



The Global Language of Business



GS1 Japan Handbook

2017-2018

Message from the President

The past year was another very busy and successful one for GS1 Japan. We enjoyed a steady and healthy increase in membership with more than 11,000 new companies and individuals obtaining GS1 Company Prefix from us last year. This makes altogether 130,877 GCP holders in Japan.

GS1 Japan Partners, an alliance program for solution providers established in 2015, is on track. We regularly perform seminars and site visits, since better understanding of GS1 standards on the part of solution providers is crucial to a global optimization of the supply chain.

In 2015, we went through another major reorganization --- from a standards-based format to an industry-wide structure --- to offer tailored support and solutions to our members. The reorganization enabled us to better hear our members and understand their issues in order to take a more problem-solving approach.

The sector-oriented action plan is functioning well, too. As for CPG, our core sector, we have been proactively working with the industry. Earlier this year, we published "Source Marking Guidelines for Raw Materials" after more than 2 years of joint work with food manufacturers and their suppliers. This will surely drive the use of GS1 keys in the upstream of the supply chain.

Ryutsu BMS (the EDI standard) is becoming popular, as well. According to our survey, it has already been implemented in over 10,000 companies. Some pharmacies have decided to adopt it, not only for sundries and OTC drugs, but for prescription drugs, as well.

With regard to the healthcare sector, the number of GS1 Healthcare Japan members reached 100 last year. Thanks to recognition of GS1 standards by the manufacturers and wholesalers of medical devices and pharmaceuticals, we are now touting the benefits of using GS1 standards in hospitals for patient safety.

The use of GRAI and RFID to track returnable assets and reduce losses is attracting many. This is an area where we see great potential.

The challenge we are facing at the moment is the ever-increasing demand for accurate product information by consumers. We have long provided B2B product catalogue services. But, we are now being in the process of further refining them to harness even more attributes and more high-quality data by adopting a more flexible design.

Collaboration with MOs, especially Asia Pacific ones, is something we greatly value. In October of this year, we are hosting AP Regional Forum to further strengthen ties. I am looking forward to seeing you in Tokyo.

Lastly, to our GS1 member companies, GS1 MOs, and GS1 GO, I would like to express my sincerest wishes for your continued success in achieving increasingly higher levels of consumer satisfaction through the implementation of GS1 standards. I firmly believe that these standards have the power to transform the way we live and work.



A handwritten signature in black ink, consisting of stylized Japanese characters: '林' (Hayashi) and '洋和' (Hirokazu).

Hirokazu Hayashi
President GS1 Japan

GS1 Japan Handbook 2017 - 2018

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1. Sector

1.1 Retail & CPG

1.1.1 Case Study: Promoting the use of GTIN in Commercial Products: Packaging Materials for Prepared Foods and Perishable Foods

Packaging materials for foods such as containers for boxed lunches and prepared foods or trays for raw meat or fresh fish, except for some materials, are commercial-use products which consumers do not buy at retail stores. Distilling the needs of industry wholesalers and markers for GTIN source marking of products, GS1 Japan prepared GTIN source marking guidelines targeting such packaging materials for prepared foods and perishable foods and issued them in February 2015. Since completing the guidelines, GS1 Japan has focused on publicizing the guidelines and promoting the use of GTIN throughout the industry. For information concerning the preparation of the guidelines, refer to:

http://www.gs1jp.org/2015/industry/5_5.html

In February 2017, nine wholesale companies in the industry jointly planned and held an information session on GTIN source marking. The 40 participants were mainly manufacturers in the industry. GS1 Japan took an active role in arrange for this information session along with HOWNET, which provided VAN service for the industry.

During the session, Mr. Masaoka of TATSUMI SANGYO CO., LTD representing wholesalers, explained the issues in current product management, where receiving, shipping and inventory of goods are visually checked. He also urged manufacturers to start source marking as soon as possible in order to realize product management by scanning barcode, which his company plans to introduce in 2018. Additionally, he emphasized the importance of GTIN source marking. He stated that it was not just something that his company was asking for, but the desire of all wholesalers in the industry and essential to optimizing the industry as a whole. Furthermore, Mr. Osada of TOMO JAPAN SYSTEM PLANNING, a label supplier, presented examples of how manufacturer were utilizing source-marked bar codes. In his company, the source marked EAN/UPC symbols are used in product verification operations by scanning them when products are delivered to warehouses, ordered products are shipped and inventory is taken. Compared with how things were done before barcode scanning was introduced, product management operation has become streamlined and inventory accuracy has increased. For example, discrepancies between book inventory and actual inventory have decreased, shipping errors have decreased and product

Fig. 1.1.1-1 Specific examples of packaging materials: Containers for boxed lunches (left), trays for raw meat (center), examples of the minimum transaction unit containers (right)



Fig. 1.1.1-2 A source marking information session



check operations have become easier even for employees with limited experience.

The nine wholesalers intend to continue to hold information sessions to promote spread of GTIN use throughout the industry.

1.1.2. Case Study: Preparing the GTIN Management Guideline

GS1 Japan established its Retail & CPG WG with the members of retailers, wholesalers, manufacturers and database providers for industries related to general consumer goods supply chains. This WG mainly share and discuss about GS1 Standards. For example, it provides latest trend of GS1 Standards and develops tools to promote the adoption of GS1 standards in Japan.

Following the release of GTIN Management Standard and Decision Support Tool by GS1 in June 2016, a GTIN subcommittee consisting of members from the Distribution Code Committee studied tools. As a result of their discussions, it was decided that the GTIN Management Guidelines would be prepared based on the comments of the committee members. The guidelines were issued in February 2017 and released on the GS1 Japan website (http://www.dsri.jp/standard/identify/gtin/pdf/GTIN_guideline201702.pdf).

The contents of the guidelines are based on the GTIN

Management Standard and Decision Support Tool. A Japanese version of the GS1's GTIN Management website was not created as it was deemed imperative to establish a one-stop reference material site housing all GTIN operational rules, including not only contents of the new GTIN Management Standard but also the differences between the old and new guidelines, the basics of GTIN, actual examples of the application of the rules and the FAQs.

The following contents are in the GTIN Management Guideline.

• **About the GTIN Management Guideline**

Differences between the old and new guidelines and other information are described.

• **The Basics of GTIN**

Overview of GTIN, its fundamentals and its major utilization forms are explained.

In order to spread the name of GTIN - since the local name JAN code is widely established in Japan, various utilization forms of GTIN, such as EPC/RFID and a barcode displaying GTIN and attribute information by using AI, are explained in this part.

• **Description of 10 GTIN Management Rules and Practical Examples**

Focusing on cases where new GTIN management is necessary, the core contents of the GTIN Management Standard, which are now organized in 10 rules (reduced from the former 46 rules) are described along with practical examples set in Japan, accompanied by illustrations.

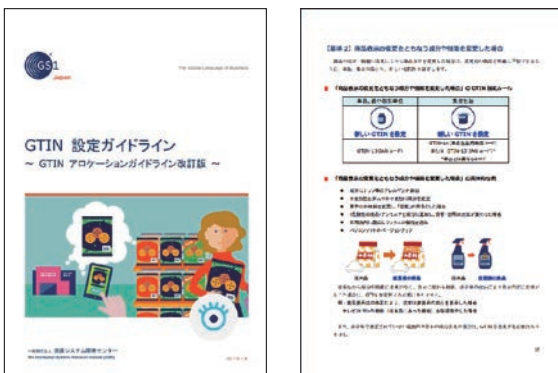
• **Frequently Asked Questions**

Answers for frequently asked questions and clarifications of major misunderstanding concerning GTIN are included.

Especially for assembled packages such as carton units, the use of GTIN-14 is common in Japan, whereas GTIN-13 is not generally known enough except in some product categories. Due to reports from users who experienced problems using GTIN-13 for carton units, we have included detailed explanations of how to utilize GTIN correctly.

The new GTIN Management Guideline have been favorably received by users in Japan, as it contains comprehensive and organized information on GTIN use from the basics of GTIN to the utilization methods, making it easier to refer to and understand.

Fig. 1.1.2-1 Cover of GTIN Management Guideline (left), example of contents (right)



1.1.3 Case Study: Using Ryutsu BMS for Prescription Drug at SUGI Pharmacy CO., LTD. (EDI)

SUGI Pharmacy, one of the major drugstore chains in Japan, updated its EDI system for its prescription pharmacy section and started to operate the new system using Ryutsu BMS from November 2016. (For details about Ryutsu BMS, refer to 2.2.) Through the introduction of the new EDI system, SUGI Pharmacy has worked to streamline its overall operation, including order, delivery and accounting.

About SUGI Pharmacy

SUGI Pharmacy is a drugstore chain based in Aichi

Fig. 1.1.2-2 Easy-to-understand explanations with illustrations on the fundamentals of GTIN use



prefecture operating 1,048 stores (*1) mainly in the central region in Japan. Approximately 70% of these stores have a prescription pharmacy. The pharmacy section accounts for approximately 18% of their sales.

Business practices in the Japanese pharmaceutical industry

Chain stores in Japan set unique order IDs generated when orders are placed. These IDs serve to streamline not only the ordering process, but inventory management and accounting as well. Also for drugstore chain stores, sales sections except the prescription pharmacy section introduce systems mainly utilizing such order IDs.

However, old business practices persist in the Japanese pharmaceutical industry and pharmaceutical industry VAN led by drug wholesalers is widely used. In this industry VAN, only product names and quantities are determined at the time an order is placed by the retailer and the order ID and prices are set by the wholesalers when shipping. Additionally, the delivery date cannot be specified at the time the order is placed.

Fig. 1.1.3-1 Mr. Sunao Kawasaki, Executive Director of SUGI Pharmacy



Fig. 1.1.3-2 LTD Headquarter Obu Center of SUGI Holdings Co. LTD.



For these reasons, delivery data cannot be checked against order data using order IDs upon product delivery. The information such as supplier, GTIN and quantity had to be examined visually to confirm the delivery data manually at the store. This places a heavy burden on the stores and may lead to calculation errors.

SUGI Pharmacy's Introduction of Ryutsu BMS

SUGI Pharmacy also used to use one of pharmaceutical industry VANs called MEDICODE VAN to order prescription drugs. However, it decided to introduce a system whereby retailers assign unique order IDs when orders are placed, as in sections except the prescription pharmacy section. One of the triggers for this decision was the launch of the new enterprise system SAMCING in the other sections in 2014. Using this system as a core, SUGI Pharmacy started to work on renovating the ordering system for prescription drugs in 2015. Ryutsu BMS was chosen as the new EDI system in December 2015. Then, after careful explanation of the changes it had made to trading partners, all of them began accepting transactions using Ryutsu BMS. Test operations began in August 2016 and moved into actual operations in November.

Executive Director of SUGI Pharmacy Mr. Sunao Kawasaki, who played a central role in introducing Ryutsu BMS, explained the effects of introducing Ryutsu BMS and its outlook for the future as follows.

Effects of Introducing Ryutsu BMS

Even for prescription drugs, secure management of the overall process from ordering and purchasing to invoicing and payment becomes possible with order IDs determined by SUGI Pharmacy. Additionally, we now can issue return slips for returning goods, whereas before wholesalers used to issue them. This eliminates discrepancies between accounts receivable and

Fig. 1.1.3-3 Toranomom Store of SUGI Pharmacy (Minato-ku, Tokyo)



*1 As of the end of February 2017

accounts payable and streamlines operations from ordering to payment.

Future Outlook

SUGI Pharmacy plans further optimization and cost reduction starting with the introduction of Ryutsu BMS. Firstly, we will promote further improvement of efficiency in ordering and payment operations and then move on to “payment without billing (*2)” as with the other sections.

Furthermore, we are now able to specify the date when goods are received, thus making the receiving process more flexible. We are examining if this enables operations to receive drugs that are only for specific patients at the time of their visits.

We also want to link our ordering operation and distribution system in order to change distribution routes for prescription drugs from direct delivery between wholesalers and stores to delivery through distribution centers. We expect this to enable bulk purchases.

1.2 Healthcare

1.2.1 Case Study: Utilization of GS1 DataBar at HAGA RED CROSS HOSPITAL

HAGA RED CROSS HOSPITAL is one of the first hospitals that recognized the effectiveness of GS1 DataBar and has utilized GS1 DataBar for patient safety. In Japan, the pharmaceutical industry has promoted barcode labelling on prescription drugs for many years. For prescription drugs, GS1 DataBar is marked not only on sales packages but also on primary packages. In

Japan, oral medicines are provided to outpatients in not sales packages but primary packages, so barcoding on primary packages is needed to prevent medical errors and improve patient safety. According to research data released by the Ministry of Health, Labour and Welfare in September 2016, the barcoding ratio of Global Trade Item Number (GTIN) on primary packages and sales packages is already approaching a level close to 100%.

Summary of HAGA RED CROSS HOSPITAL

HAGA RED CROSS HOSPITAL, located in Moka City about 100km North from Tokyo, is playing a central role in local healthcare services.

Summary of the system of the Pharmaceutical Department

The pharmaceutical department of the hospital is operating multiple systems that utilize the GS1 standards for the management of medicines and to ensure patient safety. This article focuses on the following two systems: 1) oral medicine preparation checking system and 2) injection set preparation checking system.

