

EXPANDING THE BOUNDARIES OF SELF-MEDICATION IN A GLOBAL CONTEXT

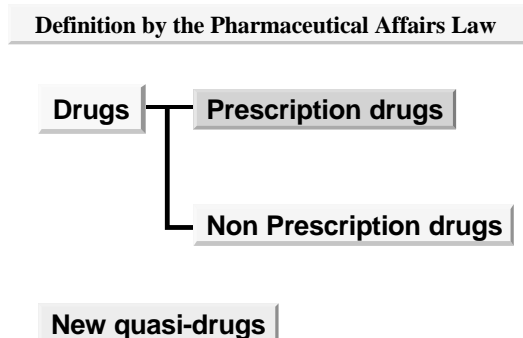
Changing legal status and distribution channels

Mr Seiichi Sato, President, Sato Pharmaceuticals Co and Vice-Chairperson, Proprietary Association of Japan (PAJ)

Ladies and Gentlemen, I would like to thank you for having the opportunity to discuss the changing legal status and distribution channels of drugs in Japan. It is an honour and a privilege to be here among such esteemed panellists.

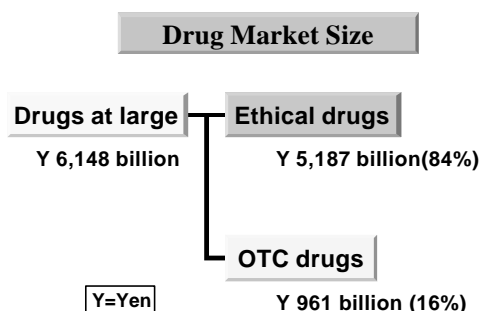
I am Seiichi Sato, President and Chief Operating Officer of Sato Pharmaceuticals. Sato Pharmaceuticals is one of the largest over-the-counter (OTC) pharmaceutical companies in Tokyo, Japan and is proud to be celebrating its 84th year in business. We directly distribute OTC and other related healthcare products to over 42 000 pharmacies and drugstores.

For many years, drug control has been very stringent in Japan. All OTC drugs, could only be sold at pharmacies, drugstores with pharmacist, drugstores without pharmacist and other minor outlets. This law applied to non-prescription or over the counter drugs.



This past April, after many years of restrictions by law, deregulation went into effect in Japan. This allowed some over-the-counter drugs to be sold in other retail outlets, convenience stores and kiosk in a category defined as new quasi-drugs. Today I would like to discuss what impact this deregulation brings to the health care market in Japan.

In my discussion this afternoon, I would first like to explain about the present status of the OTC market in Japan. Second, I would like to describe the present status and use of convenience stores and other new outlets. Third, I would like to talk about the current situation of deregulation and conclude by expressing my views on future expectations and issues.

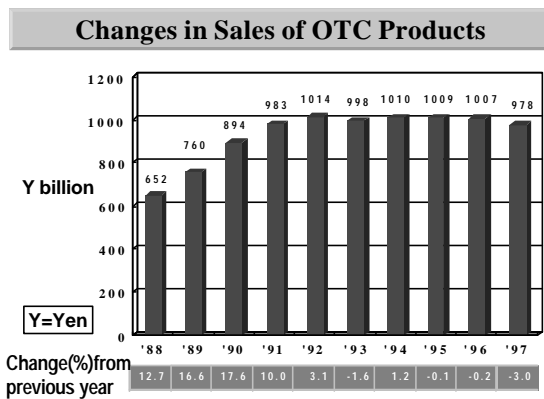


Source:1997 Pharmaceutical Industry Production Statistics

1. Present status of the over-the-counter (OTC) market in Japan

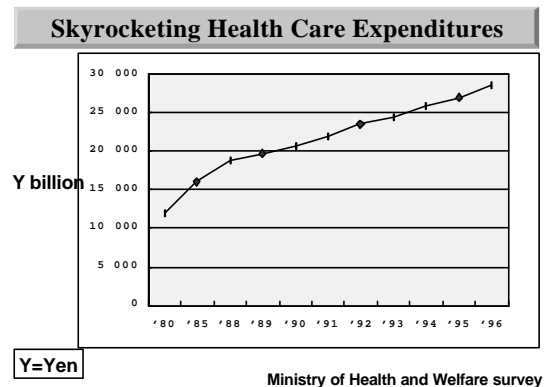
In fiscal 1997, roughly 6.15 trillion yen or 60 billion dollars worth of pharmaceuticals were produced. Ethical or prescription drugs accounted for 84% of the total, with over-the-counter drugs, or OTC making up the remaining

16%. It should be noted that this 84-16 ratio has remained constant for several years.



