No.3

December
1997

JETRO Japanese Market Report

– Regulations & Practices –

Nonprescription (OTC) Drugs

Contents

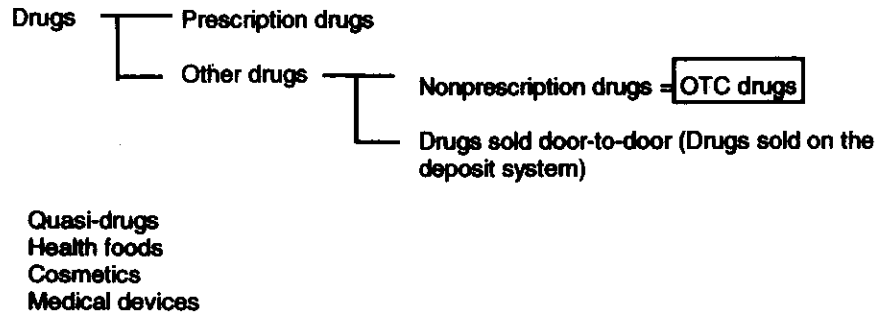
Yen-Dollar Exchange Rates

Year	Yen/US$
1992	127
1993	111
1994	102
1995	94
1996	109

Source: "International Financial Statistics," IMF

Introduction

Nonprescription OTC (over-the-counter) drugs are defined as medicines that consumers may purchase directly, without prescriptions, at retail stores approved to engage in the sale of pharmaceuticals. This definition covers drugs that are formally known as "non-prescription drugs" in Japan.



When comparing drugs that belong to the category of "nonprescription drugs" in Japan with OTC drugs prevalent in foreign countries, several key points should be kept in mind.

Drugs sold door-to-door by salespersons who regularly visit homes to deliver medicines and collect payment have existed since before the inception of the present medical treatment system. Door-to-door and OTC drugs accounted for about 15% of the total value of drugs manufactured and sold in Japan in 1995, of which OTC drugs accounted for 13.9% and door-to-door drugs for 1.1%. Door-to-door drugs, which are limited to those designated as such by local governments, are sold in a different method than OTC drugs and are, therefore, not included in this report.

There is another category of medicines, known as quasi-drugs, which are completely distinct from other drugs. The manufacture of quasi-drugs is regulated, but sales are not. The quasi-drugs category includes:

1) Quasi-drugs to prevent vomiting, discomfort, bad breath, or body odor;

2) Quasi-drugs to prevent prickly heat, sores, or to grow or remove hair; and

3) Quasi-drugs that have only mild effects and are used to exterminate mice, rats, flies, mosquitoes, fleas, etc. for the benefit of human or animal health.

Some of these are treated as OTC drugs in other countries. As will be indicated in this report, a relaxation of OTC drug regulation is under consideration in Japan. In the future, there is a possibility that part of the current OTC category will be shifted to include the quasi-drug category, or to a new category, and sales will be deregulated.

The question of the presence or absence of vitamins, etc. is likely to play a role in determining the demarcation between health foods and general medicines.

The pharmaceutical industry also uses the general term "*taishuyaku*" (people's drugs) which may embrace the categories of OTC drugs, door-to-door drugs, kits sold for home testing, quasi-drugs, and medical devices. However, the term "*taishuyaku*" will not be used in this report.

I. Import Procedures and Regulations

A. Changes in Law and Regulations

1. Laws

The main laws relating to drugs are the Pharmaceutical Affairs Law, which prescribes a comprehensive regulatory framework for the manufacture, sales, and handling of drugs, and the following other laws.

- Pharmacists Law
- Narcotic and Psychotropic Control Law
- Opium Law
- Cannabis Control Law
- Stimulant Control Law
- Poisonous and Deleterious Substances Control Law
- Blood Collection and Donation Services Control Law
- The Organization for Drug ADR (Adverse-Drug Reaction) Relief, R&D Promotion and Product Review Law (Drug Organization Law)

Amendments to the Pharmaceutical Affairs Law, the Pharmacists Law, and the Drug Organization Law were passed in June 1996 and took effect in April 1997. The main points of the amendments are as follows.

a. Expanded consultation and guidance regarding trials

Good clinical practices (GCP) have been thoroughly enforced among pharmaceutical manufacturers in an effort to ensure the reliability of trial data and the safety of the trial subjects, and to ensure that appropriate trials are implemented. At the same time, there has been an expansion of public participation in consulting and guidance.

b. Expansion of approval framework

Inspections making use of the Drug Organization Law (full name: The Organization for Drug ADR Relief, R&D Promotion and Product Review) have been augmented in an effort to expand the approval framework. This expansion allows the Ministry of Health and Welfare and the Central Pharmaceutical Affairs Council to carry out highly sophisticated evaluations.

c. Strengthening of post-marketing surveillance

Initiatives have been taken to ensure that drugs in the market are properly inspected, to strengthen the reporting of side effects, and to promote the proper use of drugs.

d. Others

An amendment that covers the emergency import of drugs in special cases provides a legal framework for the gathering and reporting of information on infectious diseases that may require emergency treatment in Japan with foreign drugs.

The amendments mentioned in a.— c. apply to all manufacturers of pharmaceuticals, including OTC drugs. In addition, the amendment in c., which treats pharmacies and

pharmacists as providers of medical information, has a provision relating to the operation of pharmacies. This provision, which enhances the functions of conventional pharmacies, reinforces the separation between pharmaceutical dispensaries and medical practices.

2. National Health Insurance System

Japan's national medical expenditures (see Note 1), which have been increasing annually, registered a year-on-year increase of 4.5% in FY 1995 to ¥26.96 trillion. Although national medical expenditures have been rising, national income has flattened out. The ratio of medical expenditures to national income, which had been holding steady at around 6%, has been rising since FY 1991, passing the 7% milestone in FY 1995, when it hit 7.1%.

The Ministry of Heath and Welfare has established a policy of keeping the growth of national medical expenditures within the scope of the growth of national income. However, the ministry has been unable to attain this target for the past five years running. Economic growth has, on the one hand, flattened out, and on the other hand, there has been massive growth in medical expenditures for the elderly due to the fast growth of the elderly population. Without reforming the medical treatment system, it will be impossible to attain the parity target in the growth of medical expenditures and national income. Japan's medical treatment system will be reformed in steps from 1997 to 2005. An amendment to the Health Insurance Law established in June 1996 contains two provisions that affect drugs: a review of the drug tariff system and a review of the price burden on patients. The review of the drug tariff system aims to reduce the high rate of expenditure on drugs (see Note 2) in Japan compared with many other countries, and the review of the price burden on patients aims to improve government revenues from the medical insurance system. In addition, the out-of-pocket burden to health insurance users was increased from 10% to 20%, and a certain number of new charges, these include an increase in out-of-pocket payments for the health of the elderly, an increase in out-payments for drugs for out patients, were instituted in September 1997.

The increase in the users' out-of-pocket burden is expected to increase the number of cases in which patients with mild colds are not hospitalized, but are given OTC drugs instead. This is expected to increase demand in the OTC market.

3. Relaxation of OTC Drug Sale Regulations

In April 1995, the Health and Welfare Minister expanded the power of local authorities to license manufacturers and importers of drugs, quasi-drugs, and cosmetics, with the exception of certain pharmaceuticals and new drugs that require highly advanced manufacturing technology.

