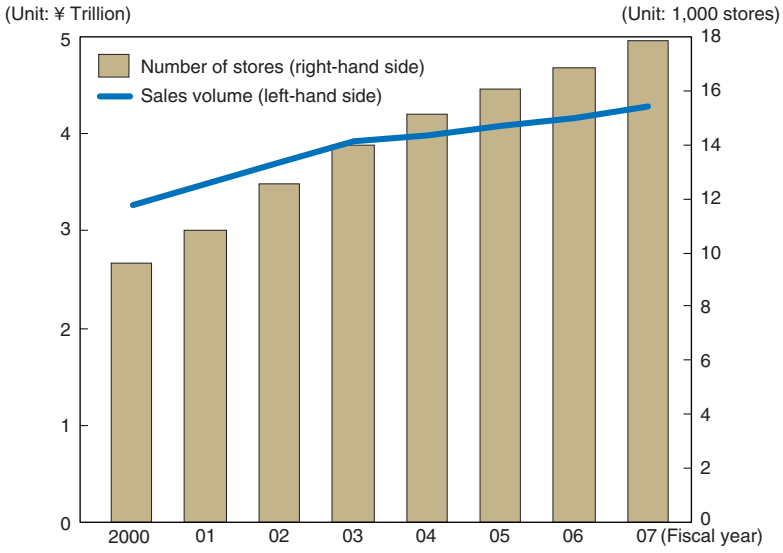
The principal purposes behind such a move were to achieve the following goals:

Figure 2. Changes in Sales Volume of Medicines by Sales Channel (2)



Source: Compiled based on *OTC Drug Data Book* published by Fuji Keizai.

Figure 3. Changes in Drug Store Sales Volume and Number of Stores



Source: Compiled based on the Report on the Survey of Japan's Drug Stores published by the Japan Association of Chain Drug Stores (JACDS).

(1) Acquiring increased buying power (ability to purchase a large amount of products) and reducing costs through joint distribution

(2) Developing private brand products

(3) Concentrated use of resources in a company's strong areas by adjusting plans to open new stores

However, these purposes for grouping will inevitably have to be changed in the future. This is because, setting aside Item (3), with respect to Items (1) and (2), supermarkets and convenience stores have had more experience in the accumulation of such expertise than have drug stores.

In other words, if drug stores are to increase their buying power, reduce costs through joint distribution and strengthen their private brands, options that will inevitably arise for consideration would include forming alliances with companies in different lines of business that have the necessary expertise in addition to grouping with drug stores in the same line of business.

Accordingly, a competitive environment after the enforcement of the revised law is expected to assume a structure that is different from that in the past by shifting from competition chiefly among companies in the same line of business to competition involving not only drug stores but also companies in different lines of business such as supermarkets and convenience stores.

III Business Opportunities Generated by the Amended Pharmaceutical Affairs Law

1 Business Innovation in Pursuit of Being "Home Pharmacies"

In view of the projected changes explained above, drug stores are taking approaches as described in Section 2, Chapter II. However, most drug store chains have embarked on a policy to strengthen their prescription-filling business, to say nothing of increasing the number of stores and extending their hours. These approaches eventually lead to "homogeneous" competition among drug stores, with only a limited number of companies striving to provide unique value to consumers.

If a company recognizes a structural change—intensified competition with companies in different lines of business—it must see the recent regulatory amendment as a good opportunity to review its business activities from the perspective of consumers without being simply affected by a system change brought about by the revised Pharmaceutical Affairs Law.

In this chapter, consideration is given to the significance and importance of "home pharmacies" that have often been talked about and recommended as the ideal status of drug stores.