1. Oral medicine preparation checking system

1) For Outpatients

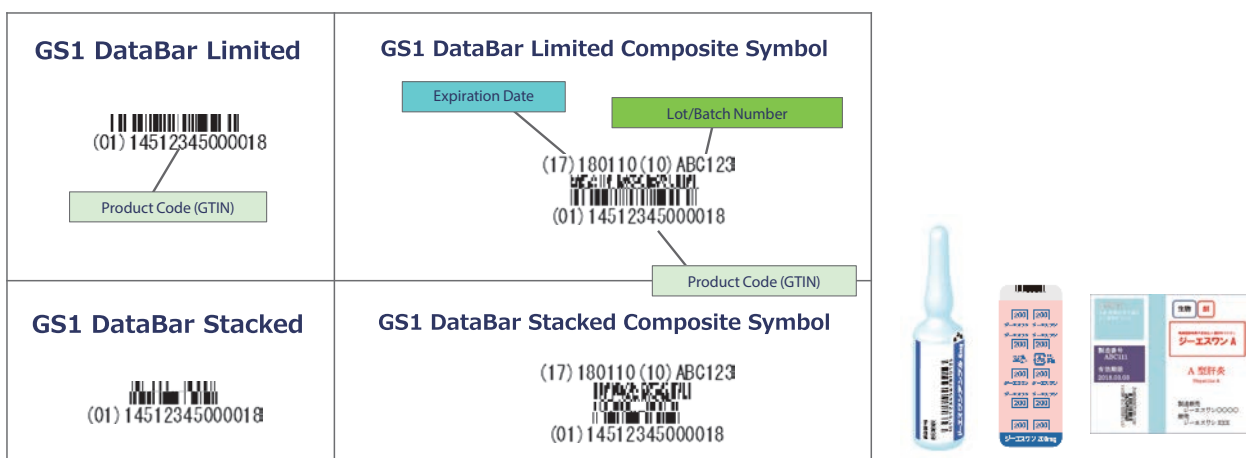
For the preparation of oral medicines for outpatients, checking is done by scanning GS1 DataBar marked on each package.

<Picking oral medicines from shelves>

Step 1: Print out a prescription.

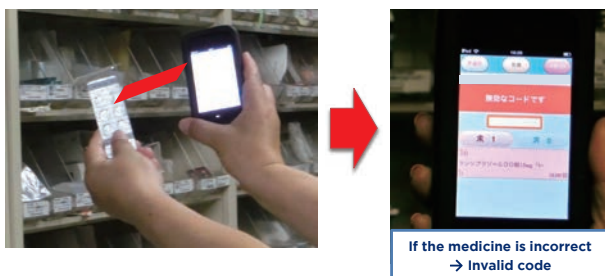
Step 2: Start the checking system, scan the barcode on

Fig. 1.2.1-1 Examples of GS1 DataBar



*2 In Japan, payment by each invoice is uncommon. Payment is usually made on a monthly basis by summing the amounts of all the transactions that occurred in that month. Additionally, “payment without billing,” the payment process where retailers calculate payment amounts from receipt data instead of suppliers issuing bills, is widely used by major distribution companies in Japan.

Fig. 1.2.1-2 Reading blister package



the name tag of the pharmacist to record the pharmacist's data.

Step 3: Scan the barcode on the prescription to retrieve the prescription data.

Step 4: Scan the GS1 DataBar on a blister package, pick up the medicines while verifying the data, and place them on a medicine tray (Fig1.2.1-2).

Step 5: After entering the prescription data into an inspection machine, put the medicine tray into the machine. The machine will take a photograph of the medicines and verify if the medicines are correct by cross-checking the barcodes or the shape of the medicines on the captured image with prescription data. More accurate medicine confirmation is done by checking twice; at the time of picking using GS1 DataBar and at the end with the inspection machine.

<Process for putting medicines into a medicine envelope for patients>

Step 1: Start the checking system, and scan the barcode on the pharmacist's name tag.

Step 2: When the prescription data is retrieved by scanning the barcode on the medicine envelope, the list of medicines will be displayed on the screen.

Step 3: Scan the GS1 DataBar on a blister package

while putting medicine into the medicine envelope. If the pharmacist scans the correct barcode, the name of the medicine and its quantity will be displayed. The name of the medicine will be deleted from the list once verification is completed. Repeat step 3 until all medicines are deleted from the list (Fig1.2.1-3). By using barcodes, pharmacists can ensure that they identify correct medicines and thus prevent errors in the picking process.

A new function was added to the checking system: it now not only verifies the accuracy but also informs users the necessary quantity for each medicine. The new function was more convenient for pharmacists and they have started to use the barcodes more proactively.

2) For Inpatients

Under an automated system, the hospital is focusing on one-dose packages, for which the system prepares one-time doses of medicines in one pack.

<Steps for one-dose packaging>

Step 1: Once prescription data is sent to an automated one-dose packaging machine, the one-dose packaging process begins. The machine is loaded with hundreds of different types of medicines, and each of them is verified by GS1 DataBar when loaded into the machine.

Step 2: Several medicines are packaged together for each part of the dosing schedule; such as, morning, noon, and evening. On each package, the patient's name, dosage regimen, names of medicines, and a barcode encoding serial number are printed.

Step 3: Put the prepared package into an image inspection machine. The image inspection machine takes a photograph of medicines in the package. It then automatically verifies the accuracy of the contents by cross-checking the barcode printed on the package and the colors and shapes of tablets and capsules with pre-

Fig. 1.2.1-3 Process for filling a medicine envelope

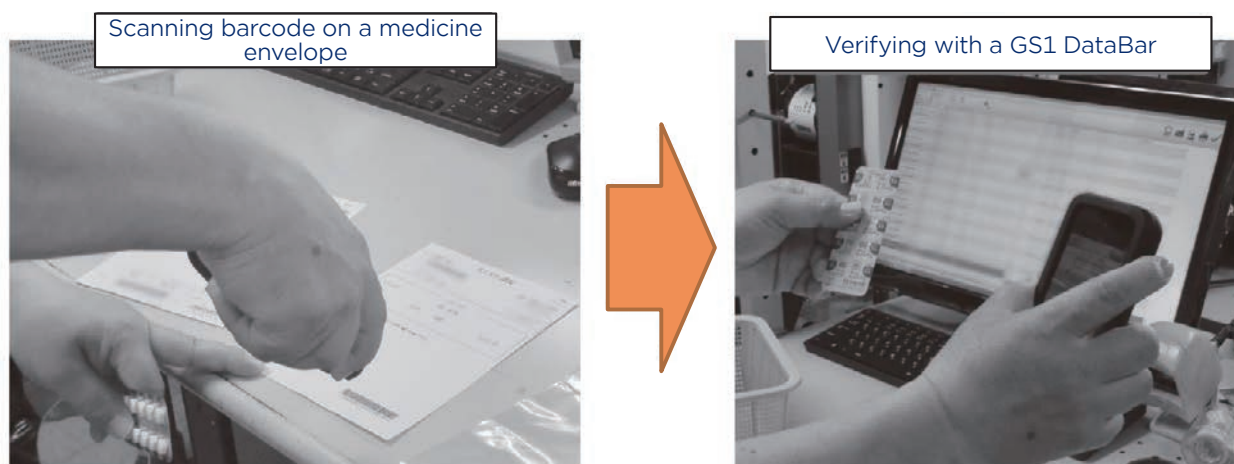


Fig. 1.2.1-4 Verifying screen for one-dose packages

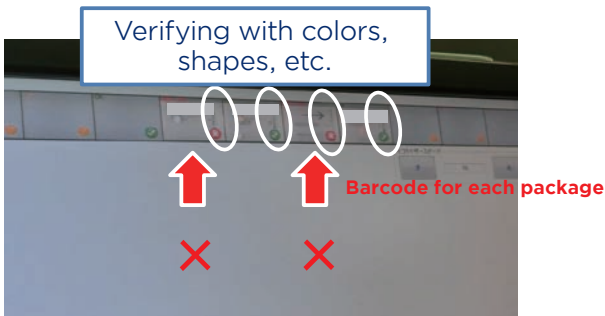
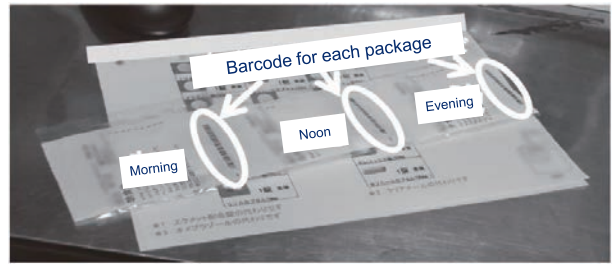


Fig. 1.2.1-5 Medicines in a one-dose package



registered medicine data (Fig1.2.1-4).

Step 4: If an error is found, a pharmacist will confirm the medicine by visual check or by enlarging the image taken by the machine (Fig1.2.1-5).

2. Injection set preparation checking system

Injections used in wards are generally administered to patients after being mixed with transfusion for use in intravenous drips. The mixing process is called coinfusion. After coinfusion, it is impossible for medical staffs to confirm the name and quantity of medicines by visual check. Therefore, accurate picking of injection sets is vital.

<Picking Process>

Step 1: A pharmacist fills a picking machine with ampules and vials. When filling, the staff scans GS1 DataBar on ampule/vial label and barcodes on racks of the machine to fill in the accurate drugs into accurate racks.

Step 2: Once prescription data is sent to the picking machine, prescriptions and drip infusion labels will be printed out (prescription data and barcodes are printed

on the label). Then, the machine automatically starts picking the drugs up.

Step 3: An assistant picks up the medicines that are not filled in the machine because of the size (such as transfusion and large containers) and prepares them in a basket.

<Checking Process>

Step 1: A pharmacist starts the checking system, and scans the barcode on the name tag.

Step 2: Scan the barcode on the prescription to retrieve prescription data.

Step 3: Scan GS1 DataBar on medicines to verify, and put verified medicines in a basket to be delivered to the ward. If the wrong drugs have been selected, there will be an error display and alarm sound (Fig1.2.1-6).

Before the implementation of the system, two pharmacists were engaged in this process; a pharmacist prepared and verified injection sets, and another pharmacist verified the sets again. After the introduction of the system, assistants can prepare injection sets and pharmacists are only in charge of the

Fig. 1.2.1-6 In the case of medicine errors



final verification, so pharmacists can do other work such as inpatient pharmaceutical services.

Conclusion

HAGA RED CROSS HOSPITAL has introduced AIDC technologies to its daily operations. Utilizing those technologies, the hospital reviewed the workflow and has achieved patient safety and cost efficiency at the same time.

Thanks to the high ratio of barcode display and the consistency of product identification code, Japan is one of the countries most prepared for the introduction of a traceability system utilizing GS1 standards. To leverage the benefit of this environment, GS1 Japan aims to introduce the advanced examples utilizing GS1 standards and promote to use GS1 standards at medical institutions. Through such efforts, GS1 Japan would like to contribute to the achievement of higher quality, safety, and efficiency in medical services.

1.2.2 Case Study: Integrated sterilization management system using GS1 standards in University of Fukui Hospital Surgical Center

Since 2014, University of Fukui Hospital had focused on the cost-effective management of its surgical operations by using GS1 standards. The hospital has successfully achieved the traceability of surgical instruments in its surgical center's sterilization process by identifying each of 20,000 instruments with the GIAI (Global Individual Asset Identifier) encoded in a laser-engraved GS1 DataMatrix. To date, the Hospital has reduced the error rate along with the time required when assembling instruments for surgical operations by 2,000 hours per year. The Hospital is the first hospital in Japan to use GLN (Global Location Number) to identify each of its locations. By using GLNs as part of its surgical container setting system, they reduced overall operation time by 500 hours per year.

Aiming to ensure the safe use of instruments

There had long been calls for safety management of surgical instruments using two-dimensional barcodes from the perspective of preventing surgical instruments from being left in a patient's body as well as eliminating any concerns about infections via contaminated surgical instruments, especially triggered by Creutzfeldt-Jakob disease. With the aim of ensuring the safe use and traceability of instruments, the Japan Association of Medical Devices Industries (Jamdi) released the *Guideline for Marking for Two Dimensional Symbol on Steel Instruments* in 2006. This guideline defines the need for direct marking and using GS1 standards for symbol engraving, recommending the use of GTIN (Global Trade Item Number) plus serial numbers and direct marking with GS1 DataMatrix. However, direct

marking on surgical instruments by manufacturers has not yet reached satisfactory level.

Outline of University of Fukui Hospital and adoption of GS1 standards

University of Fukui Hospital is located in the Fukui region of Japan with a population of around 400,000. It is the central hospital of the region with 600 beds and approximately 5,000 surgical operations performed annually.

From 2010 to 2014, the hospital was preparing to relocate its wards—the Surgical Center and the Central Sterilization Department—to a new building. During this period, the hospital introduced the “Integrated sterilization management system,” which through unique identification ensures traceability of steel instruments, for enhancing patient safety and the quality of infection control.

This system enables the linkage of patient IDs, surgical operation schedule and surgical instruments information within a hospital information system. For the identification of surgical instruments and sterilization related equipment, the hospital decided to adopt GS1 standards and obtained GS1 Company Prefix.

Adoption of the GIAI and GLN

University of Fukui Hospital adopted the GIAI as an identification key and the GS1 DataMatrix as a data carrier for UDI on steel instruments. The hospital has a laser-marking machine in place, which marks steel instruments with GIAI encoded in GS1 DataMatrix (Fig. 1.2.2-1). At the beginning of the system, the number of steel instruments marked with GS1 standards totalled approximately 18,000. The hospital spent nearly one year on the direct marking and registration of all instruments in the hospital database.

They have also adopted GLNs to identify locations. GLNs are assigned to each operating room, every location in the surgical container storage cabinet that accommodates sterilized containers and items, fixed shelves and storage racks at the hospital wards, and more (Fig. 1.2.2-2). In total, more than 1,000 of the hospital's locations have GLNs.

The integrated sterilization management system

The workflow of the integrated sterilization management system is illustrated in Fig.1.2.2-3. By using portable digital devices, the system allows them to manage information during each step of a surgical operation: the collecting, cleaning, sterilizing and storing the surgical instruments along with preparing for operations.

Fig. 1.2.2-1 GIAI on steel instruments



Fig. 1.2.2-2 The surgical container storage cabinet assigned GLN



As shown in Fig.1.2.2-3, the GS1 DataMatrix that is directly marked on each steel instrument is read twice—during the collection step after a surgical operation and during assembly.

University of Fukui Hospital has scanned the GS1 DataMatrix more than 2 million times in 3 years. By scanning barcodes, they can obtain various information about their sterilization process which achieves safer and more efficient care.