Under the Resale Price Maintenance Contract System (RPMCS), certain categories had been exempted from the Antimonopoly Law since 1953, but these exemptions were abolished at the end of FY 1996, following an amendment to the Program to Promote the Relaxation of Regulations in March 1995. OTC drugs were exempted in 1954, the year

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Note 1: National medical expenditures do not include expenses for normal births and the purchase of OTC, drugs.

Note 2: According to the Ministry of Health and Welfare, the proportion of medical expenditures accounted for by drugs in 1993 was 22.3%, compared to 17.1% in France, 14.4% in Germany, 14.8% in the UK., and 7.4% in the United States.

following the introduction of the RPMCS, and remained on the list until FY 1996.

The Ministry of Health and Welfare conducts surveillance and guidance related to health food items such as vitamins and similar items (tablets, etc.) in accordance with "the supervision of drugs that do not require approval or licenses" and "standards for differentiating between health food and drugs." The government has decided to carry out a review prior to the relaxation of regulations on these standards. As of August 1996, vitamins classified as foods that provide up to 1.5 times of daily required amounts of nutrition had been approved for manufacture as pharmaceuticals in the form of tablets. The ministry is continuing to review the classification demarcations between drugs and food in the case of vitamins taken orally.

B. Laws and Procedures Concerning the Import and Sales of OTC drugs

1. The Approval and License System

The manufacture of prescription drugs requires an approval (shonin) and license (kyoka) as prescribed in articles 14 and 12, respectively, of the Pharmaceutical Affairs Law. The same regulations apply to imported drugs.

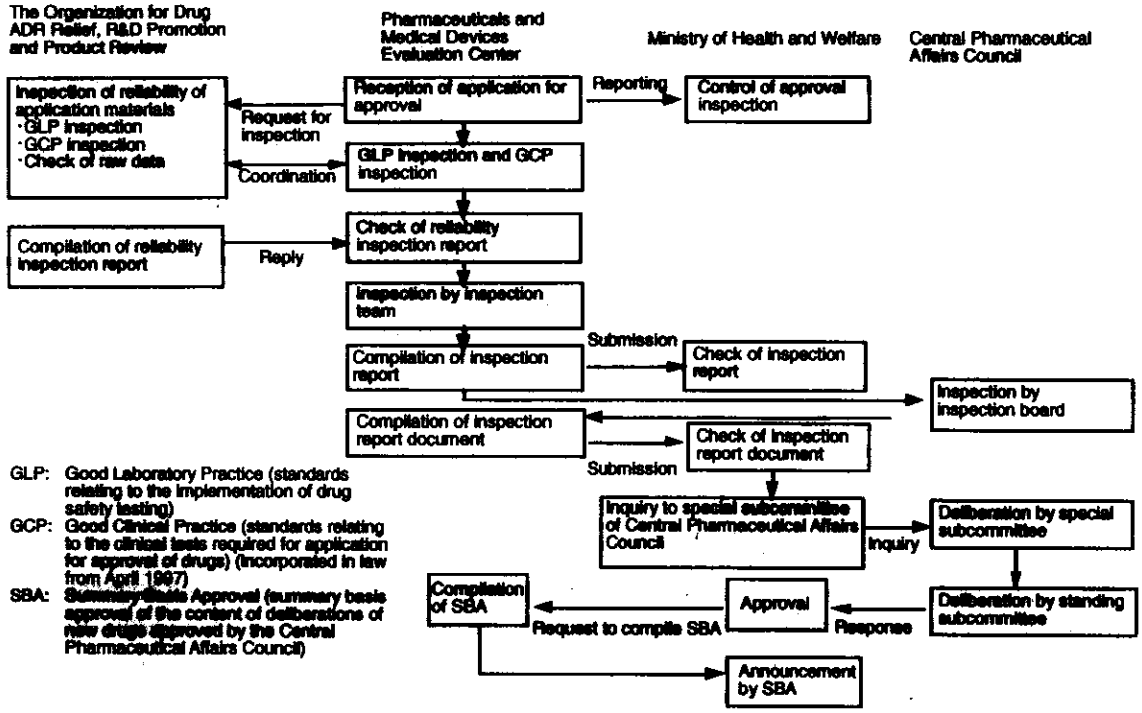
With the exception of gastrointestinal remedies, local government authorities (Drug Affairs Sanitation Section, Drug Affairs Dept., Sanitation Bureau in the case of Tokyo) inspect and confer approval (shonin) on OTC drug categories for which approval standards have been formulated (12 drug-effect groupings), including cold medicines and medicines to alleviate fever and headache pains. In the case of other categories of medicines (drugs for which no approval standards have been established, or new OTC drugs), an inspection similar to that applied to categories that have already been approved (a reliability inspection in the case of new drugs) is carried out at the Drug Organization. The process of new drug inspection is illustrated in Figure 1.

Approval inspections for OTC drugs are carried out in accordance with the following principles:

- The types of ingredients in the candidate drug and their relative amounts should be within a range that assures efficacy and safety of the drug.
- Their indications should be kept within the scope needed for the drug to treat or prevent minor ailments or to preserve and improve health.
- The directions for administration and dosage levels should be described in such a way as to be easily understandable by the general public.

The inspection period for OTC drugs for which approval standards have been formulated runs about 10 months, according to the results of previous applications.

Figure A: Approval Process of New Drugs



If the drug in question has received approval (shonin), a license (kyoka) may be granted to each of the manufacturing plants (or sales office) involved upon the determination of the Ministry of Health and Welfare (MHW) that the manufacturing plant (or sales office) that seeks to manufacture (import) the drug is competent to do so in terms of public health and hygiene.

The applicant for a license granted to a manufacturer or importer-reseller of drugs, quasi-drugs, and cosmetics is inspected to ensure that its manufacturing plant (sales office in the case of an importer-reseller) conform to the standards set by MHW in terms of the structure and facilities of the plant (office), as well as in production and quality control, and that the applicant has no disqualifications. From April 1997, MHW expanded the scope of power of local authorities over the licensing of manufacturers or importers of drugs, quasi-drugs, and cosmetics, with the exception of prescription drugs and new drugs that require highly sophisticated manufacturing technology. Generally speaking, applications for approval (shonin) and licenses (kyoka) are filed simultaneously in the case of drugs over which local authorities exercise approval and licensing powers.(see Note)

2. Import Tariffs

Imported drugs, including all items ranging from bulk powder, bulk liquid, and pellet materials to items packaged for retail sales, are entirely free of import tariffs.

Note: Refer to "Overview of the Japanese OTC Drug Market," published by The Proprietary Association of Japan, for a list of the materials required when making an application.

3. Regulations on Advertising

The main advertising channels for OTC drugs are TV (accounting for about 70%), newspapers, and magazines. Article 66 of the Pharmaceutical Affairs Law prohibits false and exaggerated advertisements, stating, "It is prohibited to make false claims and exaggerated advertisements concerning the name of drugs, their manufacturing methods, indications, effects, and efficacy. Furthermore, it is prohibited to advertise statements made by physicians or other persons in a way that may be misunderstood to guarantee the indications, effects, and efficacy of the drugs." It is also prohibited to run advertising that may be misinterpreted as suggesting physics guarantees the drug in question. An official notification by the head of the Pharmaceutical Affairs Bureau(see Note), MHW, entitled "Standards for Appropriate Advertisements of Pharmaceuticals" (originally issued in 1964 and revised in 1980) provides detailed instructions, including sample expressions and phrasing, covering drug advertisements in Japan.