2 What is a Home Pharmacy?

A home pharmacy refers to a pharmacy where a pharmacist provides consultation and advice to a patient (consumer) about medicines in the same way a home doctor does about sickness. A home pharmacist provides advice on the following topics:

- Matters that must be noted with respect to interactions between drugs and between drugs and food
- Selection of OTC drugs based on a patient's symptoms and history of medicines taken in the past

Because the use of a home pharmacy is also effective in preventing the occurrence of adverse drug reactions,

Table 3. Purchasing Behavior by Product Category

	Product category	Average number of referenced information items
Food products	Rice, bread, noodles	1.5
	Perishable food	1.5
	Fresh food with a short shelf life	1.5
	Seasonings	1.7
	Prepared take-out food items	1.8
	Candies and other confections	1.7
	Processed food	1.6
Beverages	Alcoholic drinks	1.9
	Other beverages	1.6
Sundries, drugs, cosmetics	Toiletries	1.9
	Household utensils	2.0
	Baby goods	1.7
	Drugs	3.1
	Health supplements	2.2
	Cosmetics	2.3

Source: "Changes in Shopping and the Retail and Distribution Industries" by the Japan Consumer Marketing Research Institute.

through adopting policies such as those facilitating the separation of pharmaceutical dispensing from medical practice[2], the government encourages consumers to utilize their home pharmacies.

Actually, do consumers seek advice when they purchase drugs?

Research that analyzed the purchasing behaviors of consumers revealed that many want to have as much reference information as possible when they buy medicines (Table 3).

Other survey findings[3] indicate that there are even a greater number of consumers, regardless of gender and age, who prefer to purchase a medicine recommended by a salesperson without adhering to a particular brand.

3 Business Innovation Will Bring about Change in the Focus of Competition

As explained in Chapter II, moves to form company groups before the enforcement of the revised Pharmaceutical Affairs Law have principally aimed to win the competition to reduce costs. In the future, however, it is reasonable to assume that the major objective to form company groups will shift from cost to sharing expertise to strengthen the technical knowledge and skills needed to become home pharmacies.

In other words, the major factor in the future that will motivate a purchasing company to acquire particular companies for grouping will not be "the ability to supply products at low cost," but "a particular expertise" and/or "convincing a purchasing company that while it is difficult to develop true home pharmacies on its own, it is likely to be possible if joint efforts are made with that company."

IV New Functions Required of Drug Stores

In order for drug stores to strengthen their own technical skills and knowledge as home pharmacies and to provide workplaces where qualified pharmacists (those who completed a six-year program at a university's department of pharmacy) are able to deal confidently with customers, Nomura Research Institute (NRI) suggests that drug stores have two functions, which are described below.

1 Providing Counseling and Information based on Reliable Data

The first function required of drug stores is to have tools to provide information to consumers that is backed by well-accepted evidence (clinical research data).

Even though pharmacists are experts in medicines, in order to build trust among their customers, the advice and information they provide must be easy to understand and convincing.

Rather than acting in the capacity of a "sales agent" who sells medicines recommended by a particular pharmaceutical manufacturer and/or the drug store head office, a pharmacist must provide information in the capacity of an "agent of the customer" who is aware of the patient's history of medication, information on contraindications and the customer's needs.

For this purpose, multiple sources of information and tools that can systematically and effectively use these sources are needed.

The first source necessary relates to information on an individual patient's history of medications taken in the past, history of illnesses, smoking and drinking habits, as well as a history of products purchased in the past including food and beverages. This information source can be provided through integrating information that the drug store has with information that the dispensing section has.

Currently, there are only few cases in which these two types of information are managed on an integrated basis. Nevertheless, this information source is essential for any effort to provide advice on a one-stop basis.

The second source refers to databases of medicines and healthful foods. These databases enable pharmacists and salespersons to readily search and view information such as composition, how best to use, dosage and contraindications concerning each product.

When providing advice to customers who are choosing a medicine or healthful foods, these databases can be effectively utilized. Nonetheless, the author believes that not only general product information but also additional useful information should be included in these databases.

By way of example, if a pharmaceutical manufacturer and a drug store can jointly implement clinical research after an OTC drug or a health-related food product is put on the market and clarify the attributes (e.g., age, various test values, food that is to be simultaneously eaten) that facilitate the generation of effects from such drug or food, more specific advice and/or recommendations can be provided to consumers (Figure 4).