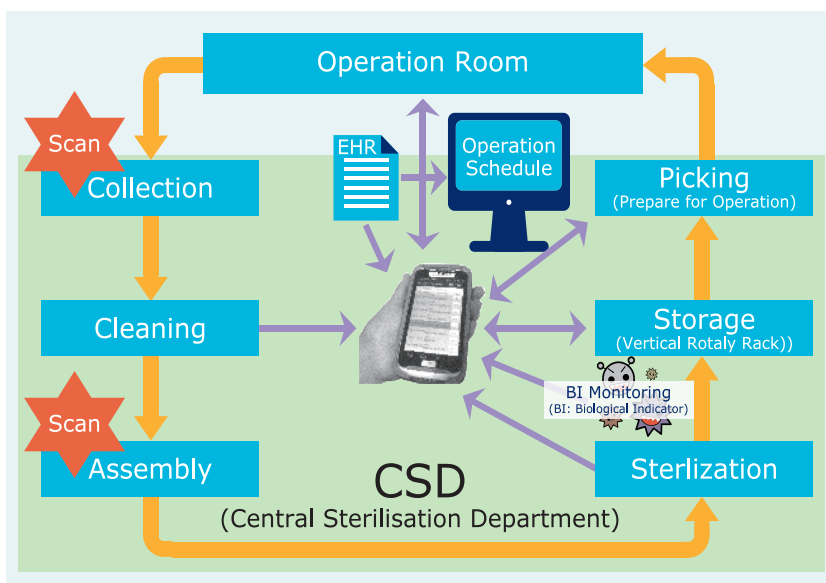
Benefit

Specific benefits of the new system using GS1 standards include improved medical safety measures by ensuring traceability on individual steel instruments. This includes the prevention of leaving surgical instruments in a patient’s body, the prevention of errors in counting, the more precise assembly of surgical sets, and the prevention of loss and unauthorized takeout.

The system also enables easy analysis on the frequency of use or turnover as well as the status of stock instruments at piece and set levels, leading to a highly efficient stock management and a reduction of surplus stock.

Furthermore, the analysis regarding the frequency of use by type of surgical method can help the hospital optimize the number and content of surgical sets. In University of Fukui Hospital, assembling steel instruments into containers (assembling operation) used to be conducted by experienced nurses with specialized skills and knowledge. Thanks to the new system, this process can be performed by staff members without these specialized skills and knowledge; therefore the hospital was able to consign the work to outsource staff. The assembling operation under this system is quick and accurate. They estimate

Fig. 1.2.2-3 Workflow of the integrated sterilization management system



that the system has contributed to a reduction of approximately 2,000 hours annually for the overall operation time, including the confirmation of steel instruments after surgery.

In addition, container storage and picking tasks, part of the preparation process for surgical operations, have become automated, paperless processes based on the real-time status of stock of sterilization containers. They estimate the time for such work has been reduced by approximately 500 hours annually. The management of steel instruments directly marked with GIAI and the management of locations using GLNs have saved a total of 2,500 hours annually. This allows nurses to concentrate on other duties, and furthermore, can contribute to a reduction of their overtime work.

Next steps

University of Fukui Hospital aims to introduce a similar system for all of its medical devices and establish a real-time traceability system. In addition, the hospital will expand the scope of traceability management to single-use medical devices and materials using GTINs that are source-marked on packaging, and take necessary measures to ensure higher medical safety, further increase efficiencies and prevent incomplete reimbursements.

The hospital will adopt this kind of traceability scheme to loan instruments, as well. A new system is under development to collect location information of carts in preparation for a surgical operation in real time. Using this system, they will further improve the existing workflow so that it can confirm the transportation of carts in an operating room and respond to an urgent change of surgery procedure and/or operating room. The hospital believes that the GTIN, GIAI, GLN and other GS1 identification keys can be widely used on various scenes in medical institutions.

1.2.3 Case Study: Barcoding on Medical Devices: Benefits of barcodes and Consideration of barcode placement

The situation surrounding UDI

UDI is an acronym for Unique Device Identification. According to the IMDRF (*1), UDI is defined as a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific medical device on the market. In recent years, the attraction of UDI of medical device has been increasing.

The IMDRF published “UDI Guidance: Unique Device

Identification (UDI) of Medical Devices” in 2013. The guidance states that a globally harmonized and consistent approach to UDI is expected to increase patient safety and help optimize patient care by facilitating the:

- a. traceability of medical devices, especially for field safety corrective actions,
- b. adequate identification of medical devices through distribution and use.

In 2013, the US FDA released UDI rule amidst the increased importance of worldwide consistency.

The main requirements of the UDI rule are as follows;

- a. Develop Unique Device Identifiers for all devices
 - b. Place UDI on label and the device
 - c. Submit data to US FDA’s Global UDI database
- GS1 is accredited by the US FDA as one of the UDI Issuing Agencies, fulfilling conditions laid out by the UDI rule.

The legalization of UDI has been a broad worldwide trend. In EU, UDI rule was also released in May 2017.

Japan’s efforts to date

Ahead of the movement above, barcode labelling on medical devices has been promoted for many years in Japan.

Medical device industry issued guideline to promote barcode labelling in 1999. Reflecting on the movement of the industry, the Ministry of Health, Labour and Welfare (MHLW) officially decided to encourage barcode labelling on medical devices and published “Guidelines for Placing Standard Codes (Barcode Marking) on Medical Devices” in 2008.

According to the survey on medical device by the MHLW in September 2016, the ratio of barcode labelling on sales package reached around 95%. On the other hand, the ratio of barcoding on medical device itself is not high. This is because the guideline by the MHLW deemed barcoding on medical device itself to be a point for future consideration.

Given the current situation, the JFMDA (Japan Federation of Medical Device Association) is now making efforts to improve the ratio of barcoding on medical devices. The JFMDA clearly states in its 2016 publication, “UDI Operation Manual for Medical Devices”, that it promotes barcoding on not only 1) inhalators, 2) defibrillators except AED, 3) infusion pumps, 4) syringe-type pumps, but also 5) medical devices that are used repeatedly after washing, sterilizing, and decontaminating, 6) transportable medical devices.

Efforts by GS1 Healthcare Japan

As mentioned above, although UDI has started to

*1 International Medical Device Regulators Forum is the forum which consists of the regulating authorities of nine countries.

become mandatory worldwide; the regulations do not standardize the barcode placement. As a result, there are cases in which barcodes are put in positions inconvenient for medical staffs to scan (such as the back or bottom part of medical devices.)

In order to utilize barcodes in medical institutions to ensure traceability, barcode placement should be considered in light of ease of use for medical staffs. GS1 Healthcare Japan established a working group to discuss barcode placement on devices. In March 2017, the group released a report, “Barcoding on Medical Devices: Benefits of barcode and Consideration of barcode placement”.

The report outlined the fields of application and benefit for medical staffs to utilize barcodes on medical devices. In addition to the benefits, the report showed basic points to consider regarding barcode placement and specific examples of barcode placement.

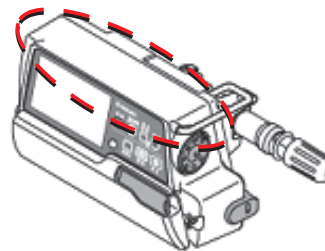
[Benefits]

- **Device registration** : Increasing efficiency in entering data into device registries
- **Appropriate allocation** : Appropriate inventory setting based on equipment utilization ratio.
- **Entering device information to medical records** : Reducing burden of nurses, improved accuracy of medical records
- **Invoices and insurance claims** : Prevention of incomplete medical billing and insurance claims.
- **Medical safety** : Preventing the use of incorrect device.
- **Device maintenance** : Ensuring regular maintenance by cross-checking with maintenance logs and generating notification of inspection dates.
- **Management of devices that are sterilized and used repeatedly** : Improving safety due to device-based traceability and accuracy of device assembly.
- **Management of medical device rentals** : Large reduction in administrative workload related to device rentals.
- **Rapid product identification and recall** : More accurate medical device information shared among medical institutions, device manufacturers, and suppliers, rapid identification and recall of defective devices.

[Basic points for barcode placement]

- Barcodes should be placed where users can view it easily when the device is used in medical institutions (avoid the back or bottom part of devices).
- Barcodes should be easily accessible for scanning, without hindering the use of devices.
- Barcodes should not affect the original functions, capabilities, or qualities of devices.
- Barcodes should not easily be unreadable due to blots, stains, break or deterioration.

Fig. 1.2.3-1 An example of a barcode position



We hope this report will stimulate discussion about barcode placement on medical devices in Japan and facilitate progress in ensuring traceability through UDI.

1.3 T & L

1.3.1 Case Study: NIPPON ACCESS Uses EPC/RFID to Track Cage Trolleys

NIPPON ACCESS, INC. (NIPPON ACCESS) is a general food wholesaler with approximately 500 distribution centers located nationwide across Japan. Logistics is also one of the core businesses and services including “3PL operations” where the company operates the customer’s distribution center from warehouse management to delivering goods to retail stores. The company also provides transportation services as a logistics company specializing in food.

To cope with changes in the environment surrounding logistics such as aging workforce, increases in working hours and declines in salary levels, NIPPON ACCESS has adopted various tools for improving operational efficiency. Tracking cage trolleys using RFID is one such example.

To track individual trolleys, NIPPON ACCESS uses a GS1 Identification Key, GRAI (Global Returnable Asset Identifier), which uniquely identifies assets such as reusable transport tools and containers.

Motivation for EPC/RFID Implementation

NIPPON ACCESS originally tracked its cage trolleys by barcode. Having to scan the barcode on each trolley one by one, however, complicated the operation and also there were durability problems; barcode labels often got detached from trolleys due to rubbing. The company purchased 300 new cage trolleys every year to compensate for missing ones. For these reasons, NIPPON ACCESS decided to use RFID.

At the beginning, RFID tags were read only with Handheld RFID Terminals (HHTs). Additional workers were engaged to perform this task and it resulted in reduced productivity.

To solve this problem, NIPPON ACCESS adopted the “Access Gate-through System (AGS)” in 2014, developed jointly with KIBUN TRADING, INC. and NIPPON FILING CO., Ltd. With this system, the RFID

tag placed at the top of each cage trolley is read by gate-type RFID readers. As a pair of RFID antennas is installed at each gate (i.e. dock shelter), a truck driver can simply load cage trolleys onto a truck through a gate. RFID tags on the cage trolleys are read automatically.

System Features

NIPPON ACCESS uses passive UHF (Ultra-High Frequency) RFID tags for AGS since UHF can read multiple tags at the same time and its read range is much wider than other frequency bands. At this particular distribution center, approximately 1,200 RFID tags on cage trolleys can be read in 30 minutes. The RFID tags are attached to cage trolleys using durable and longer life attachment. The attachment also works to keep tags from being directly attached on the metal surface of a cage trolley and thereby ensures reading performance. (See Fig. 1.3.1-1) Identification keys encoded in the RFID tags are GRAI. By using this globally unique identification key, NIPPON ACCESS can uniquely identify its own cage trolleys even in situations where they get mixed up with other companies' trolleys on the premises of the destination retail store.

Fig. 1.3.1-1 RFID tag attached to the top of a cage trolley



Fig. 1.3.1-2 Workflow using AGS

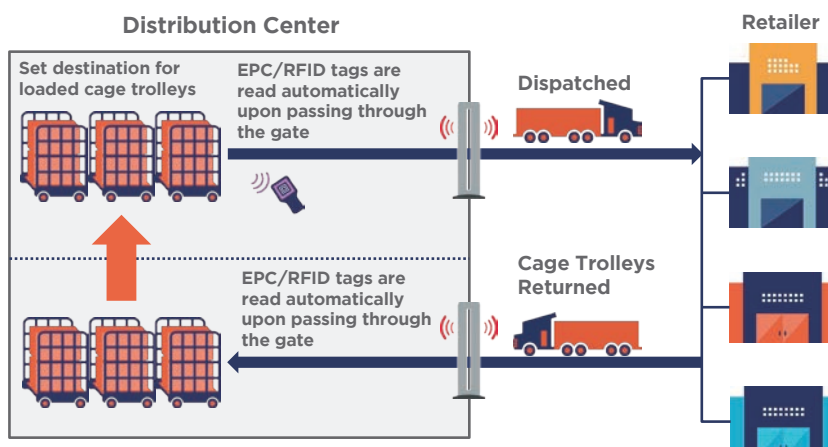


Fig. 1.3.1-3 Cage trolleys passing through the gate



Workflow Outline

The dispatch workflow is as follows;

- (1) Distribution center personnel set the shipping destination for cage trolleys loaded with items using an HHT.
- (2) The transport truck driver enters the shipping destination data into one of the RFID gate readers at the loading dock using an HHT.
- (3) Now the driver only needs to carry out the normal loading operations as dispatch data processing and the loading check are performed automatically when the cage trolleys pass through the gate (See Fig. 1.3.1-3).
 - Each time the tag on a trolley is read, the driver will hear an automated voice stating the gate number that allows him/her to confirm the tag was read properly.
 - If the driver tries to load incorrect cage trolleys for the destination or trolleys for which the shipping destination has not been entered, the driver will hear an error sound indicating loading errors.
- (4) When cage trolleys are returned from retail stores, this is automatically recorded by simply passing the trolleys through the gate. Some cage trolleys come in without going through the gate due to space limitations. These tags are read manually with an HHT to eliminate differences in the received quantity.
 - When a new data set of a cage trolley and its destination is sent to the server, the corresponding trolley is automatically processed as received. Therefore, once trolleys return from retail stores, new destinations can be assigned.