II. Distribution

A. Drug Distribution Channels

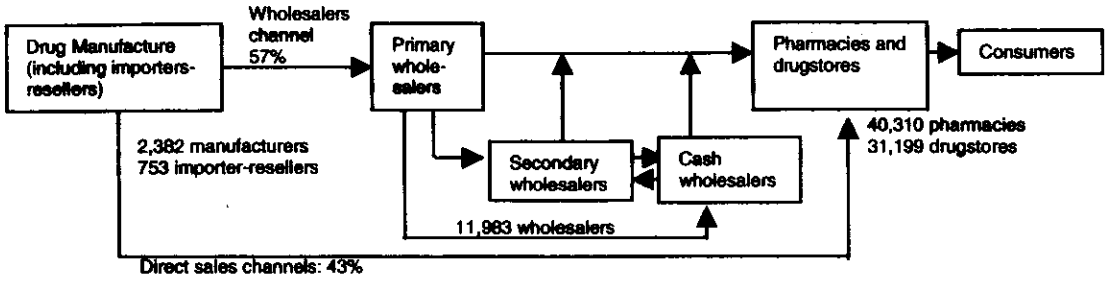
OTC drugs reach pharmacies and drugstores by one of two channels: by being sold to pharmacies and drugstores after passing from the manufacturer through wholesale channels or by being sold directly to pharmacies and drugstores without passing through wholesale channels. Taisho Pharmaceutical, SS Pharmaceutical, and Sato Pharmaceutical, all of which are leading manufacturers of OTC drugs, have built direct sales networks, selling directly to franchised outlets in their network of pharmacies and drugstores. The ratio of direct sales to sales through wholesale channels is 43% to 57%.

The drug manufacturing industry licensed under the Pharmaceutical Affairs Law consisted of 2,382 manufacturing facilities as of the end of 1996, and the drug import-sales industry consisted of 753 sales offices. The number of firms, including importer-resellers, in the drug industry is about 1,300, of which about 500 manufacture prescription pharmaceuticals. As of September 1997, 86 leading firms were members of the Japan Pharmaceutical Manufacturers Association and 98 firms were members of The Proprietary Association of Japan (PAJ), which is the trade organization of the OTC drug industry. It is estimated that the production value of OTC drugs exceeds ¥1 billion at about 50 drug manufacturers. Among the six leading OTC drug manufacturers in FY 1995, the ratio of net profit to net sales was 21.8% and the ratio of sales cost to net sales was 31.5%.

The drug wholesale industry is generally thought to be strongly influenced by *keiretsu* ties with drug manufacturers, with the exception of certain leading wholesalers. The reasons for this are largely attributable to the sales strategy of the prescription drug manufacturers. More specifically, most wholesalers developed from franchised outlets of the leading drug manufacturers; the manufacturers, in an effort to expand their sales channels, intentionally strengthened their relationships with wholesalers with close ties to local medical institutions; and the manufacturers are heavily dependent on their Medical Representatives (MRs), who have the specialized knowledge needed to conduct sales activities, and prices for drugs are generally set in consultations between the MRs of manufacturers, and the medical institutions.

Note: The Pharmaceutical Affairs Bureau was abolished in a reorganization of the MHW in July 1997 and converted into the Pharmaceutical and Medical Safety Bureau. The Economic Section and Research and Development Promotion Section of the Pharmaceutical Affairs Bureau, which was in charge of the promotion of the pharmaceutical industry, were transferred to the Health Policy Bureau. Hereinafter, past notifications, etc. will be attributed to the names carried by the organizations at the time the notifications were made.

Figure B: Drugs Distribution Channel



Note: Figures for manufacturing facilities and business locations are as of the end of 1996 from the "A numerical study of the Business conditions related to the Drug Industry" conducted by MHW. Direct sales wholesale ratios are estimated from industry reports and others.

As of the end of 1996, there were 11,983 firms in the drug wholesale industry in Japan, of which 272 firms were members of the Federation of Japan Pharmaceutical Wholesalers' Association. The ratio of gross profit to sales of the drug wholesale industry runs in the 12-15% range; moreover 7-8% of sales consist of rebates. It is thought that the gross profit of OTC drugs is slightly less than the gross profit on prescription drugs. A survey announced in March 1996 by the Federation of Japan Pharmaceutical Wholesalers' Association indicated that the gross profit ratio on sales of OTC drug and cosmetic divisions of its members amounted to 11.1%.

The retailing of drugs takes place largely through pharmacies and drugstores (general retailers and retailers specializing in drugs). In addition to pharmacies and drugstores, two other types of retailers exist. The first consists of special retailers that originally were given permission to handle drugs at the time when the retail industry was in its formative stages (this business type was designated by the local authorities to handle a limited set of product categories in regions where the penetration of pharmacies and other drug retailers was inadequate). The second type consists of the door-to-door drug retail industry (drug salespersons make regular visits to each customer, leave a box of medicines, and collect fees in the amount of the drugs used).

The difference between pharmacies and drugstores (in the general retail industry) is that pharmacies have a dispensary where drugs are prepared while drugstores do not. However, it is mandatory for pharmacies and drugstores to have a pharmacist who controls the dispensation of drugs. Within the drugstore category, there is the sub-category of retailers specializing in drugs, which does not require the presence of a pharmacist. In this sub-category, the control and sales of certain OTC drugs may be handled by a person who has a certain level of knowledge and experience in handling such drugs. Pharmacies and drugstores tend largely to be small, private business operations. According to an industry study, the monthly sales of pharmacies and drugstores average around ¥3,560,000. About 40% of all the outlets studied have monthly sales under ¥2,000,000.

In recent years, drugstores belonging to franchise chains—"chain drugstores"—have been showing noteworthy growth. Large chains such as Matsumoto Kiyoshi, Kokumin, Segamimedix, and Higuchi, which operate 200-400 outlets nationwide, handle drugs, cosmetics, toiletries, health foods, and miscellaneous items of daily use. These chain outlets tend to have more floor space (around 500 square meters), are located more conveniently, and handle much larger product assortments than ordinary pharmacies and

drugstores. In addition, it has recently become permissible to open large-scale outlets with floor space up to 1,000m2 due to relaxation of the Large-Scale Retail Store Law regulations. As a result, chain operators are currently planning large-scale outlets that will feature extremely large assortments of cosmetics, health-food products, and other products.

As of the end of 1996, Japan had 71,509 drug retailers, including 40,310 pharmacies, 13,875 drugstores (general retail), and 17,324 retailers specializing in drugs. In addition, pharmacies and drugstores boasted a gross profit ratio on sales of over 30%.

B. Retail Pricing

MHW has carried out a survey of the differentials in prices between OTC drugs in Japan and overseas. According to the results of the survey in March 1997, which compared prices in Tokyo and seven major cities abroad, Tokyo had lower prices for cold medicines, analgesic, and antipyretic (fever-relieving) medicines, whereas it had higher prices for antacid medicines. The reasons for Tokyo having higher prices are thought to be the high personnel expenses as well as differences in distribution practices and in the number of ingredients in the medicines. In Japan, cold medicines have 3.8 ingredients on average, antacid medicines average 4.2 ingredients, and fever-relieving medicines average 3.8 ingredients. Comparable products in the other cities generally average under two ingredients.