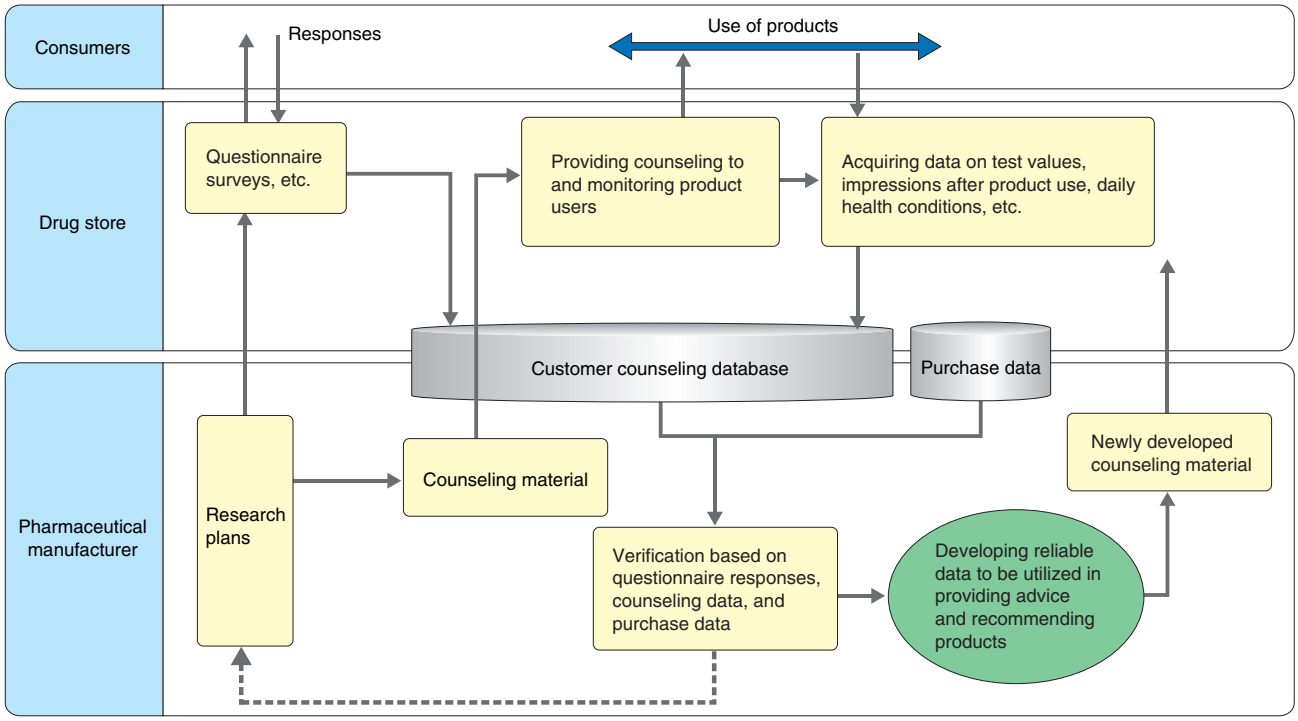
While this collaboration between a pharmaceutical manufacturer and a drug store attempts to use the drug store as the final testing ground of clinical research, it can generate various advantages in addition to the fact that more appropriate advice can be provided to consumers.

On the part of drug stores, data regarding what items are effectively appealing to consumers can be accumulated, leading to the building of strong relationships between drug stores and consumers.

On the part of pharmaceutical manufacturers such as those producing OTC drugs, consumers' everyday purchase data can be acquired from drug stores, enabling manufacturers to embark on more detailed research, which was difficult to conduct in the past.

For drug stores to realize this function, the need arises for tools to measure body weight and to conduct various

Figure 4. Overview of a Model Providing Information and Counseling Based on Clinical Research Data



tests, and personnel to manage the monitored consumer data. Pharmaceutical manufacturers would face the ambiguity of determining to what extent purchase data acquired from drug stores can be utilized.

Nevertheless, if it becomes possible for drug stores to provide appropriate advice to consumers, drug stores can enjoy more solid loyalty from consumers and can increase the value of the services they provide. In view of these advantages, efforts to provide this function deserve full consideration.