As this graph shows, there was a rapid growth in OTC products from 1988-1992. This corresponds with the burst of the Japan bubble and the difficult period that Japan went through. As we are aware, people tend to get more headaches during stress related times and need our products more.

After reaching its peak in 1992, OTC sales dipped in 1993, then stabilised for a few years, exceeding 1 trillion yen from 1994-1996. However, sales dropped in 1997, causing some concern in the industry.



As illustrated here, medical costs have risen dramatically in Japan, as it has throughout the world. With insurance costs rising, people are debating whether to seek medical treatment or to use alternatives such as self-treatment with OTC products, or other healthy alternatives.

In Japan, a major breakthrough was the introduction of switched OTC products many years ago. H2-Blockers, however, did not have the same kind of impact when introduced in 1997.

The following graph describes the 10 top ranking OTC products in Japan. It is important to note that most of these products can only be sold in drugstores or pharmacies. Number 1 is the mini bottled nutritive drink.

I am humbled to say that one of our products, Yunker, falls into this category. Yunker products are used as a nutriment supplement in cases of physical fatigue. The primary differences between the mini bottled nutritive drink products and the Number 2 OTC product of bottled nutritive drinks, is not only size and cost but also ingredients.

10 Top-ranking Products in the OTC Market

	Value (Y billion)	%
1 Bottled Nutritive Drink, Mini	118.4	13
2 Bottled Nutritive Drink	102.1	11
3 Common Cold Remedies	93.7	10
4 Skin Preparations	62.2	7
5 Topical Anti-inflammatory Analgesics	58.1	7
6 Gastrointestinal Preparations	58.0	5
7 Eye Drops	42.9	4
8 Other Nutritives and Tonics	40.0	4
9 Antipyretic analgesics	35.0	4
10 Vitamin B1 Preparations	32.8	4

1997 SDI Annual Report

Most of this category of product has been categorised as a quasi-drug, and is available in convenience stores and vending machines, shown here, throughout Japan. These drinks are primarily vitamin nutritive drink products.



Common cold remedy products make up the third major category of OTC products. These products generally contain ibuprofen and other ingredients. The other 7 categories make up smaller market share and are self-explanatory.

While the availability of OTC products has made it easier for the consumer, it is important to note that the Number 1 & 2 products are tonic drinks and not cold remedies or aspirin. This is unique, I feel only to Japan.

Retail Outlets of OTC Products

Pharmacy	42,412	58%
Drugstore with pharmacist	14,117	19%
Drugstore without pharmacist	16,764	23%
Total	73,293	100%

There are three primary outlets for OTC products: pharmacies, drugstores with a pharmacist and drugstores without a pharmacist. Pharmacies and drugstores with a pharmacist make up the major share. The increase in market share was due to the ability to fill prescriptions issued by medical institutions.

Retail Outlets of New Quasi-drugs

Total	93,025
Convenience Stores	38,225
Other outlets	
Super Markets	46,900
Discount Stores, etc.	2,900
Kiosks	5,000

Deregulation has now opened the market to more than 90,000 new retail outlets. The new category of quasi drugs is now offered at convenience stores, other outlets such as retail food corner outlets, as well as train station kiosks.

15 categories of New Quasi-drugs

- 1 Vitamin-containing tonics (Bottled Nutritive Drinks)
- 2 Vitamin C preparations
- 3 Vitamin E preparations
- 4 Vitamin E-C preparations
- 5 Calcium preparations

However, the new quasi drugs are very limited for there are only 15 categories. This chart describes the top 5 categories of quasi drugs that are now available at most retail outlets. I need to point out that each category of drugs has different rules. The new quasi-drugs have requirements for the ingredients and their usage.

This chart shows products that are primarily vitamin supplements. In Japan, bottled nutritive drinks are very popular, and some of those products that contain limited amounts of vitamins shift into this category.