Table A: Price Differentials of Nonprescription Drugs in Japan and Overseas
(price per daily dose of cold medicine)

Unit: yen

Brand	Tokyo		New York		Chicago		London		Paris	Duesseldorf	Singapore
	Specialty outlets	General Merchandise Store	Specialty outlets	General Merchandise Store	Specialty outlets	General Merchandise Store	Specialty outlets	General Merchandise Store	Specialty outlets	General Merchandise Store	General Merchandise Store
1	146	123	116	95	122	100	66	71	251	58	150
2	183	116	550	513	328	196	180	180	106	72	263
3	253	190	163	109	138	140	81	81	223	87	56
4	203	141	181	175	209	192	134	134	-	139	49
5	101	91	455	434	663	480	166	144	-	308	-
Average	177	132	293	265	292	222	125	122	193	133	130
Ave. no. of ingredients	3.8		2.6				1.6		2.6	1.8	1.8

Source: "Survey of Price Differentials of Drugs in Japan and Overseas," MHW (carried out in March 1997)

Note: The survey covered the top five best-selling brands in each city. Exchange rates (as of March 31, 1997) were $1=¥124.05, £1=¥203.19, 1 FF=¥22, 1 DM=¥74.02, and Singapore $1=¥85.94.

In addition, the remaining 14 categories of nonprescription drugs, which had been listed under the Resale Price Maintenance Contract System (RPMCS), were eliminated from the list in March 1997. From April 1997 on, retailers have been free to set prices on all non-prescription drugs. Delisting of various drug categories from RPMCS has not yet had a noticeable effect on prices of the drugs; however, the following changes, which occurred previously after the delisting of various categories from RPMCS, may indicate what will happen (from a survey carried out by the Japan Fair Trade Commission in the March-December 1996 period).

In the past, approximately 80% of the retail outlets had reduced prices of some or all products that were not covered by RPMCS, and slightly more than 50% of the retailers had

also reduced prices of products formerly covered by RPMCS. Immediately following the delisting of combined vitamins and drinks (multi-metabolized preparations) from RPMCS in January 1995, the proportion of retailers that discounted the prices of such items rose from 53% to 72%. Price competition spread, but did not lead to disruption of the market due to massive price-cutting.

C. Regulations and Practices in the Distribution Process

Articles 24 and 25 of the Pharmaceutical Affairs Law require businesses to secure licenses to engage in the sale of drugs. The requirements cover the type of wholesaler known as "wholesale general sales" (oroshiuri ippan-hanbai gyo), and five types of retailer: operators who have established pharmacies (yakkyoku); general sales (ippan-hanbai gyo); retailers specializing in drugs (yakushusho-hanbai gyo); special retailers (tokurei-hanbai gyo); and door-to-door drug distributors (haichiyaku hanbai gyo). Applicants for these business licenses must submit the application forms and supporting documents to the local authorities. Renewal of the license is required every three years.

As mentioned above, cosmetics and 14 categories of nonprescription drug products, which had hitherto been listed under the Resale Price Maintenance Contract System (RPMCS), were removed from the list in March 1997.

D. Distribution-Related Matters

The Federation of Japan Pharmaceutical Wholesalers' Association voluntarily observes a set of standards known as Japanese Good Supplying Practice (JGSP), which cover the assurance of quality in the distribution process and the dissemination of technological data. JGSP stipulates the implementation of 10 rules covering 57 topics. The members of Federation of Japan Pharmaceutical Wholesalers' Association incorporate these rules, taking into account of the characteristics of the region or firm, and have documented their GSP rules in writing.

JGSP stipulates implementation of the following items:

1. The establishment of double-checks.
2. Measures to ensure the maintenance of quality (the maintenance of a clean environment in work facilities and measures to keep drugs from deteriorating or becoming contaminated.
3. Explanation of the JGSP organization and staffing, and training for company employees.
4. Measures to prevent mistakes (provision of proper working environments, instruction/training of employees, and implementation of a self-check system).
5. Control of shipments from warehouses.
6. Handling of drugs for field testing.
7. Proper disposal of rejected or returned goods.
8. Proper disposal of defective drugs.
9. Self-check systems.
10. Method for processing complaints, etc.

III. Market Entry

A. Foreign-Capitalized Firms in the Japanese Market

Foreign drug manufacturers have been active in the Japanese market for a relatively long time. In 1924, Hoffmann-Roche of Switzerland established the general partnership N.S.Y., which was the predecessor of Nippon Roche, founded in 1932. Other foreign drug manufacturers entered the Japanese market after the end of World War II. Among the manufacturers that entered in the 1950s and 1960s were U.S. firms such as Pfizer, Merk, American Cyanamid, and Upjohn; German firms such as Hoechst and Schering AG; and Swiss firms such as Geigy and Sandoz. Later, German firms such as Bochringer Ingelheim, U.S. firms such as Eli Lilly, and Swiss firms such as Ciba moved into the market.

The first foreign drug manufacturers to enter Japan went through an initial period in which their lack of information on Japan's complex distribution system held them back from full access to the Japanese market. However, market liberalization has advanced significantly since the latter half of the 1980s, and foreign-capitalized drug firms have rapidly expanded their markets in Japan.

The Japanese drug distribution system (especially the system for distributing prescription drugs) has an important characteristic: wholesalers are said to have close affiliations to the leading drug manufacturers, and their power within the close network is extremely weak. For this reason, foreign-capitalized drug firms have generally opted to develp sales channels through sales tie-ups with leading Japanese drug manufacturers. Nonetheless, a few foreign firms established their own sales channels at an early date. These include Ciba-Geigy (Japan) (prior to Ciba-Geigy's establishment of its own sales channels in 1985, products of the former Ciba were sold through Takeda, and products of the former Geigy were sold through Fujisawa), Nihon Hoechst Marion Roussel (formerly Hoechst Japan), Pfizer, and Merk, which secured sales channels by acquiring a Japanese drug manufacturer (Banyu).

In addition, more than 40% of OTC drugs are sold via direct sales channels from the leading OTC drug manufacturers. In the past, this has definitely not been an attractive market for foreign drug firms because the size of the market is smaller than that of prescription drugs. Nonetheless, this market is becoming more attractive to domestic manufacturers of prescription drugs and to foreign firms as pressures mount to constrain spiraling health-care costs.

For this reason, foreign-capitalized drug firms that have not previously secured their own sales channels are now switching to a policy of setting up their own. The latest trends in the OTC drug-related area reflect this movement. Bochringer Ingelheim's acquisition of a stake in SS Pharmaceutical (it became the major shareholder), the establishment by Chugai and Merk U.S. of a joint venture in the OTC drug business, and Bayer's tie-up with Eisai for sales of OTC drugs exemplify this movement.