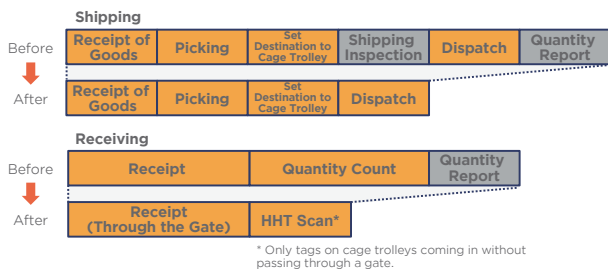
Results of AGS Adoption

Prior to the adoption of AGS, cage trolleys were lost track of one after another during busy seasons. As there was no way of knowing their locations, NIPPON

1. Sector

ACCESS would send a request to all the partner retailers to return missing trolleys. After the adoption of AGS, dispatch and receipt of cage trolleys to and from the retail stores are tracked daily. As the location of trolleys can be identified, NIPPON ACCESS can now ensure all trolleys dispatched are returned. Moreover, since 1,000 previously missing cage trolleys were returned, purchase of additional trolleys is not necessary for some time in the future. In addition, loading errors, such as cage trolleys being left behind or being loaded onto the wrong truck, are prevented by using a dispatch schedule that contains data of cage trolleys and their shipping destinations. AGS also reduced the workload of drivers and distribution center workers by eliminating tasks such as manual barcode scanning at dispatch. (See Fig. 1.3.1-4)

Fig. 1.3.1-4 Operations before and after the adoption of AGS



Next Step

By using EPC/RFID to track cage trolleys, data is constantly accumulated on how many trolleys are at each store and how long they stay there. For the next step, NIPPON ACCESS is considering utilizing this accumulated data to better manage cage trolleys by, for example, specifying the optimum number of trolleys at each store at any given time based on the data. In the future, NIPPON ACCESS also expects to establish visibility of transported items for both distribution centers and retailers by associating the data of a cage trolley with the items loaded on it and the truck transporting it. In addition, with the visualization of the movement of items, NIPPON ACCESS hopes to achieve labor saving in the area of correspondence with retail stores on the item shipment status.

1.4 New Industry

1.4.1 Case Study: GPC Translation and OECD Product Recall Portal

Global Product Classification (GPC) is a product classification developed and managed by GS1. GPC is a required attribute when registering product information into data pools of Global Data Synchronization Network (GDSN). As of December 2016, the development of 38 broad categories including Food/Beverage/Tobacco, Kitchen Merchandise, Beauty/Personal Care/Hygiene,

Pet Care/Food have been completed and released on the GS1 website (<http://www.gs1.org/gpc>).

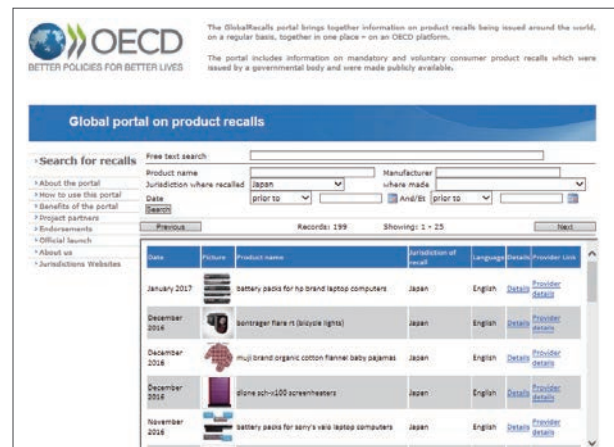
Multilingual access has been progressing, with translations into 16 languages, including Japanese, which are available for viewing on the GS1 website. Since 2005, GS1 Japan has been translating seven segments, such as Food, Beverage, Tobacco, Household Goods, Home Appliances, and Pet Items.

Recently, there has been a move to use GPC for other purposes than GDSN. The OECD- managed recall portal website has adopted GPC for its product categorization. The aim of this portal site is to facilitate efficient sharing of international product safety information in multiple languages, as a response to current trends in global trading. The portal site started operation in October 2012 in English and French with the participation of U.S., Australia, Canada, and EU countries. Japan also began participating in January 2015, providing product-recall information of Japanese products, as well as adding a link to the Japanese-language version on the top page of the site.

In response to that move, GS1 Japan translated all 38 segments of the December 2016 version of GPC into Japanese.

We expect the use of GPC to expand in the future as more OECD-member nations start providing recall information on this portal site.

Fig. 1.4.1-1 The GlobalRecalls portal showing Japanese products subject to recall.



Source : <http://globalrecalls.oecd.org/>

2. Service & Solution

2.1 JICFS/IFDB (JAN Item Code File Service/Integrated Flexible DataBase)

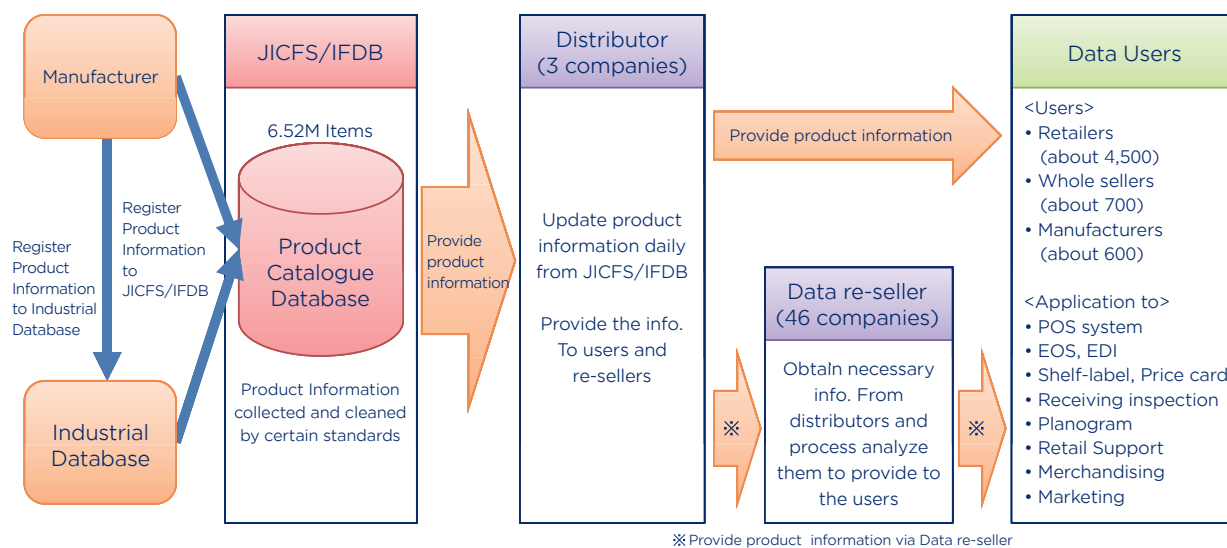
Since 1988, GS1 Japan has been operating the JICFS/IFDB database of product catalogues and has been collecting and maintaining basic product attributes, e.g., GTIN, product names, product categories, weights, and amounts. This database is used for two purposes: POS product masters at retailers and EOS masters between wholesalers and retailers. The JICFS/IFDB database is recently being used for a variety of other purposes, including online shopping portals and for marketing research. Since many stores on online shopping portals manage the product information using their own codes and product names, the same products are often sold under different names and categories.

To solve this problem, several companies operating online shopping portals use GTIN for product information control.

The use of the JICFS/IFDB has been promoted not only in the distribution industry, where the database is already in wide use, but also in the area of social welfare. For instance, this database has been used for voice guidance experiments in which vision-impaired consumers themselves can scan a product's barcode and have their personal computer or other device speak the name of the product.

Product data is collected and arranged according to JICFS/IFDB standards and is then offered at cost to retailers, wholesalers and other users via distributors (Fig. 2.1-1). As of March 2017, product information data registered in the JICFS/IFDB covered over 6 million

Fig. 2.1-1 JICFS/IFDB system flow



	2013	2014	2015	2016	2017
Food	1,209,636	1,291,008	1,371,489	1,465,218	1,544,912
Commodity	673,700	714,237	759,793	807,882	855,876
Recreation and Miscellaneous	417,922	453,135	492,503	532,678	575,471
Durable Goods	230,718	262,309	281,236	311,321	337,560
Apparel, Personal items & Sporting goods	222,660	245,395	270,240	301,951	331,360
Other	3,315	3,262	3,230	3,172	3,147
Active item Total	2,757,951	2,969,346	2,969,346	3,422,222	3,648,326
Inactive Data	3,104,154	3,104,154	3,104,154	3,104,154	3,104,154
Grand Total	5,862,105	6,073,500	6,282,645	6,526,376	6,752,480
Increase in number of items (year-on-year)	202,778	211,395	209,145	243,731	226,104
Rate of increase (year-on-year)	103.58%	103.61%	103.44%	103.88%	103.46%

products from 30,000 manufacturers. About 5,800 companies, of which 77% are retailers and 12% are wholesalers, currently use the database. By using product information managed by the JICFS/IFDB, user companies can perform the communications, inquiries and registration tasks related to product data promptly, precisely and at a low cost. As such, the product information is being widely utilized by small and medium businesses.

The product information in JICFS/IFDB includes JICFS classification codes that indicate product categories. These codes are used as search keys for extracting the necessary product groups, and as aggregate keys for aggregating similar products for data totaling, processing, and analysis.

The JICFS categories are revised as necessary. In March 2014, minor changes were made for OTC (Over the Counter) drugs. Revision of the JICFS categories for confectionary is also being discussed now, together with confectionary industry associations.

2.2 Ryutsu BMS (Business Message Standards)

The use of EDI in the retail sector in Japan started with the Electric Ordering System (EOS) using the JCA Protocol (*1), a standard data communication protocol drawn up in 1980 by the Japan Chain Stores Association (JCA). In the 1990s and thereafter, EDI also came to be adopted for business processes other than ordering. Furthermore, in the 2000s, based on Efficient Consumer Response (ECR) and Quick Response (QR) procedures, Ryutsu (*2) Business Message Standards (known as Ryutsu BMS) were established for the purpose of achieving improved information sharing between Retailers and suppliers.

2.2.1 Development of Ryutsu BMS

The JCA Protocol drawn up in 1980 became widespread as an EOS for retail businesses. In 1990s, the business procedures covered by EDI expanded from the EOS to the shipping and receiving of goods, invoicing and payments. However, from the

late 1990s to the early 2000s, the following problems with the system were identified:

- Low speed
 - Inability to deal with Kanji characters and images
 - The necessary communication equipment was discontinued
 - Difficulty in adding new data fields due to a fixed-length data format
 - Message formats that differed from retailer to retailer
- Concerned about this situation, Japan's two supermarket organizations agreed to cooperate and started to develop a next-generation EDI in June 2005. With the support of METI (Ministry of Economy, Trade and Industry), the Ryutsu BMS were created as the new EDI standard in April 2007. The Ryutsu BMS is now being increasingly adopted throughout the Japanese retail industry.

2.2.2 Outline of the Ryutsu BMS

The Ryutsu BMS define the following:

Communication infrastructure

There are three standard communication protocols for exchanging Ryutsu BMS messages;

- Server-to-Server Protocols: ebMS and AS2
- Client-to-Server Protocol: JX Protocol (*3)

In addition, guidelines for secure internet communications are prepared, and the use of certificate authority that meet the guidelines is recommended.

Standard Messages

There are 2 types of messages:

- Basic messages

Intended for use at supermarkets, drugstores, etc. The 27 basic messages were published based on the Order to Cash business model. In 2010, retailers and the apparel industry worked together to develop a system of peer-to-peer product information data messages.

- Department store messages

Japanese department stores have unique transaction models, which are different from those of other retailers. For example, they register a merchandise purchase when the merchandise has been actually sold; and also they need to manage the pre-ordering of seasonal gifts for the Japanese custom of giving gifts

*1 JCA Protocol

This is the standard communications protocol for electronic ordering, established in 1980 by the Japan Chain Stores Association (JCA). The communication circuits available for the protocol are public circuits (2,400 bps) and DDX circuits (9,600 bps), and it cannot transmit Kanji and images. DDX circuits are packet-type communication services that use telephone circuits.

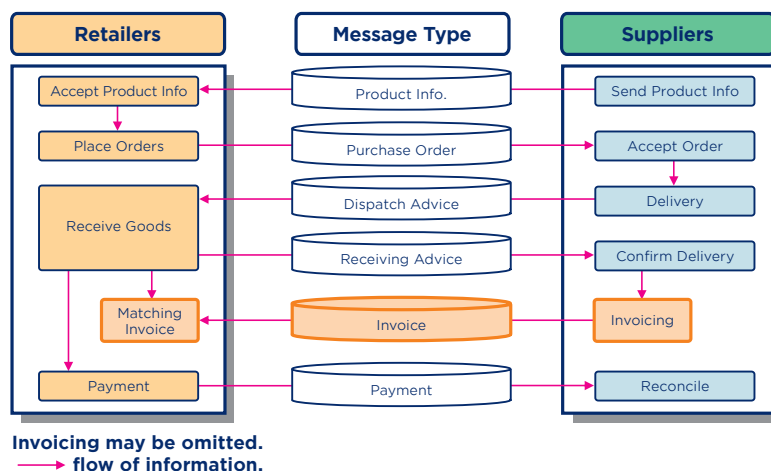
*2 Ryutsu

Ryutsu is the Japanese equivalent of a supply and demand chain, which typically consists of three groups; Manufacturers, Wholesalers and Retailers.

*3 JX Protocol

This is the communications protocol for transmitting messages from a client terminal to a corresponding server on a TCP/IP network. Using the international SOAP-RPC standard, the protocol realizes functions that are equivalent to those of the J Protocol. The JX Protocol has become a standard communications protocol for exchanging EDI messages between clients and servers in the Ryutsu BMS.

Fig. 2.2.2-1 Typical Turnaround Business Processes and Ryutsu BMS Messages between Retailers and Suppliers



twice a year (in the summer and at the year's end). Therefore, the department stores use 27 unique messages in their transactions.

2.2.3 Efforts to promote the Ryutsu BMS

GS1 Japan, together with the Supply Chain Standards Management & Promotion Council (see 3.2), have taken various efforts to encourage the wider use of the Ryutsu BMS.

- Trainings and seminars:

GS1 Japan has offered a wide range of training courses ranging from introductory to advanced implementation courses. Some of these courses have been provided as e-learning. We also hold seminars to introduce the best

practices to the Ryutsu BMS users and solution providers.

- Promotional materials:

Flyers, brochures and videos have been made available to anyone interested in the Ryutsu BMS. We also have an Ryutsu BMS dedicated website, which is kept up-to-date.

2.2.4 Users' commitment to the Ryutsu BMS

According to a survey conducted by GS1 Japan, 190retailers and 226 wholesalers or manufacturers have already adopted or intend to adopt the Ryutsu BMS. The details of this survey are described in Fig 2.2.4-1.