15 categories of New Quasi-drugs

- 6 Throat candies
- 7 Digestive aids containing herbal stomachic remedies
- 8 Topical Disinfectants
- 9 Adhesive plasters containing disinfectants
- 10 Ointments containing Chlorhexidine

The next chart describes the next 5 categories. Most of the products are commonly available in the US at supermarkets and convenience stores, but are new to Japanese stores.

15 categories of New Quasi-drugs

- 11 Ointments containing Menthol, Camphor
- 12 Ointments containing Vitamins A and E
- 13 Adhesive plasters containing Salicylic acid
- 14 Ointments containing Urea
- 15 Products of external application with Zinc oxide

And this last chart completes the list. These are primarily the external-use products that are available.

2. Present status and use of convenience stores (CVSs) in Japan

The growth of the convenience store in the past 10 years has been phenomenal. It has changed the lifestyle of many of the people living in the metropolitan areas.

Top-ranking Convenience Stores

Rank	Name	Location of Head office	No. of Stores	Sales (1997)	
				in Y million	%
1	Seven-Eleven	Tokyo	7 362	1 740 960	30.5
2	Lawson	Tokyo	6 649	1 093 760	19.1
3	Family Mart	Tokyo	6 085	710 095	12.4
4	Daily Yamazaki	Chiba	2 826	385 495	6.7
5	Circle K	Aichi	2 328	380 504	6.7
6	Sunkus	Tokyo	2 252	282 303	4.9
7	am/pm	Tokyo	758	167 256	2.9
8	Ministop	Chiba	1 274	153 755	2.7
9	Seiko Mart	Hokkaido	694	113 064	2.0
10	Kokubu Community Store	Tokyo	644	109 000	1.9
	Others		7 535	579 063	10.2
	Total		38 225	5 715 255	100

At present, Japan has 38 225 outlets equalling one store per 3 000 people. Convenience store sales continue to increase steadily, while the rest of the industry has declined. These stores have assumed their place as a typical mode of business in retailing. This chart reflects the reality of the impact of convenience stores in our society.

Convenience stores are growing as a mode of distribution that meets the needs of Japanese consumers, whose daily schedules are becoming more diverse. In Tokyo especially, many people live alone and there are many couples with both partners working.

The opportunities that these outlets will have on the new quasi drug remains to be seen. We feel that the sales potential, especially for bottle nutritive drinks, is tremendous.

3. The current situation of deregulation

We recently conducted a consumer survey of some 1 000 people in the Tokyo area ten days after deregulation went into effect. The telephone survey was conducted from April 9 through April 15 with Tokyo residents between the ages of 15-64.

Survey of Consumer Awareness of Deregulation

1,006 peoples of both sex aged 15-64 years in the Tokyo district

Age	Total	Males	Females
15-19	86	40	46
20s	255	135	120
30s	190	100	90
40s	205	105	100
50s	190	95	95
60-64	80	40	40

Method
Telephone survey

Survey period
April 9 through April 15

86% of those interviewed said they were aware of the deregulation. Considering the short period of time elapsed since the start of deregulation, consumers' awareness can be considered rather high.

A Result of Consumer Survey for Deregulation

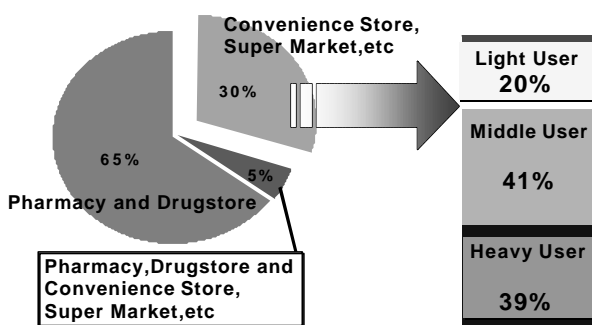


43% said they had actually seen products displayed in stores. These results reflect a high interest with the consumers. This is also obvious from the fact that pharmaceutical deregulation is appreciated by many consumers who often buy drinkable preparations and is attracting their attention. 70% of the consumers have a positive, supportive view of such deregulation.

Given that consumers' awareness of pharmaceutical deregulation tends to be high among consumers who often make purchases at CVSs and people in their 20s to 30s, sales at CVSs seem to have a significant effect on the consumers' awareness of pharmaceutical deregulation.