B. Firms that Have Entered the Market

The net sales of the top twenty foreign firms that have entered the Japanese drug market are shown in Table B. The business results that certain of these firms, including Pfizer, SmithKline Beecham, and P&G Healthcare, have demonstrated in the OTC market are attributable to their own sales channels. SmithKline Beecham has taken a large share of

Table B: Major Foreign-affiliated Companies

	Settlement	Net sales (¥1 billion) 1995	Stake taken (established)	Percent foreign capital	Type of stake	Approach to OTC drugs	Imports	Distribution channels
Banyu Pharmaceutical Co., Ltd. (Merk)	March	130.5	Apr. 1917	62.9	Merger with Merk (US) in 1983		-	Major nationwide wholesalers
Pfizer Pharmaceuticals, Inc.	November	87.6	Jun. 1955	100.0			69.0	Major nationwide wholesalers
Sandoz Pharmaceuticals, Ltd.	December	68.0	Jul. 1960	100.0			100.0	Through domextic phamaceutical firms (Sankyo, Mochida, Santen,Tanabe)
Bayer Yakuhin, Ltd.	December	90.6	Apr. 1973	75.6	Bayer AG 75.6%, Takeda 14.6%, Yoshitomi 9.8%	Sales tie-up with Esai and Taisho	75.0	Major nationwide wholesalers
Nippon Roche K.K.	December	54.8	May 1932	100.0		Sales of Sanridon are via Fujisawa	-	Through domestic pharmaceutical firms
Nippon Boehringer Ingelheim Co., Ltd.	December	62.8	jun. 1961	100.0		Became main shareholder of SS Pharm. in 1996	100.0	Major nationwide wholesalers, and Tanabe, Sankyo and Kissei
Ciba-Geigy, Japan Ltd.	December	62.0						
Bristol-Myers Squibb K.K.	December	27.5	Jun. 1960	100.0			-	Major nationwide wholesalers
Nihon Schering K.K.	December	58.6	Aug. 1952	100.0			100.0	Major nationwide wholesalers
Zeneca K.K.	December	50.3	Dec. 1985	100.0			100.0	Zeneca Pharmaceuticals
Nippon Glaxo Ltd.	December	26.4	Aug. 1953	100.0	Took a 100% stake in its former Japanese partner, Shin Nihon Jitsugyo, in 1996			
Roussel Morishita K.K.	March	55.9	Oct. 1959	80.0	80% stake by Roussel Uclaf (France), 20% stake held by Chugai		-	Through Chugai and Esai
Nippon Wellcome K.K.	December	42.8	Apr. 1971	55.0	The Wellcome Foundation Ltd. 55.0%, Sumitomo Chemicals 45.0%		100.0	Through Sumitomo Pharm.
Novo Nordisk Pharma Ltd.	December	36.7	Jun. 1980	100.0			100.0	Through Yamanouchi, major nationwide wholesalers
Nihon Hoechst Marion Roussel Japan	December	37.5	Nov. 1976	99.0	Took over the pharmaceuticals business of Hoechst Japan in July 1997		-	Through domestic firms, major nationwide wholesalers
Lederle (Japan), Ltd.	November	29.8	Aug. 1953	50.0	50:50 split between American Cyanamid Co. and Takeda			Through Takeda
Schering Plough K.K.	December	30.3	Oct. 1959	100.0			-	Major nationwide wholesalers
SmithKline Beecham Seiyaku K.K.	December	28.1	Mar. 1977	100.0	Acquired the 1.22% of its shares owned by Fujisawa in 1993, now 100% owned by SB (Britain)		100.0	Own sales channels (to about 100 firms)
Upjohn Pharmaceuticals Ltd.	December	38.0	Jul. 1959	100.0	The operations of Nihon Upjohn and Pharmacia Upjohn were consoldiated in Sept. 1996 by a merger with the parent company		-	Through franchised wholesalers
Astra Japan Ltd.	December	25.6	Apr. 1975	90.0	Owned 90% by Astra Pharm. (subsidiary of Astra Sweden) and 10% by Fujisawa		20.0	Through Fujisawa, major nationwide wholesalers, hospitals

Notes: Net sales refers to net sales of pharmaceuticals. Nippon Glaxo changed its settlement date, which resulted in a change of settlement principle. The net sales ranking shown in the table is based on an annualized rate. The net sales shown for Pharmacia & Upjohn Limited are those of the former Nihon Upjohn

Sources: Japan Pharmaceutical Manufacturers Association, DATA BOOK 1996-97
Toyo Keizai Shimbun-Sha, Overview of Foreign-Capitalized Firms 1997

the cold remedy area with "Contac," its cold medicine for runny noses. Similarly, P&G Healthcare's "Clearasil" acne medicine holds a top share, and its "Vicks Drops" are the second-ranking cough suppressant. Pfizer is marketing the cold remedy "Aneton Stratus," which is an "Rx switched to OTC drug" (drug switched from the prescription category to OTC category) to treat fungal and ringworm infections, and "Juscoat," a plaster for external use to reduce pain and inflammation. Lastly, Nippon Roche is marketing its "Saridon" painkiller via Fujisawa, in an example of a sales tie-up between a foreign firm and a Japanese manufacturer.

C. Advice on Entering the Japanese Market

As far as drugs are concerned, the most important factor in creating a market is the effectiveness of the drug, followed by having an effective sales channel.

1. According to a study by The Proprietary Association of Japan, consumers gave the following responses for their selection of a certain drug: "It was recommended by the pharmacist" (46.3%) and "I always use this drug" (36.6%). These responses may be interpreted to mean that pharmacists and consumers do not select drugs on the basis of brand, but rather on the basis of their effectiveness.

The efficacy of any new product — whether it is a big ticket product such as the switched OTC drug H_2 blockers that went on sale from September 1997 or not — is its key tool for gaining entrance to the market. Therefore, an understanding of the disease structure and Japanese attitudes toward health are crucial to gaining access to the Japanese market.

2. Increased Awareness of Drugs with Special Efficacy

In addition to the leading domestic OTC drug manufacturers with full assortments of OTC drugs and direct sales channels, many domestic drug manufacturers are gradually developing and expanding the market for drugs with special efficacy, such as eye medicines, anti-inflammation medicines, and plasters medicines. Among foreign-capitalized firms, SmithKline Beecham is marketing its "Contac" brand cold symptom reliever under a variety of formulations and thereby raising its name awareness.

In the case of OTC drugs, it appears that the most viable strategy is to enter the market by focusing on the special efficacy of a certain drug, as the launch of a new drug requires a substantial investment in advertising and publicity.

3. Securing Sales Channels

There are various ways to obtain sales channels. A firm may build its own sales channels from scratch, arrange a tie-up with an established company, acquire a company that already has sales channels, or take an equity stake in such a company. The market is already full of companies that have built their own sales channels, so any newcomer that is thinking of taking this route should be aware that it will take a great deal of time and significant investment to accomplish it.

Most foreign-capitalized firms follow a step-by-step process beginning with the sale of products through a tie-up with a Japanese manufacturer, followed by the establishment of a joint venture, the building of a research and production system in Japan, and finally the establishment of their own sales channels. The most practicable method is to enter the Japanese market via tie-ups with other companies.

The route of acquiring a Japanese company that already has sales channels or taking an

equity stake in such a company has seen only limited use, as when Bochringer Ingelheim became the top shareholder in SS Pharmaceutical, a leading Japanese OTC drug manufacturer. However, the potential for such an approach could grow if Japanese partners are to be expanded to include middle-scale companies such as the manufacturers of so-called "home remedies."