Fig. 2.2.4-1 Number of Companies with their Names Made Public (As of Jan. 4, 2017)

Retailers			
Classification	Implemented	Planning to Implement	Subtotal
1. Supermarket	128	13	141
2. Department Store	9	2	11
3. Drug Store	24	0	24
4. Home Improvement Store	4	0	4
5. Co-operative Federation	4	0	4
6. Storage-type Membership Store	1	0	1
7. Voluntary Chain Headquarters	1	0	1
8. Discount Store	3	1	4
Total	174	16	190

Wholesalers/Manufacturers			
Classification	Implemented	Planning to Implement	Subtotal
1. Food/Beverage Wholesaler	57	0	57
2. Confectionary Wholesaler	21	4	25
3. Daily Goods/Cosmetics Wholesaler/Manufacturer	27	0	27
4. Medical Goods Wholesaler/Manufacturer	6	2	8
5. Apparel/Shoes/Sports Goods Wholesaler/Manufacturer	29	8	37
6. Food Manufacturer	30	2	32
7. Household Goods Wholesaler/Manufacturer	10	1	11
8. Packaging Materials/Secondary Materials Wholesaler/Manufacturer	15	7	22
9. Toys/Hobby Goods Wholesaler/Manufacturer	3	0	3
10. Home Electric Appliances Wholesaler/Manufacturer	2	0	2
11. Other Wholesaler/Manufacturer	2	0	2
Total	202	24	226

2.2.5 Connecting the retail industry with the banking industry using the Ryutsu BMS

GS1 Japan is now working on the standardization of the EDI infrastructure which will go beyond the retail sector. Thanks to the diffusion of an XML-based Ryutsu BMS, more and more exchanges of trade transaction information between retailers and suppliers have been automatically processed in Japan. However, between companies and banks, EDI standards that use fixed-length message and public phone lines are still common. The message format allows for only 20 characters of information regarding the payment.

Therefore, no more than a reference code and the total payment amount can be entered. Linking payment details for information regarding the payment and the trade transaction information is also difficult. As a result, when the payments were received from buyers, the suppliers were often unsure about which trade transaction the payment was for, and whether the items balanced or not. These cases make the bank reconciliation and accounting work inefficient.

Under such circumstances, the banking industry has been considering utilizing a financial EDI with the internet for a long time. The 6th Generation Zengin System (*), which came into operation in November of 2011, makes it possible to send and receive information in an XML format (ISO20022). This system significantly

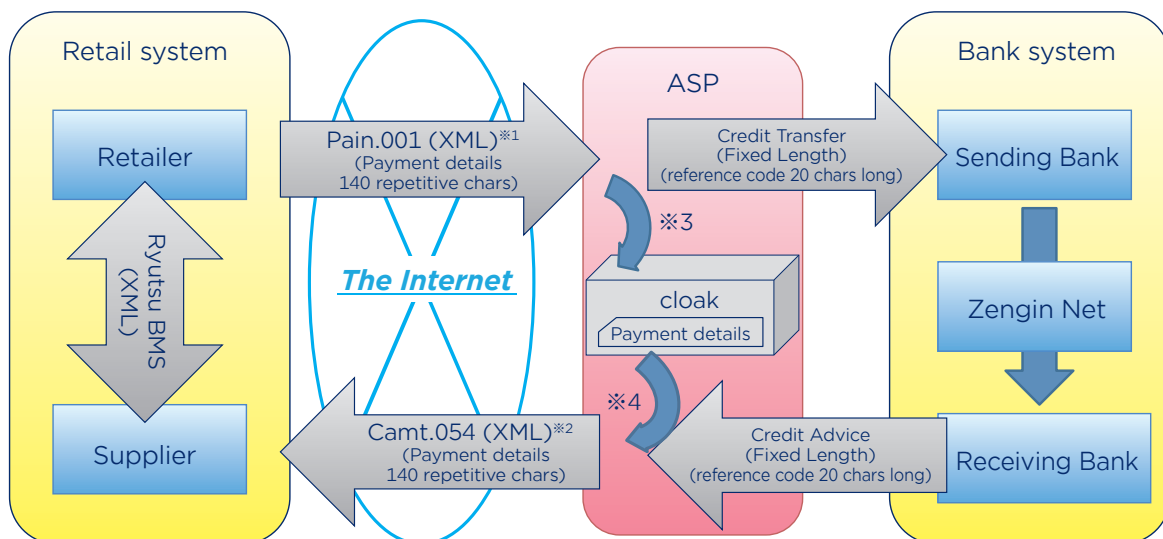
increases the amount of payment information available in messages from 20 characters (allowing for a reference code) to 140 repetitive characters (allowing for full payment details). As this example shows, an environment that will enable mutual data utilization with industries is starting to be established.

GS1 Japan, in cooperation with the banking industry, conducted a pilot in fiscal year 2014/15 to connect the transaction information that was exchanged with the Ryutsu BMS and the settlement information exchanged by companies and banks. In the banking industry, the environment to implement the ISO20022 was not sufficiently prepared, so the information was shared using a cloaking function (shown in Fig 2.2.5-1) that would receive the payment information. Specifically, the following items were studied and confirmed:

1. Rules on the items to be set for the payment information
2. Possibility of the information transfer, according to the system shown in Fig 2.2.5-1

With this pilot, the cooperation between the distribution industry and the banking industry was strengthened, and the distribution industry was able to raise the efficiency of its accounting operations and improve their accuracy, through techniques such as a simplified reconciliation of the account receivables. Given the results of these efforts, the banking industry has decided to build a similar system that will begin operations in the fiscal year 2018.

Fig. 2.2.5-1 Using “cloak” to communicate trade information between retailers and suppliers using ISO20022 messages



※1 ISO20022 pain. 001 (Credit Transfer)
 ※2 ISO20022 camt. 054 (Credit / Debit Notification)
 ※3 Cloak stores details of the payment (140 chars repetitive) and pass 20 char long reference code to bank system.
 ※4 Upon receiving reference code, cloak pass details of the payment (140 chars repetitive) to retail system.

* Zengin System: Inter-bank network system that allow individuals or companies to request transfers with financial institutions.

2.3 GEPIR

GEPIR (Global Electronic Party Information Registry) is a unique, internet-based service that gives access to basic contact information for basic contact information about GS1 Company Prefix licensees.. Since 2003, GS1 Japan provides the GEPIR service in Japanese on the GS1 Japan website.

In 2007, a GLN location search function was added to the GEPIR by GS1 Japan, followed by GTIN information display services in 2013.

In March 2017, the upgrade to GEPIR version 4.0 was completed.

The following information is available on GEPIR

- GTIN
- Information Provider GLN
- Information Provider Name
- Information Provider Link
- Manufacturer GLN
- Manufacturer Name
- Item Name
- Classification Code

Currently, GEPIR is used by many companies, with more than 2 million accessing the service annually.

Fig. 2.3-1 GS1 search results of company information

The screenshot displays the GEPIR Japan search interface. On the left, there are search options: 'Search by Barcode (GTIN)' with a text input field containing '4912345678904', and 'Search for' with radio buttons for 'Trade Item Ownership' (selected) and 'Trade Item Info'. A 'Search' button is at the bottom of this section. The main content area shows 'Search Results' with a 'Status' section indicating 'Number of Hits: 1'. Below this is a 'Company Information' table with the following data:

N	Entity G	Contact Information	GS1 Company Prefix	GLN Information
1	4569951 110009 The Distribution Systems Research Institute 〒107-0052 東京都港区赤坂7-3-37 プラース・カナダ 3 F JP		4512345 456995111 4912345 499687	GLN List

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3. Community Engagement and Standard Implement

3.1 GS1 Japan Partners

In April 2015, GS1 Japan launched the program “GS1 Japan Partners”, mainly for solution providers. This program aims to share information on the latest trends and cases of systematization, while promoting the systematization of information and efficiency in the overall distribution industry with use of GS1 standards. The number of members in fiscal year 2016/17 is 118, including many of the major solution providers representing Japan. (Fig 3.1-1)

3.1.1 Activities of the GS1 Japan Partners

Under the GS1 Japan Partners membership system, GS1 Japan annually hosts four regular seminars and one site visit. It also holds non-regular seminars. The seminars, in which key persons in the distribution industry are invited to take part as speakers, and experts give lectures on topics that are seen as having a big impact on the distribution industry, have enjoyed a good reputation.

In addition, as part of GS1 Japan’s efforts to share information, it has distributed reports on its regular

seminars and publications from GS1 Japan..

Furthermore, as part of its efforts to support the sales of member companies, GS1 Japan has introduced these companies and their products on its website and allows the companies to display their products at the GS1 Japan’s booth at Retail Tech, the largest trade fair for distribution systems in Japan, at a discounted price. Members can also put the “GS1 Japan Partner Logo” on flyers, pamphlets, websites and business cards from 2016.

Fig. 3.1-1 Membership Structure (as of March 2017)

Sales	Number of Members
Less than 1 billion yen	51
1 billion - 10 billion yen	26
10 billion - 1 trillion yen	35
1 trillion yen and above	6
Total	118

Fig. 3.1-2 Events in Fiscal Year 2016/17

	Event Name	Main Topics/Lectures
2016/7	EPC/RFID Seminar	GS1 EPC/RFID standard description EPCIS EPC Tag Data Standard ALE/LLRP
2016/8	1st Regular Seminar	Reduced tax rate system Image recognition cash register, etc.
2016/10	2nd Regular Seminar	Direction of information utilization in the wholesale industry Latest trends in computerization of intermediary distribution Computerized wholesale marketing
2016/11	3rd Regular Seminar	Distribution efficiency and its outlook with use of IT Trends of widespread use of GS1 QR Code centering on the distribution industry, etc.
2016/11	Auto-ID Lab Japan Tour	Keio University
2016/12	EPC/RFID Seminar	EPC/TDS LLRP/ALE
2017/1	Special Seminar	Introduction of “Barcode guidelines for recognition of raw materials” GS1 standard medical equipment barcode display
2017/3	4th Regular Seminar	Omni channel strategy in the retail industry EC’s back office operational efficiency, etc.

Fig. 3.1-3 FY2016/17 Auto-ID Lab Japan Tour



Fig. 3.1-4 GS1 Japan Partner Logo



3.2 Supply Chain Standards Management & Promotion Council

Supply Chain Standards Management & Promotion Council was founded in April 2009 by various industry groups and businesses to help promote efficient supply chain information system in Japan’s retail sector. The activities of the council include maintaining and promoting the Ryutsu BMS (see2.2), which was initially developed with the support of the Ministry of Economy, Trade and Industry. At present, GS1 Japan acts as the secretariat of the council.

The Council held its inaugural General Assembly in Tokyo in April 2009. The council consists of trade associations of manufacturers, distributors and retailers in the consumer goods industry as full members. As of January 2017, the council has 49 full member organizations. In 2016, the council is being operated with the following structure:

Organizational structure

(1) General Assembly

Once a year the Council holds a general assembly at which it approves the results of activities of the previous year as well as the new agenda for the next year. The officers of the council are also appointed at

the general assembly for two-year terms.

(2) Executive Committee

The role of the executive committee includes making important decisions on the council’s management, such as admitting new members, establishing and abolishing working groups, and appointing working group members. In 2016, the committee is composed of representatives from 15 full member organizations.

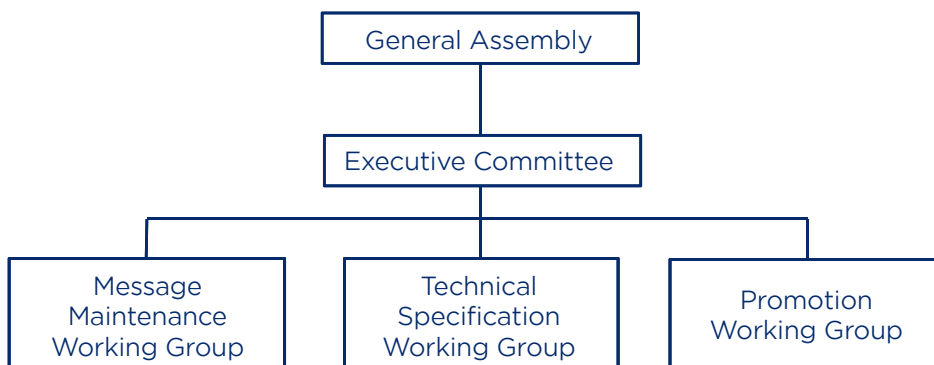
(3) Working Groups

The Council has three working groups as follows (See Fig.3.2-1).

1) Message Maintenance Working Group

This group maintains and manages the Ryutsu BMS messages and various guidelines. The work is done in response to requests from full members for changes or additions to the established standards. The group examines such requests, decides on the steps to be taken, revises the relevant guidelines and publishes new standards. In 2012, the group set the standard for product images (image size, resolution, filenames etc.) for online supermarket and published a guideline.

Fig. 3.2-1 Organizational Structure of the Council



- 2) Technical Specification Working Group
This group maintains and manages the guidelines for network technology and information processing technology used for exchanging the standard messages of the Ryutsu BMS via communications circuits.
- 3) Promotion Working Group
This group examines and implements steps to encourage wider adoption of the Ryutsu BMS among SMEs. The group also monitors “off the standard usage” of Ryutsu BMS.

Activities for promotion and increasing adoption

GS1 Japan and the council take various efforts to encourage wider use of the Ryutsu BMS. For details see 2.2

Registration of the Ryutsu BMS trademark

GS1 Japan has registered the Ryutsu BMS logo to be used for products and services that comply with the Ryutsu BMS specifications. As of January 2017, there are 122 products accredited and permitted to use the logo.

Fig. 3.2-2 Ryutsu BMS logo



3.3 GS1 Healthcare Japan

GS1 Healthcare Japan is a voluntary group that is made up of domestic medical institutions, pharmaceutical and medical devices manufacturers, wholesalers and system vendors. The group works with GS1 Healthcare, the Ministry of Health, Labour and Welfare and other institutions to promote standardization in order to ensure patient safety, secure traceability, and enhance the efficiency of distribution and medical management within the medical industry.

As of January 2017, GS1 Healthcare Japan consists of 105 members.

Activities

Within GS1 Healthcare Japan, members are actively engaged in the following two groups; the International Standards and Regulations Study Work Group and the Medical Solutions Study Work Group.