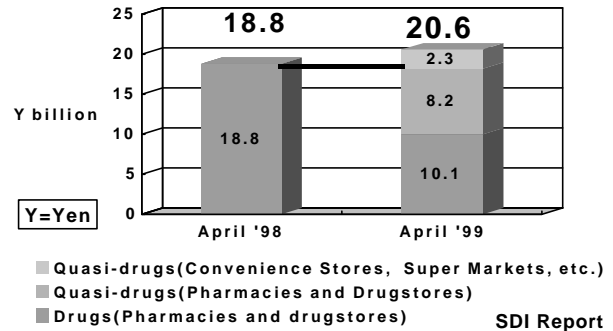
At the time of the survey, the only deregulated products actually being sold at pharmacies were vitamin-containing tonics or bottled nutritive drinks. Purchases at CVSs and other non-pharmacy outlets accounted for more than 30% of the total market sales.

Expansion of New Bottled Nutritive Drink User



Among these 30%, 20% of consumers who never purchased drinks at a pharmacy or drugstore actually purchased them at a convenience store. This seems to indicate that deregulation has already had a good impact of expansion for new potential drink users. It is projected that the purchase ratio will increase in July and August, during the summer period of high demand.

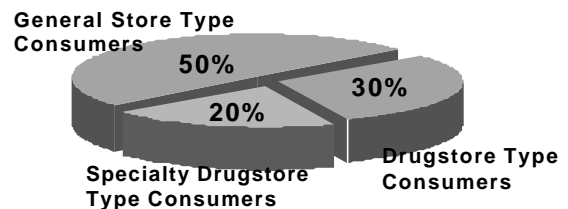
Increase in Sales of Bottled Nutritive Drink



In fact, total sales of bottled nutritive drinks in April 1999 after deregulation in March was increased by 20.6 billion which was a 9.5% growth as compared with April 1998, while total sales at pharmacies and drugstores were remaining steady.

What we are seeing is that consumer acceptance of deregulation has a correlation to the convenience of being able to obtain health-maintaining products at a nearby retail store any time of the day. This gives support to the ease and freedom with which the consumer can choose products on his/her own.

Acceptance of New Quasi-drugs by Different Types of Consumers



From the survey, consumers have been categorised into three types: General Store Type Consumers, Drugstore Type Consumers, and Specialty Drugstore Type Consumers.

General Store Type Consumers

- Males and company employees who rarely visit drugstores
- Consumers are willing to use quasi-drugs and wish to their category expanded
- Consumers who want to select products of their own accord

General Store Type Consumers are described as:

- Males and company employees who rarely visit drugstores
- These consumers are willing to use quasi-drugs and wish to see the category expanded
- And they want to select products of their own accord.

This General Store Type Consumer looks for outlets that are very convenient and highly appreciate pharmaceutical deregulation. They have relatively limited concerns that specialists are not available when drugs are purchased and make up 50% of the market.



- Consumers who often visit drugstores for quasi-drugs
- Look for product line and prices; wish to have the category of quasi-drugs expanded
- Consumers want to select products of their own accord

30% of the market is made up of Drugstore Type Consumers:

- These are consumers who often visit drugstores for quasi-drugs
- They look for product line and prices, wish to have the category of quasi-drugs expanded
- These consumers want to select products of their own accord.

Buyers of nutritive drinks and vitamin products constitute a relatively large segment of this group. They seem to have a mind-set to purchase at cut-rate outlets to save money.



- Consumers are primarily women
- Often visit various sales outlets, exercise discretion when purchasing drugs
- Depend on expect specialists to make recommendations
- Consumers do not highly value pharmaceutical deregulation

The smallest segment is the Specialty Drugstore Type Consumer:

- Most are women
- They often visit various sales outlets, exercise discretion when purchasing drugs
- Depend on specialists to make recommendations
- These consumers do not highly value pharmaceutical deregulation.

They have trust in the specially drugstores.

From these profiles, we feel that 80% of consumers desire further deregulation of pharmaceutical products sales outlets. Most consumers want a full line-up of new quasi-drugs. These people want medical drugs such as throat remedy products, vitamin C, E, E&C and calcium preparations and digestive aids more available. However, these consumers are concerned about the safety of drugs that they can purchase on their own.

4. Future expectation and issues

The pharmaceutical market for many years focused on specially treatment of ailments and ethical drugs. These were available only at hospitals and clinics.