In the past, Japanese companies have been the targets of tie-ups and acquisitions; however, the partners in future tie-ups and alliances are not likely to be limited solely to Japanese companies, but are likely to broaden to embrace foreign firms that are active in the Japanese market or even their parent firms. There have already been cases in which mergers between parent firms in the field of prescription drugs have resulted in a realignment of sales channels in the Japanese market. Similar cases are expected to lead to an expansion of sales channels in the future.

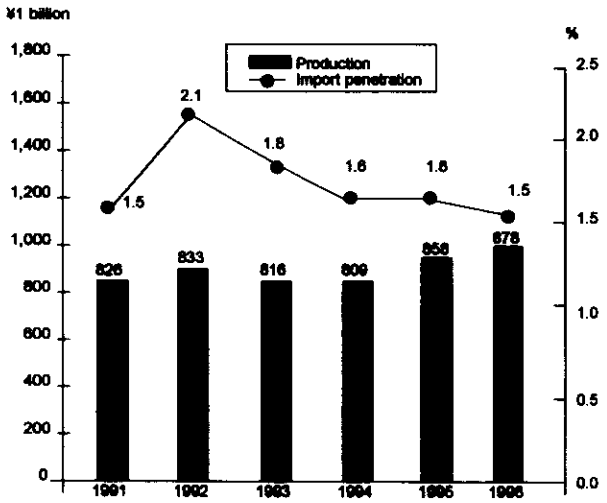
Appendix

Appendix 1. Market Overview

A. Size of OTC Drugs Broken Down by Efficacy

Production of OTC drugs (including production of bulk powder, bulk liquid, etc.) in Japan amounted in value to ¥877.8 billion in 1996, accounting for 14.4% of the total pharmaceutical market. The value of imported products (finished products) amounted to ¥130 billion, which means they accounted for only 1.5% of apparent domestic demand for OTC drugs, lower than the 10.0% of prescription drugs. In addition, the proportion of products manufactured from imported ingredients (bulk powder, bulk liquid, bulk products, and pellet materials) amounted to 26.9% in terms of production value in the case of prescription drugs, but only to 2.3% in the case of general (OTC) drugs.

Figure 1: Value of Production of Nonprescription Drugs and Import



Source: "Statistics of Production Trends in the Pharmaceutical Industry," supervised by MHW

Note: The import penetration is calculated as imports / (production + imports - exports). However, "imports" refers to finished products only.

Table 1: Production, Imports, and Domestic Demand of Nonprescription Drugs

Unit: ¥1 million

	Year	91	92	93	94	95	96	Average annual growth rate
Production	Prescription drugs	4,812,216	4,680,204	4,819,341	4,881,157	5,243,575	5,156,439	1.4
	Nonprescription drugs	825,824	833,451	815,764	808,677	858,228	877,822	1.2
	Door-to-door drugs	59,203	60,566	59,962	60,489	66,259	65,785	2.1
	Total	5,697,244	5,574,220	5,695,068	5,750,322	6,168,062	6,100,046	1.4
Imports	Prescription drugs	473,348	571,022	569,890	558,000	575,040	568,718	3.7
	Nonprescription drugs	12,144	17,674	14,759	13,157	14,070	12,952	1.3
	Door-to-door drugs	11	82	26	141	87	95	53.0
	Total	485,501	588,778	584,476	571,299	589,196	581,764	3.7
Exports	Prescription drugs	36,990	43,956	38,492	35,787	45,551	42,836	3.0
	Nonprescription drugs	5,666	5,798	5,632	6,028	5,437	5,449	-0.8
	Door-to-door drugs	92	143	195	214	176	248	22.0
	Total	42,748	49,898	44,320	42,029	51,164	48,533	2.6
Domestic demand	Prescription drugs	5,248,572	5,207,270	5,350,539	5,403,371	5,773,064	5,682,321	1.6
	Nonprescription drugs	832,302	845,327	824,892	815,806	866,861	885,324	1.2
	Door-to-door drugs	59,123	60,504	59,793	60,416	66,170	65,632	2.1
	Total	6,139,997	6,113,101	6,235,224	6,279,592	6,706,095	6,633,277	1.6

Source: "Statistics of Production Trends in the Pharmaceutical Industry," supervised by MHW

Note 1: Domestic demand is calculated as production + imports - exports.

Note 2: Exports are calculated on the basis of reports from manufacturers and do not include transactions of trading companies, etc. Imports are calculated according to reports from importers of medical drugs. Exports and imports cover only finished products and do not include bulk powders, etc.

B. Trends in Imports

Japan's biggest trading partners in drugs (including prescription drugs) are by far the United States and Germany with imports from each running about ¥110 billion. The U.K. is the distant third with imports of ¥67 billion.

Table 2: Value of Imports of Drugs by Major Countries

Units: case, ¥1 billion

Year	91	92	93	94	95	96	Average annual growth rate
U.S.	121,096	116,170	118,711	117,168	122,995	119,132	-0.3
Germany	114,835	123,578	125,887	136,375	128,152	111,939	-0.5
U.K.	63,170	63,498	66,042	76,972	68,381	67,017	1.2
Sweden	38,313	48,191	61,773	53,312	57,675	57,464	8.4
Switzerland	38,642	43,081	41,651	43,617	47,494	49,127	4.9
Denmark	29,031	32,244	34,108	36,391	41,954	44,040	8.7
France	15,860	15,870	17,288	19,290	39,177	37,104	18.5
Ireland	17,916	71,925	52,869	30,236	12,473	24,258	7.9
Belgium	-	9,056	12,518	12,635	15,790	14,448	12.4
Singapore	-	9,104	9,079	-	8,333	11,664	6.4
Others	46,636	65,165	53,629	38,845	46,631	45,571	-0.5
Total	485,501	588,778	584,476	571,299	589,196	581,764	3.7

Source: "Statistics of Production Trends in the Pharmaceutical Industry," supervised by MHW

Note1: The presence of a hyphen (-) indicates the value has been included in the "Others" row as it has not been made public.

Note2: Average annual growth rates for Belgium and Singapore begin with '93 and '96 figures respectively.

In 1995, there were 320 cases of imports of technology, amounting in value to ¥36.7 billion. In the past five years, the trend has been for the number of cases of exports of technology to exceed imports. Imports have tended to exceed exports in terms of value; however, in 1995 the value of imports and exports was roughly equal.