Activity of Each Work Group

International Standards and Regulations Study Work Group

- Research on the trends in international regulations and standardization

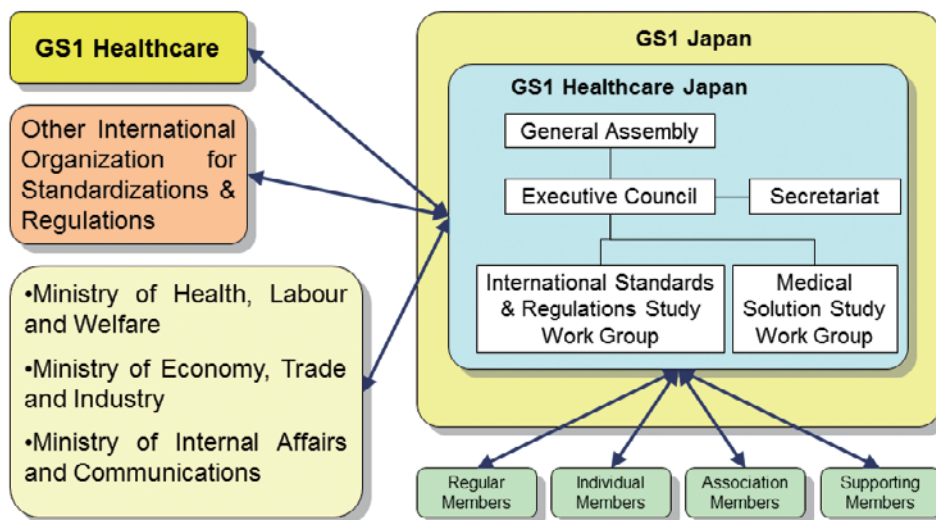
Medical Solutions Study Work Group

- Promotion of measures to improve safety and the supply chain efficiency in the medical industry

Topics in 2016/17

In the fiscal year 2016/17, GS1 Healthcare Japan actively promoted the use of GS1 standards in medical institutions. The group created a new brochure to

Fig. 3.3-1 Governing structure of GS1 Healthcare Japan



introduce GS1 standards to medical staffs. In addition to that, the group released two documents relating to barcoding on medical devices and direct part marking.

Fig. 3.3-2 New brochure



At the Global GS1 Healthcare Beijing Conference in October 2016, the Chairman of GS1 Healthcare Japan, Dr. Chikayuki Ochiai, M.D., D.M.Sc. gave a presentation titled “Implementation of Standardized Traceability System in Japan”.

In March 2017, an open seminar was held by GS1 Healthcare Japan following last year. Medical professionals who used GS1 Standard barcodes on medical devices and drugs gave lectures on their cases and the benefits they derived. More than 200 people attended the seminar including medical staffs, medical device/drug manufacturers, wholesalers.

Fig. 3.3-3 Open Seminar



3.4 ICT-Oriented Wholesale Industry

In 1985, we set up a study group aimed at promoting the computerization of the wholesale industry, with GS1 Japan as the Secretariat of the group. In Japan’s supply chain system, wholesalers play a major role, as most manufactured products are delivered to retailers through wholesalers.

The study group is operated primarily by wholesalers dealing in FMCG in different industries (foods, pharmaceutical products, etc.), and the membership is currently about 48 companies.

The group is further divided into several sub-working groups, according to themes related to the members’ interests, and each sub-working group holds monthly meetings. Other activities of the study group include an Annual Forum, which is the biggest event, and a “future solution study tour”.

With its mission of “Initiatives toward total optimization of Japanese distribution”,

The study group worked on the following 5 topics in FY2016.

- Promotion of wider adoption of Ryutsu BMS: Challenges and measures for total optimization
- Assumed response of wholesalers to 2016 invoicing (Response to reduced tax rate system)
- Cost reduction by improvement of distribution centers
- Joint efforts for creating an index of distribution services
- New IT utilization for “sales expansion”

Fig. 3.4-1 ICT-Oriented Wholesale Industry Forum



3.5 The Collaborative Council of Manufacturers, Wholesalers, and Retailers

The Collaborative Council of Manufacturers, Wholesalers, and Retailers was formally established in May 2011 for the purpose of improving the nation's industrial competitiveness, and of contributing to an affluent standard of living for the nation's citizens, through extensive innovations and improvements in supply chain management. The Council's Vision states the objectives of the activities of this collaboration by the retail supply chain stakeholders. Member companies can participate in the Council based on their endorsement and support of the Vision by their executive management, and an agreement to act while upholding the Vision.

GS1 Japan, and the Distribution Economics Institute of Japan, jointly serve as the Secretariat of the Council. Under the auspices of both Institutes, 15 founding member companies have participated in the Council, and have continued to hold preparatory meetings since May 2010. They have discussed the adoption of the Vision and how to manage the full-scale activities of the Council with the active support of the Ministry of Economy, Trade and Industry (METI). They have also established working groups and continued discussions on three specific themes: "Reducing Returns"; "Optimizing Deliveries"; and "Promoting the Introduction of a new EDI standard known as Ryutsu BMS". In May 2011, the founding companies announced the formal establishment of the Council in the "Collaborative Forum of Manufacturers, Wholesalers, and Retailers".

In FY2016, 3 working groups addressed the following topics:

Processed Food Working Group and Daily Commodity Working Group shared their efforts with industry groups and community organizations with the use of "Guidelines - how to promote reducing returns" and "Guidelines - how to promote shipping efficiency" that were created as a result of activities thus far, and promoted publicity and education campaigns. Reducing returns is also an important issue in terms of the demand in society for reducing food loss, particularly in the processed food industry. On the other hand, there are still many issues concerning returned products in the daily commodity industry, such as ambiguous return policies in new retail businesses, return of seasonal items, etc.

Product Information Multiple Languages Working Group built an actual data pool for multilingual products and an application for mobile terminals to access it, and

conducted field tests in stores. This data pool provides a common infrastructure linking manufacturing, distribution and sales to provide product information in many languages, and is being improved by analyzing the results of field tests for its practical use.

The Council reported its output at the "General Meeting" and The Collaborative Council of Manufacturers, Wholesalers, and Retailers now has a four-tier structure consisting of a general meeting, strategic meeting, steering committee, and working groups.

"The Forum of the Collaborative Council of Manufacturers, Wholesalers, and Retailers" will be held in July 2016. The executive management of each company has confirmed the responsibility for their activities, and will lead specific on-site improvements and innovations within the company.

Fig.3.5-1 General Meeting and Forum of The Collaborative Council of Manufacturers, Wholesalers, and Retailers



3.6 Information Systems in Food, Beverage, and Alcohol Industry

This study group is a voluntary group of liquor and processed food businesses established in 1983 with the aim of studying the most appropriate information systems for use between food producers and wholesalers. It is important for members to cooperate with wholesalers, as they are positioned between retailers and product manufacturers. Therefore, the study group has a system for continuous consultation with the Japan Processed Foods Wholesalers Association, a national organization of processed food wholesalers. The study group has about 60 corporate members that are representative of Japan's processed foods, marine products, and liquors businesses. GS1 Japan serves as the group's secretariat.

The study group conducts joint studies on new issues concerning standardization of B2B data exchanges among companies in the supply chain. It holds regular

meetings four times a year where best practices are introduced. It also organizes seminars on the latest topics by invited outside lecturers and study tours to pioneering businesses. The group also serves as a place for gathering and summarizing the opinions of those in the industry.

Fig. 3.6-1 Regular meetings



3.7 User support

For better understandings of GS1 standards, GS1 Japan offers users both various classroom style courses and distance e-learning courses. Followings are offered as scheduled courses:

- Introduction to Barcodes
- Introduction to EPC/RFID
- Introduction and Implementation of Ryutsu BMS
- Introduction to Barcode for Prescription Drugs and Medical Devices

3.7.1 Introduction to Barcodes

This scheduled program offers basic knowledge on GS1 barcodes accelerating GTIN usage and application. Classroom locations are Tokyo and Osaka and participants, mostly new members who want to learn

Fig. 3.7.1-1 Classroom of “Introduction to Barcodes”



about barcodes from the basic and to know how to display barcode to products, are expected to obtain general knowledge of barcodes. “On-site training” is also available accordingly upon applicant’s request at specified place and time.

In addition to the classroom courses above, e-learning program was introduced in 2016 enabling learners free from location and time constrain.

3.7.2 Introduction to EPC/RFID

This program targets EPC/RFID beginners in order them to obtain deeper understandings of the approach of its utilizations.

Classroom locations are Tokyo and Osaka, and participants are expected to learn about those characteristics of RFID, successful implementation case examples of EPC/RFID systems, GS1 EPC/RFID standards, and other related information.

After the lecture sessions, a demonstration will be carried out simulating shipping and receiving item check, conducting RFID batch reading.

Participants can also get hands-on experience of the simulation.

E-learning is also available with the title of “Guide to EPCIS System Construction,” which, we believe, will be of the help constructing individual system.

3.7.3 Introduction and Implementation of Ryutsu BMS

The program “Introduction of Ryutsu BMS” is to explain Ryutsu EDI from basics through to Ryutsu BMS outline, consequence of implementation and more.

This program is primarily intended for persons assigned newly to task of those in charge of operating ordering system, or studying Ryutsu BMS introduction at operation site or system management sectors. In addition, it is also useful for solution providers or consultants to support user organizations.

Main classroom locations are Tokyo and Osaka, and its e-learning version was launched in May 2017.

Next step program is also prepared as e-learning explaining key points how effectively introduce Ryutsu BMS complying with the standard specifications under the title of “Ryutsu BMS Implementation Course.”

3.7.4 Introduction to Barcode for Prescription Drugs and Medical Devices

This program provides practical knowledges about the guidelines released by the Ministry of Health, Labour and Welfare (MHLW), which specifies barcode marking rules for prescription drugs and medical devices. This program is designed for the people who are working at drug or medical device manufacturers, wholesalers, medical service providers and related solution providers, and the classroom is scheduled regularly in both Tokyo and Osaka.

3. Community Engagement and Standard Implement

Another but not least unique activity from GS1 Japan is the “Junior Intern” for middle and high school students. Throughout the several hours of lectures and trainings, the future GS1 users learn about barcodes and GS1 standards.

This program is supported by “Specified Non-profit Corporation - School Support Center” as one of their school support activities.

Taking the opportunity of school trip, students get a chance to learn business through actual scene and its social roles, soaking up the actual atmosphere of business at any of public institutions, government offices and private companies.

As one of the host organizations, GS1 Japan is trying to have them get much more familiar with barcodes through practical trainings with barcode readers in their hands.

This program has been well appreciated by the students.

We are even proud of finding their words “I was able to understand the usefulness of the barcodes” and “Now I feel I am more familiar with barcodes” in their reports.

Fig. 3.7.4-1 Students learning and experiencing scanning barcodes



3.8 Publications

GS1 Japan has been delivering information regarding GS1 system operations and domestic SCM related studies to retailers, wholesalers, products manufacturers, and Solution Providers, which, we believe, are beneficial to them. The information are published, and most of materials are also available on our website in order to promote GS1 standards . Followings are the examples of our current printed publications:

Addition to the above, we also issue two periodical publications that, in each issue, deliver information on the latest trends in distribution information systematizations, such as the GS1 Standards systems, barcodes, EDI, SCM, GS1 EPC/RFID and databases, as

Fig. 3-8-1 Guide to Barcodes for Beginners



Fig. 3-8-2 Barcode Guideline for UDI



Fig. 3-8-3 Revised Version of GTIN Allocation Guidelines



Fig. 3-8-4 Source Marking Guideline for Raw Materials



well as trends of industry standardizations, policies, and international standardizations.

Moreover, GS1 Japan creates educational videos including “Basics of JAN Code): JAN Code, Product Code for Assembled Packages,” “GS1-128 Barcode GS1 DataBar: Barcodes Containing Various Information,” “GS1 EPC/RFID Standards,” and “Ryutsu BMS, the Foundations of Growth.”

Besides the above videos, we also created many other informative educational videos which are mostly used during classroom programs. All the videos are available either on our website or DVDs.

3.9 Events

GS1 Japan organizes and sponsors various events. Major events are explained here below.

3.9.1 GS1 Japan Annual Seminar

The FY2016 GS1 Japan Annual Seminar was held on December 6 at Meiji Kinenkan with approximately 300 attendees from various organizations and corporations. Mr. Kazuo Narita, President of the leading drug store

chain Matsumotokiyoshi Co., Ltd. was invited as a guest speaker. He made the speech titled “Practical marketing for sales expansion” and addressed the company’s strategy. The company focuses on leveraging the Big Data and establishment of new business models such as “omni-channel retailing” and “vertical integration” to strengthen the company’s management capabilities.

Fig. 3.9.1-1 Mr. Narita, President of Matsumotokiyoshi Co., Ltd.



Fig. 3.9.1-2 Networking



3.9.2 GS1 B2C (Mobile) Seminar

This seminar shares trends of GS1 standardization activities and excellent use cases of leading domestic and foreign companies, and is targeted to mobile

Fig. 3.9.2-1 Mobile Seminar



marketing professionals in manufacturing and retail, and to system planners and developers of mobile devices including software services. The theme of GS1 B2C (Mobile) Seminar 2016 was “Omni-channel environment business innovation utilizing GS1 Standards - GS1 Standards implementation trends and excellent use cases by world leading companies,” and number of participants was counted to about 120.

3.9.3 EPC/RFID Forum

In June 2016, GS1 Japan and Auto-ID Lab (Keio University) hosted 12th EPC RFID FORUM attended by over 150 participants. This forum aims to raise public awareness and provide education on EPC/RFID systems.

We invited Mr. Ken Traub as a keynote speaker of the forum. He delivered a lecture on GS1 standards and EPCIS use cases. Ken was an inspiring visionary, teacher and mentor to many GS1 people and contributed in the development of numerous GS1 standards including EPCIS. We would like to express our deepest condolences to Ken.

Fig. 3.9.3-1 EPC/RFID Forum



Fig. 3-9-3-2 Mr. Ken Traub speaking at 12th EPC/RFID FORUM in Tokyo.