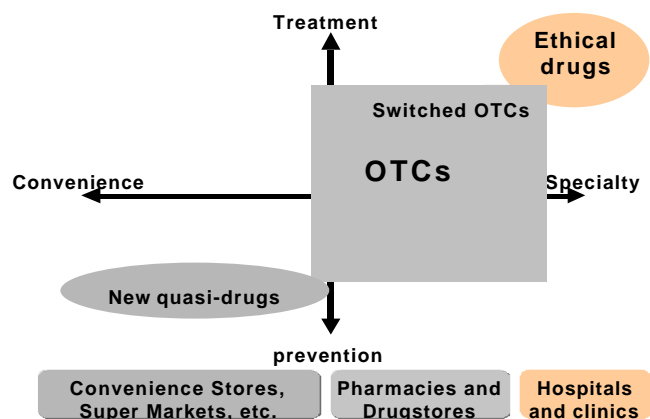
Recently, through the introduction of OTC products, we have been trying to find not just a treatment for ailments, but to seek mitigation and preventive treatments. These OTC products include many basic drugs, such as ibuprofen, and vitamin supplements.

These OTC products, however, were still only available at drugstores and pharmacies. It is important for the industry to work towards making preventive products more accessible to the consumer. We need to be able to reconcile the achievement of public health objectives with the public's limited budgets.

Today, with deregulation, we are seeing a shift in health care – a movement more towards mitigation and prevention with the availability of quasi-drugs at convenience stores, supermarkets and other outlets.

The present 15 categories of new quasi-drugs are limited to those that prevent or relieve symptoms.

The group of consumers illustrated includes households with children where parents work. This includes people who want to relieve the symptoms of a night-time illness until the morning and people who want fever and pain relief products for children.

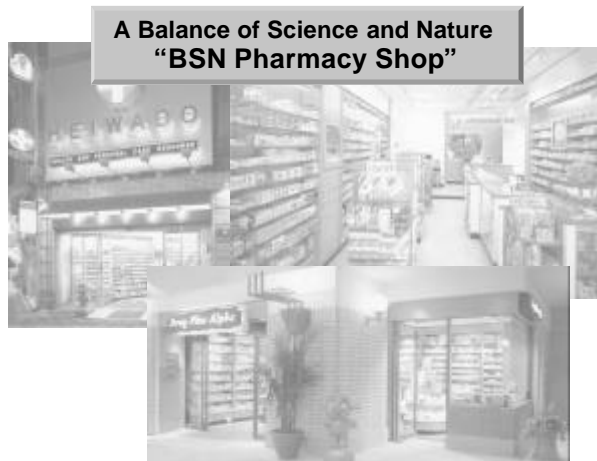


However, the current new quasi-drugs do not meet the needs of these consumers.

The availability of a greater variety of new quasi-drugs for retail outlets raises the question of the need for pharmacies and drugstores that have specialised in over-the-counter drugs. It also raises the concern that further deregulation will have on our distribution system.

Can pharmacies and drugstores appeal to local residents? It can be said that there is a growing need to get away from “selling things” and establish the “health-

maintenance function for local residents”. Sato Pharmaceuticals has been working with these pharmacies and drugstores in trying to develop the “BSN pharmacy shop” concept of health care. This Balance of Science and Nature – BSN – provides three concept theme options: Energy, Nature, and Purity. We feel that by creating these outlet environments, it will enhance customer satisfaction.



In order for pharmacies and drugstores to be significant in health care, specialised knowledge and products are required as well as the creation by drug manufacturers of over-the-counter drugs that take this point into account.

Japanese pharmaceutical companies must put continuous effort to contribute a self-medication philosophy to pharmacy and drugstore through the creation and marketing of innovative health care products.



However, we must be flexible and recognise that the future generations are starting to change our retail strategies. While education for self-medication products is the future of our industry, where we market and retail these products will be the key to our success.

First it was the availability of OTC product, now it is the new quasi-drug product being sold in CVSs and other outlets. While we accept this new challenge, we must be very cautious.

We are very fortunate in Japan, to be able to study what has happened in other markets such as Europe and the United States.

It is our challenge to ensure that the sales of the products that we manufacture are more controlled, and will lead to a longer and more productive life for our customers.