Table 3: Imports/Exports of Drug Technology

Units: case, ¥1 billion

	Fiscal Year	91	92	93	94	95	Average annual growth rate
Exports	Cases	399	408	434	421	418	1.2
		(40)	(54)	(53)	(41)	(40)	0.0
	Value	28.5	27.8	31.0	31.2	36.7	6.5
		(1.8)	(1.7)	(3.0)	(2.4)	(2.3)	6.3
Imports	Cases	270	319	303	327	320	4.3
		(23)	(52)	(33)	(46)	(42)	16.2
	Value	29.2	34.3	34.6	32.5	36.7	5.9
		(3.5)	(2.0)	(2.4)	(3.0)	(5.8)	13.5
Exports - Imports	Cases	129	89	131	94	98	–
	Value	-0.7	-6.5	-3.6	-1.3	0.0	–

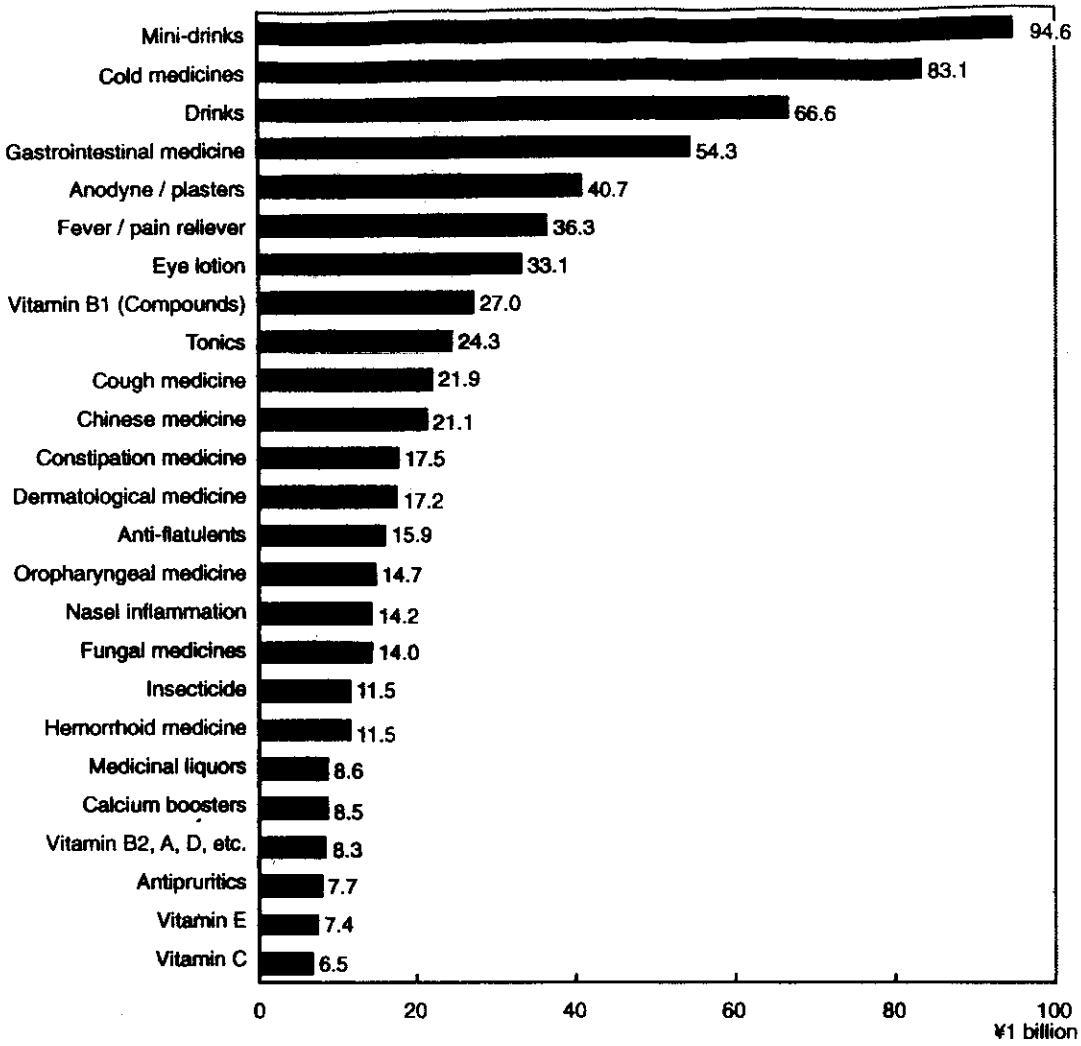
Source: "Report on a Survey of Research in Science and Technology," Statistics Bureau, Management and Coordination Agency
Note: Figures in parentheses ( ) represent new portions.

C. Sales Value of OTC Drugs Broken Down by Efficacy

Mini-drinks boast the top share of Japan's OTC drug market. Drinks fall into two categories: mini-drinks with a volume of 100ml or less and general drinks. "Ripovitan D," which was launched in 1957, is representative of the drink category. It was followed by the launch of health drinks in similar containers that were, however, classified as soft drinks. Because of the confusion this created among consumers, the category of therapeutic drinks has since 1977, been limited to drinks of 50ml or less. All drinks approved since then have 50ml in volume and known popularly as mini-drinks.

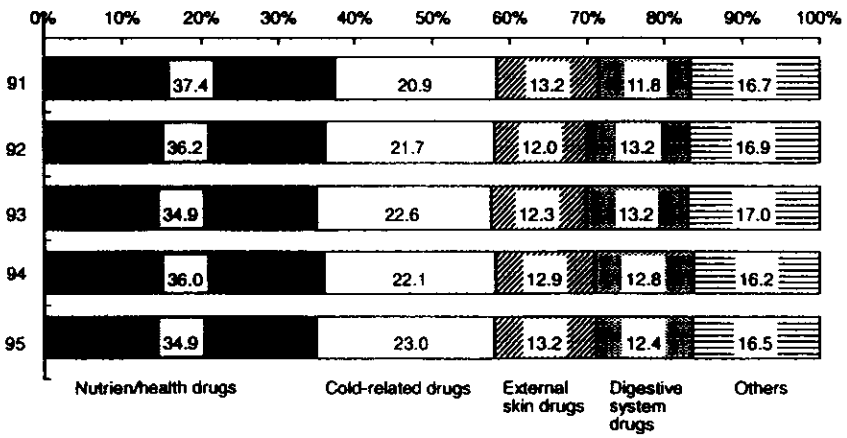
In terms of OTC market share, drinks are followed by cold remedies and gastrointestinal drugs. Switched OTC drug H2 blockers were launched in 1997, creating something of a stir in the gastrointestinal drug category. There is keen interest in the effects they will have on net sales from 1997 onward.

Figure 2: Retail Value of Sales of OTC Drugs (top 25 best-sellers in FY 95)



Source: "Pharmaceutical Affairs Handbook," Yakugyo Jiho Ltd.

Figure 3: Sales Value of OTC Drugs Broken Down by Efficacy



D. Major Manufacturers of OTC Drugs

A survey institution estimates that Japan has approximately 80 manufacturers of OTC drugs with annual sales of ¥1 billion or more. Manufacturers of OTC drugs are classified into the following categories according to the type of sales-distribution they use.

1. New drug manufacturers: they tend largely to be manufacturers of prescription drugs.

2. Direct-sales manufacturers: they tend largely to be manufacturers of OTC drugs with a direct sales network centered on franchised outlets.

3. Home remedies drug manufacturers: specializing in drugs with special efficacies, they tend to be manufacturers of OTC drugs that do not have a direct sales network.