3.9.4 RETAILTECH JAPAN

RETAILTECH JAPAN is a trade show organized by Nikkei Inc. specializing in information systems in logistics, retail and foodservice, with over 200 exhibitors and more than 130,000 visitors. GS1 Japan is supporting the show as the Special Collaborator. GS1 Japan has a joint booth with the Supply Chain

Standards Management and Promotion Council to actively promote the Ryutsu BMS (see 2.2) and GS1 standards. GS1 Japan also holds one day seminar at the trade show and illustrates the latest trends in retail systems leveraging GS1 standards. The seminar was again well received and recorded more than 200 participants in this year.

Fig. 3.9.4-1 GS1Japan Booth



Fig. 3.9.4-2 GS1 Japan Seminar



4. Corporate Information

4.1 Overview

GS1 Japan was founded in 1972 mainly through the efforts of the then Ministry of International Trade and Industry (present Ministry of Economy, Trade and Industry or METI) as the Distribution System Research Institute (DSRI), a non-profit organization for promoting the introduction of distribution systems and rationalizing and increasing the efficiency of supply chains. At first, the institute conducted studies on the standardization of national product codes for apparel and grocery. Following the move towards standardized symbols as well as product codes in the U.S. and Europe, the institute started working to build a system for standardized product codes and symbols in Japan. Then in 1978, it applied for participation in EAN Association and was admitted as the first member except European countries.

In the second half of the 1970s, GS1 Japan paved a way to adopt EAN system in Japan, starting with the introduction of EAN symbols into the Japanese Industrial Standards (JIS). Source marking was tested with cooperation from Kikkoman Corporation (a soy sauce manufacturer), Coca-Cola Japan, Kai Corporation (a cutlery manufacturer), while retailers began to conduct storefront experiments with POS system.

In the 1980s, Jusco Co., Ltd. (present AEON Co., Ltd.), Co-op supermarket stores and other retailers conducted pilots on the POS system. GS1 Japan held many seminars on EAN system and POS system throughout Japan and encouraged stakeholders to adopt source marking.

The important milestone for the widespread use of source marking was the fact that, in 1982, Seven-Eleven Japan, a convenience store chain, adopted POS system at all of its stores (which totaled 1,650 at that time, but are about 12,800 at present). Another factor contributing to the diffusion of POS system was the introduction of consumption tax in 1989. GS1 Japan created study groups for several industries in the 1980s and worked together with these industries to study how to improve their business process using computer systems. These industries included processed foods, sporting goods, consumer electronics, and books and magazines. A study group of wholesalers was also established by organizing representatives from different industries. These study groups soon came to cooperate in the adoption of EAN standards.

In addition, it is worth noting that GS1 Japan started the service for collecting and providing POS data and began to operate the Japan Item Code File Service (JICFS), the product catalogue, as early as in the mid-1980s.

During the 1990s, GS1 Japan studied product codes, EDI messages and other subjects in cooperation with the apparel industry under METI-funded study of quick response (QR) system. Retailers used to assign their proprietary code to apparel products. Our joint study with the apparel industry led to the diffusion of EAN source marking on apparel products. It was also a landmark event when the GS1-128 was introduced for the labeling of crates containing various products delivered to department stores. The Japanese EDI messages, JEDICOS, based on the EANCOM was also completed around that time.

In the 2000s a new business model was established in Japan in which convenience stores acted as agencies for receiving public utility payments from customers. As the tool for realizing this service, the GS1-128 was adopted on the bills for the public utility charges. And the meat industry also decided to adopt the GS1-128 for its standard labels for traceability. The second half of 2000s was characterized by the fact that the GTIN began to be used for the online music service, an intangible product, and that Internet and mail order companies started to adopt the GTIN for their product management purposes. During the 2003-2009 period, GS1 Japan founded EPCglobal Japan and worked to solve the problems of introducing RFIDs tags into various industries (e.g., apparel, footwear, books, consumer electronics, international distribution) by supporting METI's RFID pilot programs and thus established the basis for the diffusion of RFID.

In 2009, GS1 Healthcare Japan was established as a voluntary group for promoting GS1 Standards in healthcare sector. This move can be regarded as the outcome of our pioneering activities after the late 1990s, including our publication of guidelines for the use of the GS1 System for medical devices in cooperation with the healthcare industry. In the area of EDI, GS1 Japan created an XMLformat EDI standard (Ryutsu BMS) for supporting domestic business practices and has worked to spread the standard together with 49 trade organizations. There have been new developments in several recent years. As public interest in food safety has increased, GS1 Japan started a joint study with Japanese supermarkets and supply

chain stakeholders on the use of GS1 DataBar including pilot testing of the symbol with discounted price or sell-by-hour information at retail stores

In 2015, GS1 Japan launched the programme “GS1 Japan Partners”, aiming to share information and best practices among solution providers.

4.2 GS1 JAPAN

GS1 Japan joined GS1 in 1978 and obtained the GS1 prefix “490 - 499”. We subsequently applied for an additional prefix in 1992, obtaining the prefix “450 - 459”.

Initially, GS1 Japan was allocating 7-digit GS1 Company Prefixes, but since January 2001, we have started to allocate 9-digit GS1 Company Prefixes, given the rise in the number of registered companies and a recommendation from GS1.

Currently, in principle, GS1 Japan allocates 9-digit GS1 Company Prefixes to new applicants. However, for companies with 50,000 or more product items, GS1 Japan allocates 7-digit GS1 Company Prefixes.

When a company continues to use the GS1 Company Prefix, it needs to renew the registration every 3 years. In the fiscal 2016, we had 11,812 new registrations.

As of the end of March 2017, the number of registrations for GS1 Company Prefixes reached 130,877.

Recently, sole proprietorships are leading the number of registrations, accounting for around 37% of the new registrations in the first half of fiscal 2016. That number compares to about 21% five years ago, recording a significant increase. Another trend to highlight is the

increase in applications to sell products on online shopping sites.

The top product categories for newly registered companies during the first half of fiscal 2016 were: 1) processed food (16%); 2) clothing (12%); 3) daily goods and sanitary health products (7%); 4) audio-visual contents (digital distribution, CDs, etc.) (6%); and 5) cosmetics (5%). Compared to past figures, it is notable that “clothing”, which is traded actively through online shopping sites, marked a large increase. It was also notable that many companies listed online-shopping business operators, such as Amazon, as their main clients.

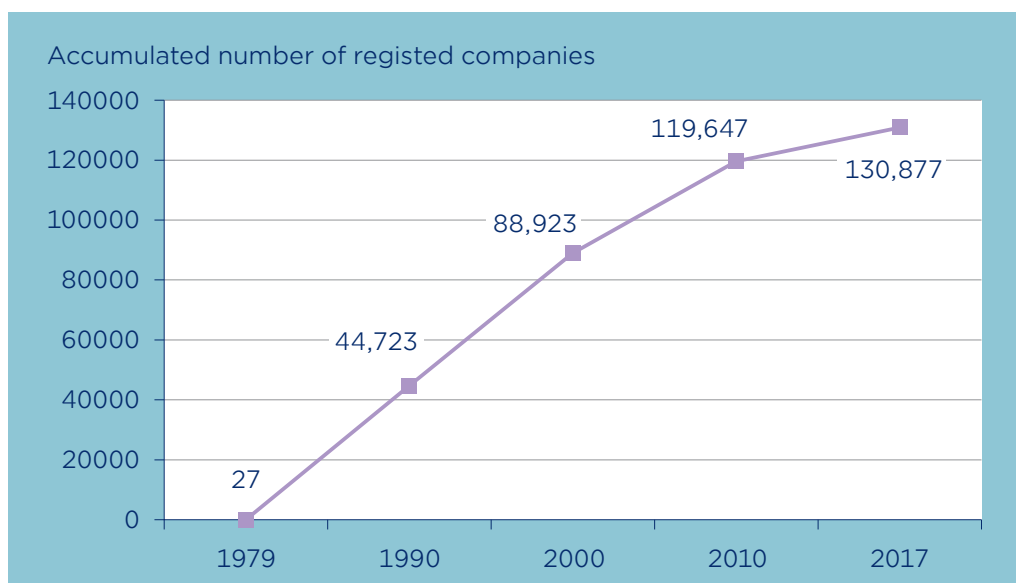
The other trend to highlight is the increase in registrations by producers of agricultural products, marine processed foods, and other local specialties aiming to expand their sales channels.

By source-marking their products, producers can distribute products through new sales channels such as Roadside Stations and outlets of agricultural products.

GS1 Japan offers seminars on a regular basis to promote the correct understanding of the GS1 standard, in addition to onsite seminars held across the nation when there is a request. Recently, the number of onsite seminars requested by the producers of agricultural products, marine processed food, and local specialties have increased, supporting the trend seen in the registration data.

We expect the registration for GS1 Company Prefixes will continue to increase, given the expansion of online sales channels as well as the spread of source-marking in areas such as clothing and professional goods, where the source-marking ratio used to be low.

Fig. 4.2-1 GS1 Company Prefix allocation



4.3 Chronology

- 1972 DSRI (Distribution Systems Research Institute) established.
- 1973 Supply chain information network models developed.
“Distribution and Systems Review” launched
- 1974 Uniform trade codes studied for each business category.
- 1975 Capacity building courses on Distribution systems started for both managers and system engineers
- 1977 Study Group for Supply Chain Information Systems established.
GS1 Japan established (Previous name: DCC Japan).
Allocation of common supplier codes started.
- 1978 Joined EAN International.
EAN/UPC Symbol became Japanese Industry Standard
Allocation of GS1 Company Prefix started.
- 1979 First POS pilot conducted at a supermarket in Tokyo.
- 1980 Japanese communication protocol for retail industry established.
POS pilots conducted at AEON, Nada Coop.
-
- 1981 POS pilot conducted at a voluntary chain (SME).
- 1982 “DCC Japan Newsletter” published.
7-11 Japan (convenience store) introduced POS.
- 1983 Low-interest financing for POS introduction provided to small and medium retailers by government.
- 1984 Study Group for Information System in Food, Beverage, and Alcohol Industry established.
Study Group for ICT-Oriented Wholesale Industry established.
- 1985 Ryutsu POS Database Service (RDS) Project started.
JICFS (Jan Item Code File Service) Project started.
- 1986 Ito-Yokado (GMS) introduced POS.
Sporting Goods Information System Study Group established.
- 1987 Barcoding in magazine Industry started.
ITF symbol become Japan Industrial Standard.
Utility bills collection service system using multiple EAN-13 symbols established.
- 1988 Standard EOS system using GTIN-13 established.
EAN International General Assembly held in Tokyo.
UPC Company Prefix application service started.
- 1989 Consumption tax introduced.
Research and pilots of POS for small retailers located in shopping street
- 1990 Barcoding in Book Industry.
-
- 1991 Multi-functional cards for regional shopping streets developed.
Daiei (GMS) adopts EAN codes for all products.
- 1993 Heiwado (supermarket in Western Japan) adopts ITF.

1994	SCM (Shipping Carton Marking) /ASN (Advance Shipping Notice) with GS1-128 used for SCM label system guideline published.
1995	In addition to GS1 Prefix "49", allocation of GS1 Company Prefix starting with "45" started.
1996	Study for computerization of trade for perishables started.
1996	Open Business Network (OBN) system developed. Code-128 symbol become Japanese Industrial Standard.
1997	CRP (continuous replenishment program) tested at Heiwado. Japanese version of EANCOM established.
1999	Study and Pilot for Supply Chain Promotion for Efficient and Effective Distribution System Allocation of GLN started
2001	9-digit GS1 Company Prefix introduced.
2002	EAN International's Asia Pacific Regional Meeting held in Tokyo.
2003	GEPIR operation started. EPCglobal subscription started. Japanese Industry Standard for GS1 Application Identifier established.
2004	RFID tags for ladies' shoes used at Mitsukoshi Department Store.
2005	Guidelines for Barcoding Pharmaceuticals with GS1 standard published. Promotion of GTIN started
2006	GTIN adopted for online sales of music products. EPCglobal Board of Governors Meeting held in Tokyo.
2007	Ryutsu BMS (Japanese XML-EDI Message Standards) published. GS1 Mobile Conference held in Tokyo GS1 DataBar Study Group launched.
2008	GS1 Healthcare conference held in Tokyo. Internet shopping company utilizes JICFS/IFDB.
2009	Supply Chain Standard Management & Promotion Council established. GS1 Healthcare Japan established.
2010	Pilot for utilization of GS1 Data Bar in supermarkets Mobile Day Seminar held in Tokyo
2011	Mobile Day event held in Tokyo
2012	GS1 Advisory Council Meeting held in Tokyo
2013	GS1 Japan celebrates GS1 40th anniversary GS1 B2C mobile and omni channel Seminar held in Tokyo
2014	GS1 Healthcare Japan UDI and medicinal drug traceability Seminar held in Tokyo
2015	GS1 Japan Partners was established
2017	Published Source Marking Guideline for Raw Materials

5. Reference

5.1 Statistics on Japanese Retail Industry

Table 5.1-1 Number of Stores, Number of Employees, and Annual Sales by Type of Stores (As of 2014)

	Number of Stores		Number of Employees		Sales (¥Million)	
		Composition Ratio (%)		Composition Ratio (%)		Composition Ratio (%)
Department Stores	195	0.0	66,683	1.1	4,922,646	4.0
General Supermarkets	1,413	0.2	265,956	4.6	6,013,777	4.9
Specialty Supermarkets (Apparel)	8,594	1.1	130,006	2.2	2,189,240	1.8
Specialty Supermarkets (Grocery)	14,768	1.9	748,815	12.9	15,375,413	12.6
Specialty supermarkets (Home furnishing)	8,712	1.1	213,088	3.7	4,803,833	3.9
Convenience Stores	35,096	4.5	537,618	9.3	6,480,475	5.3
Drugstores	14,554	1.9	187,442	3.2	4,300,305	3.5
Other Supermarkets	45,154	5.8	331,445	5.7	4,537,507	3.7
Specialty Stores (Apparel)	95,754	12.4	364,941	6.3	5,728,829	4.7
Specialty Stores (Grocery)	151,950	19.6	677,392	11.7	7,390,328	6.0
Specialty Stores (Home furnishing)	373,227	48.1	2,020,596	34.8	49,338,306	40.4
Large Specialty Stores (Electronics)	2,382	0.3	81,489	1.4	4,458,503	3.6
Other Retail Stores	1,049	0.1	5,088	0.1	203,237	0.2
Non-Store Retailers	22,348	2.9	180,366	3.1	6,434,326	5.3
Total (Scope of Calculation by Type of Stores)	775,196	100	5,810,925	100	122,176,725	100

(*1) "Employees" refers to "workers/temporary employees that are loaned/dispatched to other locations" taken out of "temporary employees" and "workers that are loaned/dispatched from other locations" added to "workers". "Workers" are the total of "private business owners", "unpaid family workers", "paid officers", and "full-time employees" and do not include temporary employees.