2 Functionally Integrating Drug Stores and Dispensing Pharmacies

The second function relates to the ability to provide a home pharmacy function "at any time and anywhere."

In order for a drug store to be recognized as a home pharmacy by consumers, it is essential that it be equipped with the dispensing function to prepare medicines prescribed by medical institutions in addition to selling OTC drugs and healthy food products.

This is because, as described in Section 1, data such as a consumer's history of medication and history of diseases can only be acquired through the work of dispensing medicines.

In light of the current situation, however, it is difficult to expect all drug store outlets to have a dispensing function. This difficulty stems from the fact that the number of medical prescriptions (i.e., the number of patients) is smaller than that required to cover the cost to enable drug stores to continue the dispensing function.

The principal reason is that most patients tend to purchase medicines at a pharmacy near the medical institution where they receive the prescriptions, rather than at a drug store near their home or close to a train or bus station.

The question that then arises is if there are any solutions enabling drug stores to maintain a dispensing function for only a small number of patients. To this question, two issues hinder such solutions.

The first issue concerns how efficiently pharmacists can be deployed. Dispensing medicines is limited to pharmacists; registered salespersons are not permitted to do this work.

However, because the number of drug store functions that can be handled by registered salespersons has been expanding based on the amended law, these registered salespersons can be effectively utilized to achieve more flexible staff deployment than previously, before enforcement of the revised Pharmaceutical Affairs Law.

The second issue relates to the matter of store inventory. Patients can present any prescription issued by medical institutions located throughout the country. However, drug stores cannot keep all medicines required in stock.

While various methods could be used to solve these problems, one option would be that drug stores alone do not provide the dispensing function on their own, but that drug stores and dispensing pharmacies are virtually integrated. This solution comes from the basic idea that the functions required of a home pharmacy are respectively fulfilled by a drug store and a dispensing pharmacy, i.e., separating the required functions into those fulfilled by a drug store and those fulfilled by a dispensing pharmacy.

In sum, if it becomes possible for drug stores to view the past prescription records maintained by dispensing pharmacies, they can provide appropriate advice to customers based on these prescription records as well as on the data on purchase histories regarding OTC drugs and healthful foods accumulated at drug stores. Similarly, dispensing pharmacies can provide appropriate advice to patients based on their records and the data acquired from drug stores.

Some issues must be overcome to realize this virtual integration such as the matter of obtaining consent to share information and the matter of bearing the cost of building a database. Nevertheless, this solution would merit attention if consideration were given to the fact that drug stores would not need to equip themselves with the dispensing function without compromising the convenience of their customers.

V The Amended Pharmaceutical Affairs Law Prompts New Approaches

As described so far, the revised Pharmaceutical Affairs Law has had a major influence on the retail sector such as drug stores, supermarkets and convenience stores, and requires them to embark on innovation in terms of business structure and the functions provided.

It is reasonable to assume that such innovation required of the retail sector would in turn prompt manufacturers, especially pharmaceutical manufacturers, to adopt new approaches such as conducting joint research on their products with the retail sector and promoting the sales of products based on adequate evidence, as was explained in Chapter IV.

Given that Japan is rushing towards a super-aged society, the author hopes that the amended Pharmaceutical Affairs Law will promote the mass appeal of self-medication and that drug stores will be able to contribute to the creation of a society where people live healthfully and with peace of mind.

Notes:

1 Prescription business refers to the sales of medicines and medical treatment supplies to patients as per prescriptions issued by medical doctors to patients.

2 According to the Japan Pharmaceutical Association, the separation of pharmaceutical dispensing from medical practice means “patients are given prescriptions rather than medicines when they are examined at a hospital or clinic.” JPA points out the difficulty of managing all medicines prescribed for a particular patient because some medical institutions still provide medicines directly to patients and such separation is not implemented.

3 These surveys include the Survey on OTC Drugs conducted by Cross Marketing, a market research consulting company, whose survey findings were announced on May 29, 2009. This survey was conducted during the period from May 15 to 19 for people aged 20 – 69, and received 1,200 responses (the responses were grouped based on the rate of population by age).

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