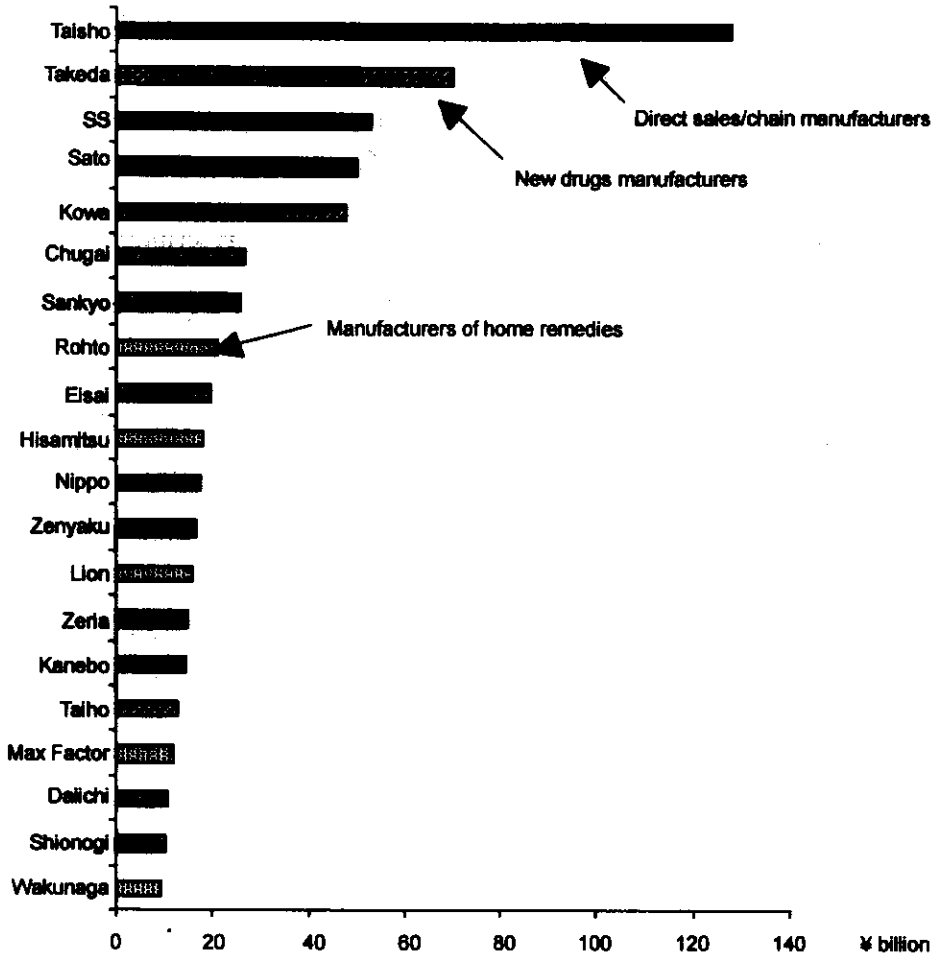
More than half of the companies are home remedies drug manufacturers, while new drug manufacturers and direct sales-related manufacturers each account for around 20% respectively. In terms of the value of sales, however, direct sales-related manufacturers are estimated to account for 43%, new drug manufacturers for 33%, and home remedies drug manufacturers for only 24% of sales value.

The top-ranking manufacturer of OTC drugs is Taisho Pharmaceutical Co., Ltd., which has a market share of about 17%. Second place is held by Takeda Chemical Industries, Ltd., a new drug manufacturer, followed in third by SS Pharmaceutical Co., Ltd.

Drug manufacturers are in an increasingly demanding business environment due to growing efforts to constrain medical costs, the difficulty of developing new drugs, rising costs, and increasing competition as players from different industrial segments enter the market. For these reasons, new drug manufacturers are devoting more effort to the proprietary drug market. Of the ten top-ranking firms in terms of the value of sales of OTC drugs, five are new drug manufacturers. At the same time, manufacturers of OTC drugs are devoting more effort to the development of new drugs. Taisho's sales of prescription drugs already exceeds 15% of its net sales, which is roughly on a par with medium-sized manufacturers of prescription drugs.

Figure 4: Net Sales of OTC Drugs by Manufacturer

(Top 20 Companies Ranked by sales in FY95)



Source: "Pharmaceutical Affairs Handbook," Yakugyo Jiho Co., Ltd.

Appendix2. International Conferences

The international trade association of the OTC drug industry, the World Self-Medicine Industry (WSMI, [see Note]), was launched in 1970. The major Japanese OTC drug manufacturers, who participated in WSMI's first international conference held in 1971, established the former organization of the Preprietary Association. Later in 1985, the Proprietary Association of Japan (PAJ) was established as an organization with a wide range of industry functions.

The WSMI holds a general meeting every three years. The next is scheduled to be held in Berlin, Germany in June 1999. Japan is scheduled to become the chair country following the close of the Berlin meeting. There is thus a great likelihood of the 2002 general meeting being held in Japan.

Note: Note that this name was changed in June 1997 from The World Federation of Propriety Medicine Manufacturers (WFPMM).

Appendix3. Organizations

1. Government-Related Organizations

Pharmaceutical and Medical Safety Bureau, Ministry of Health and Welfare
1-2-2 Kasumigaseki, Chiyoda-ku
Tokyo 100-8045
Tel: (03) 3503-1711
Fax: (03) 3597-9535
URL: //www.mhw.go.jp (Japanese only)

The Organization for Drug ADR Relief, R&D Promotion and Product Review
9th Floor, Shin Kasumigaseki Bldg., 3-3-2, Kasumigaseki, Chiyoda-ku
Tokyo 100-0013
Tel: (03) 3506-9541
Fax: (03) 3506-9417
URL: //www.iijnet.or.jp/iyakuhin-kiko/index.html (Japanese only)

Pharmaceuticals and Medical Devices Evaluation Center, National Institute of Health Sciences
10th Floor, Toranomon 33 Mori Bldg., 3-8-21 Toranomon, Minato-ku
Tokyo 105-6090
Tel: (03) 5403-1411
Fax: (03) 5403-1417
URL: //www.nihs.go.jp/index.html

2. Trade Organizations

The Proprietary Association of Japan
Kyodo Bldg., 13-4, Kodenma-cho
Nihonbashi, Chuo-ku
Tokyo 103-0001
Tel: (03)3667-9481
Fax: (03) 3667-9483

Japan Pharmaceutical Manufacturers Association
Torii Nihonbashi Bldg.
3-4-1 Nihonbashi-cho, Chuo-ku
Tokyo 103-0011
Tel: (03) 3241-0326
Fax: (03) 3242-1767
URL: www.//jpma.or.jp/

The Federation of Japan Pharmaceutical Wholeseller's Associations of Japan
Ida Bldg., 1-3-8, Yaesu, Chuo-ku
Tokyo 103-0028
Tel: (03)3275-1573
Fax: (03) 3273-7648

3. Pharmaceutical-Related Information Service and Media

Japan Pharmaceutical Information Center
3rd Floor, Nagai Memorial Hall
2-12-15 Shibuya Shibuya-ku
Tokyo 150-0002
Tel: (03) 5466-1811
Fax: (03) 5466-1814
URL: //www.japic.or.jp (Japanese only)

Yakugyo Jiho Co., Ltd.
Hokushin Bldg., 2-36 Kanda Jimbocho
Chiyoda-ku, Tokyo 101-0051
Tel: (03) 3265-7755
Fax: (03) 3265-8855

4. Other

Pharmaceuticals PL Center
5th Floor, Shin Kasumigaseki Bldg.
3-2-2 Chiyoda-ku, Tokyo 100-0013
Tel: (03) 3595-0488
Fax: (03) 3593-0489