The source : Census of Commerce in 2014 Report by Type of Store (Retail Trade)
Ministry of Economy, Trade and Industry of Japan

Table 5.1-2 Top 20 Wholesale Companies in Japan (As of 2015)

2014	2013	Company Name	Location of Head Office	Annual Sales (¥Million)	Annual Growth (%)	Business Line
1	1	Medipal Holdings Corporation	Tokyo	3,028,187	5.4	Drugs
2	2	Alfresa Holdings	Tokyo	2,576,405	6.4	Drugs
3	3	Mitsubishi Shokuhin	Tokyo	2,383,064	2.0	Grocery
4	4	Suzuken	Aichi	2,228,331	13.1	Drugs
5	5	Nippon Access	Tokyo	1,899,413	6.5	Grocery
6	6	Kokubu	Tokyo	1,638,220	2.2	Grocery
7	7	Toho Holdings	Tokyo	1,308,474	12.6	Drugs
8	8	Kato Sangyo	Hyogo	926,090	20.0	Grocery
9	9	Mitsui Foods	Tokyo	792,869	5.2	Grocery
10	11	Arata	Tokyo	676,743	5.9	Sundry Goods/Medical Supplies
11	12	Itochu Shokuhin	Osaka	653,016	5.7	Grocery
12	10	Nihon Shuppan Hanbai	Tokyo	639,893	-3.2	Books/Audio/Video/Music Instruments
13	13	Vital KSK Holdings	Tokyo	621,040	13.3	Drugs
14	14	Nihon Shurui Hanbai	Tokyo	543,426	8.0	Grocery
15	15	Tohan	Tokyo	488,362	-1.4	Books/Audio/Video/Music Instruments
16	16	Forest Holdings	Oita	462,920	11.0	Drugs
17	-	Asics	Hyogo	428,496	-	Sporting Goods
18	17	Asahi Shokuhin	Kochi	414,784	6.9	Grocery
19	18	YAMAE HISANO	Fukuoka	368,708	5.6	Grocery
20	20	Starzen	Tokyo	303,402	7.4	Grocery

The source : The Nikkei Marketing Journal

Table 5.1-3 Top 20 Retail Companies in Japan

(As of 2015)

2015	2014	Company Name	Type of Business	Annual Sales (¥Million)	Growth (%)
1	1	Aeon	Holding Co.	8,176,732	15.5
2	2	Seven & I Holdings	Holding Co.	6,045,704	0.1
-	-	Aeon Retail	Supermarket	2,177,100	2.8
3	4	Fast Retailing	Holding Co.	1,681,781	21.6
4	3	Yamada Denki	Specialty Store	1,612,735	-3.1
-	-	Ito-Yokado	Supermarket	1,289,586	0.3
5	5	Isetan Mitsukoshi Holdings	Holding Co.	1,287,253	1.2
6	6	J. Front Retailing	Holding Co.	1,163,564	1.2
7	7	UNY Group Holdings	Holding Co.	1,038,733	1.9
8	10	Amazon Japan*	Online Retailer	999,900	19.0
9	8	Takashimaya	Department Store	929,587	1.9
10	9	H2O Retailing	Holding Co.	915,690	8.4
-	-	Sogo-Seibu	Department Store	803,443	0.1
11	11	Bic Camera	Specialty Store	795,368	-4.5
-	-	Seven-Eleven Japan	Convenience Store	793,661	7.8
-	-	UNIQLO	Specialty Store	780,139	9.0
-	-	UNY	Supermarket	757,941	1.6
12	12	EDION	Specialty Store	692,087	0.1
13	15	Don Quijote Holdings	Holding Co.	683,981	11.7
14	13	Yodobashi Camera	Specialty Store	679,610	4.3
-	-	Mitsukoshi Isetan	Department Store	679,085	3.5
-	-	Daimaru Matsuzakaya Department Stores	Department Store	677,511	0.9
15	17	Izumi	Supermarket	668,783	15.4
-	-	United Super Markets Holdings	Holding Co.	663,798	-
16	14	K's Holdings	Specialty Store	644,181	1.1
17	16	Life Corporation	Supermarket	629,985	7.5
18	19	Lawson	Convenience Store	583,452	17.2
19	18	SHIMAMURA	Specialty Store	547,022	6.7
20	20	Matsumotokiyoshi Holdings	Specialty Store	536,052	10.4

A company with a hyphen (-) in the rank column is a consolidated subsidiary whose parent company is included in the top 500 list.

(*) The annual sales of Amazon Japan is calculated at the annual average exchange rate.

The source : The Nikkei Marketing Journal

Table 5.1-4 Top 10 Convenience Store Chains in Japan

(As of 2015)

2015	2014	Name	Location of Head Office	Group	Annual Sales (¥Million)	Number of Stores
1	1	Seven-Eleven	Tokyo	Seven & I Holdings	4,291,067	18,572
2	2	Lawson	Tokyo	Mitsubishi Corporation	2,360,538	12,395
3	3	Family Mart	Tokyo	Itochu Group	2,005,580	10,834
4	4	Circle K Sunkus	Tokyo	UNY Group Holdings	936,710	5,991
5	5	Ministop	Chiba	Aeon	336,332	2,221
6	6	Daily Yamazaki	Tokyo	Independent	186,447	1,518
7	7	Seicomart	Hokkaido	Independent	184,775	1,180
8	8	NEWDAYS	Tokyo	East Japan Railway Company	101,909	502
9	9	Three F	Kanagawa	Independent	79,763	539
10	10	Poplar	Hiroshima	Independent	62,357	518

The source : The Nikkei Marketing Journal

5. Reference

Table 5.1-5 Sales by Type of Merchandise in Department Stores
(As of 2016)

Type of Merchandise	Total Sales (¥Million)	%
Apparel	1,893,306	31.7%
Accessories	779,934	13.0%
Household Goods	271,247	4.5%
Grocery	1,678,829	28.1%
Restaurant	162,891	2.7%
Sundry Goods	1,006,065	16.8%
Service	63,632	1.1%
Others	122,109	2.0%
(Shopping Gift Cards) *	-162,758	-
Total Sales	5,978,014	100.0%

(*The sales of shopping gift cards are not included in the total sales.)
The source : Japan Department Stores Association

Table 5.1-6 Sales by Type of Merchandise in Chain Stores
(As of 2016)

Type of Merchandise	Total Sales (¥Million)	%
Grocery	850,773	65.2%
Apparel	111,171	8.5%
Sundry Goods	106,498	8.2%
Drugs & Cosmetics	37,916	2.9%
Furniture & Home Furnishing	62,476	4.8%
Home Electrical Apparatus	13,321	1.0%
Other living goods	41,809	3.2%
Service	3,598	0.3%
Others	76,704	5.9%
Total Sales	1,304,265	100.0%

The source : Japan Chain Stores Association
(57 member companies and 9,489 stores)

Table 5.1-7 The Growth of E-Commerce Market in Japan (As of 2015)

Type of Merchandise		2014		2015		
		Scale (¥Billion)	EC Ratio	Scale (¥Billion)	Growth (%)	EC Ratio
Retail	Grocery	11,915	1.89%	13,162	10.5%	2.03%
	Electrical Products	12,706	24.13%	13,103	3.1%	28.34%
	Books, Videos, Music	8,969	19.59%	9,544	6.4%	21.79%
	Drugs & Cosmetics	4,415	4.18%	4,699	6.5%	4.48%
	Furniture, Household Goods	11,590	15.49%	12,120	4.6%	16.74%
	Apparel & Accessories	12,822	8.11%	13,839	7.9%	9.04%
	Automobile, Automobile Parts	1,802	1.98%	1,874	4.0%	2.51%
	Office Supplies, Stationeries	1,599	28.12%	1,707	6.8%	28.19%
	Other	2,227	0.56%	2,348	5.5%	0.63%
Total (Retail)		68,043	4.37%	72,398	6.4%	4.75%
Service	Tourism	26,304	-	28,850	9.7%	-
	Restaurants	1,764	-	2,379	34.9%	-
	Tickets	3,300	-	3,750	13.6%	-
	Financial Services	6,318	-	6,192	-2.0%	-
	Beauty & Barbour Services	7,131	-	2,420	-	-
	Other (Healthcare, Insurance, Beauty & Barbour, Residence, Education)		-	5,423	-	-
Total (Service)		44,816	-	49,014	9.4%	-
Digital	Electronic Publishing (E-Books, E-Magazines)	1,276	-	1,771	38.8%	-
	Music Distribution Service	437	-	471	7.7%	-
	Video Distribution Service	630	-	650	3.2%	-
	Online Games	12,045	-	12,647	5.0%	-
	Others	723	-	796	10.0%	-
Total (Digital)		15,111	-	16,334	8.1%	-
Total		127,970	-	137,746	7.6%	-

The source : METI (Ministry of Economy, Trade and Industry) "Research on Infrastructure Development in Japan's Information-based Economy Society (E-Commerce Market Survey)"

The EC ratio in this survey refers to the ratio of the e-commerce market scale against the total amount of the overall commercial transactions.

Table 5.1-8 Top 20 E-Commerce (B2C) Players in Japan

(As of 2015)

	Company Name (Website)	Annual Sales (¥Million)	Annual Growth (%)	EC Ratio	Line of Goods	Account Closing Month
1	Amazon Japan (amazon.co.jp)	999,900	20.4	100%	General	Dec
2	Yodobashi Camera (yodobashi.com)	99,200	25.6	100%	Home Electrical Apparatus	Mar
3	Senshukai (bellemaison.jp)	77,479	-6.8	78%	General	Dec
4	Dinos Cecile (dinos.co.jp)	59,715	4.6	53%	General	Mar
5	Joshin Denki (joshinweb.jp)*	55,000	-	100%	Home Electrical Apparatus	Mar
6	Start Today (zozo.jp)	54,422	32.1	100%	Apparel	Mar
7	Nissen (nissen.co.jp)	51,682	-16.2	61%	General	Mar
8	Dell (dell.co.jp)*	48,000	-	100%	PC	Jan
9	Ito-Yokado (www.itoyokado.co.jp)	46,890	10.3	100%	Grocery	Feb
10	Kitamura (kitamura.co.jp)	41,900	-2.6	100%	Camera-Related Equipments	Mar
11	Japanet Takata (japanet.co.jp)*	40,000	-	25%	Home Electrical Apparatus	Dec
12	Jupiter Shop Channel (shopch.jp)*	34,900	-	25%	General	Mar
13	Bic Camera (biccamera.com)	34,800	-0.6	100%	Home Electrical Apparatus	Aug
14	ASKUL (lohaco.jp)	32,845	64.7	100%	Daily Necessities	May
15	Fast Retailing (fastretailing.com)	32,409	27.9	100%	Apparel	Aug
16	QVC Japan (qvc.jp)*	28,890	0.3	30%	General	Dec
17	MouseComputer (mouse-jp.co.jp)	28,843	1.7	100%	PC	Mar
18	Soukai-Drug (soukai.com)*	26,000	24.5	100%	Health-Related Goods	Mar
19	MOA (a-price.co.jp)	25,200	-9.7	100%	Home Electrical Apparatus	Jun
20	ORBIS (orbis.co.jp)*	25,040	6.0	44%	Cosmetics/Health Foods	Dec

The source : Kouibunshuppan

(*: Estimate)

Table 5.1-9 Number of Vending Machines and Annual Sales in Japan

(As of 2015)

Machine Type	Line of Goods	Number of Machines			Annual Sales (¥Million)			
		2014	2015	y/y	2014	2015	y/y	
Vending Machines	Beverages	Soft Drinks	2,203,000	2,188,000	99.3%	1,872,550	1,822,604	97.3%
		Milk	164,000	161,000	98.2%	139,400	134,113	96.2%
		Coffee, Cocoa (Cup)	175,000	174,000	99.4%	147,000	143,202	97.4%
		Alcoholic Drinks	26,600	25,700	96.6%	34,580	33,410	96.6%
		Total (Beverages)	2,568,600	2,548,700	99.2%	2,193,530	2,133,329	97.3%
	Foods	Instant Noodle, Frozen Food, Ice Cream etc.	69,600	69,400	99.7%	54,288	54,132	99.7%
	Total (Beverages and Foods)		2,638,200	2,618,100	99.2%	2,247,818	2,187,461	97.3%
	Cigarette-Vending Machine		234,000	212,400	90.8%	327,438	255,603	78.1%
	Tickets	Boarding Ticket	14,400	15,200	105.6%	1,450,080	1,454,108	100.3%
		Food, Entrance and Other Tickets	28,500	32,600	114.4%	318,051	374,719	117.8%
		Total (Tickets)	42,900	47,800	111.4%	1,768,131	1,828,827	103.4%
	Sundry Goods	Prepaid and Other Cards	721,500	721,900	100.1%	413,371	413,600	100.1%
		Other (Newspapers, Sanitary Goods, Toys etc.)	141,100	139,000	98.5%	54,178	53,372	98.5%
Total (Sundry Goods)		862,600	860,900	99.8%	467,549	466,972	99.9%	
Total (Vending Machines)		3,777,700	3,739,200	99.0%	4,810,935	4,738,863	98.5%	
Service	Money Changer	59,200	59,500	100.5%	-	-	-	
	Rental Service	17,700	17,000	96.0%	-	-	-	
	Coin-Operated Lockers, Checkout Machines etc.	1,181,000	1,186,000	100.4%	141,720	142,320	100.4%	
	Total (Automated Service Machines)		1,257,900	1,262,500	100.4%	141,720	142,320	100.4%
Total		5,035,600	5,001,700	99.3%	4,952,655	4,881,183	98.6%	

The source : Japan Vending Machine Manufacturers Association

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