

Japan

GS1 Digital Link helps deliver valuable e-leaflet information to healthcare providers and patients

Challenge

In November 2019, amendments were made by the Japanese government to the Pharmaceuticals and Medical Devices Act (PMDAct) with the aim to enhance patient safety. One amendment called for the transition from paper-based to electronic leaflets (e-leaflets) for pharmaceuticals and medical devices.

Approach

Nearly all pharmaceutical marketing authorisation holders (MAHs) have completed the registration process to link the GS1 Global Trade Item Number® (GTIN®) encoded in the GS1 barcode on the product's package to the product's e-leaflet on the Pharmaceuticals and Medical Devices Agency (PMDA) website. Healthcare providers and patients can scan a product's GTIN in the barcode and GS1 Digital Link directs them to product's e-leaflet on the PMDA website. For medical devices, some of the manufacturers have registered their e-leaflets on the PMDA website. Linking the GTINs is now in progress with the goal to complete the process in two years.



Most up-to-date information about pharmaceuticals and medical devices



Immediate access to critical product information for healthcare providers and patients



Eliminates paper waste for increased sustainability



Improves patient safety with simple scan of a product's barcode

Advancing patient safety

Today, all secondary packages of pharmaceutical products and medical devices contain paper leaflets for use by healthcare providers, and this leaflet information is registered on Japan's PMDA website.

One of the PMDA amendments specifically mandated that pharmaceutical and medical device manufacturers and other types of marketing authorisation holders (MAHs) would need to transition from paper-based to e-leaflets (Over-the-counter drugs and medical devices are out of scope.) Each product's e-leaflet would need to be accessible via a barcode on the product's package—a barcode that healthcare providers and patients could scan to easily read the latest e-leaflet's information on the website.

As early as 2006, GS1 standards have been promoted by Japan's Ministry of Health, Labour and Welfare (MHLW) as the only standards for the unique identification of pharmaceuticals and medical devices. The unique product identifier—the Global Trade Item Number—is encoded in GS1 barcodes such as the GS1 DataBar and GS1-128 for pharmaceuticals and the GS1-128 and GS1 DataMatrix barcodes for medical devices.

Today, 100% of pharmaceuticals' packages have GS1 barcodes—from primary packages (e.g., vials and blisters) to tertiary packages. For medical devices, more than 95% have barcodes on secondary packages and most high-risk medical materials such as catheters and orthopedic products have barcodes applied on primary packages.

Mr. Masayuki Muraoka, the Ministry's Deputy Director, Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau is responsible for leading Japan's barcoding strategy of pharmaceuticals and medical devices.

“There were several advantages of using GS1-based barcodes. For example, one of the benefits is that GS1 barcodes can be used on the product's multiple layers of packaging—not just on secondary packages,” explains Mr. Muraoka. “This precise level of identification ensures that pharmaceutical products can be scanned in various scenarios by healthcare providers and even patients, giving them critical information for patient safety.”

Problems with using paper

While paper leaflets describing the potential side effects and other important information are inserted in secondary packages, these inserts are frequently revised as new information becomes available. The use of electronic leaflets enables manufacturers and other MAHs to keep published information about products up-to-date—especially critical for high-risk drugs and medical devices.

Another important consideration was the Ministry’s goal to minimise the use of paper for a more environmentally friendly and sustainable approach. “We want to eliminate paper waste in favour of providing healthcare providers and patients with the latest information in a digital format,” says Mr. Muraoka.

“While QR codes were considered, the decision to use GS1 standards was made. “With GS1 standards already in place as a foundation, we knew it was possible to more easily extend the benefits of using standards to include e-leaflets.”

Mr. Masayuki Muraoka,
Deputy Director, Pharmaceutical Safety Division, Pharmaceutical Safety & Environmental Health Bureau, Ministry of Health, Labour & Welfare



Figure 1: For pharmaceuticals, e-leaflets can be accessed from every type of package with a GS1 barcode.

Made possible by the GS1 Digital Link standard

As of August 2021, the vast majority of pharmaceutical manufacturers and some of the medical device manufacturers have completed the registration process to link the GTIN encoded in the GS1 barcode on the product’s package to the product’s e-leaflet on the PMDA website.

This is made possible with GS1 Digital Link standard. Healthcare providers and patients

alike can scan a pharmaceutical package’s GTIN in the barcode and the Digital Link’s URI directs them to product’s e-leaflet on the PMDA website.

For each product, there are three URIs:

- E-leaflet for healthcare providers
- Related information for healthcare providers
- E-leaflet (for pharmaceuticals only) for patients and consumers

| | |
|---|--|
| <p>E-leaflet for healthcare providers ></p> | <p>https://www.pmda.go.jp/PmdaSearch/bookSearch/01/04912345678904</p> |
| <p>Related information for healthcare providers ></p> | <p>https://www.pmda.go.jp/PmdaSearch/rdSearch/01/04912345678904?user=1</p> |
| <p>E-leaflet for patient and consumer: pharmaceuticals only ></p> | <p>https://www.pmda.go.jp/PmdaSearch/rdSearch/01/04912345678904?user=2</p> |

Figure 2: GS1 Digital Link uses the GTIN encoded in GS1 barcodes on packages to re-direct users to e-leaflets. The GTIN in Figure 2 is an example.

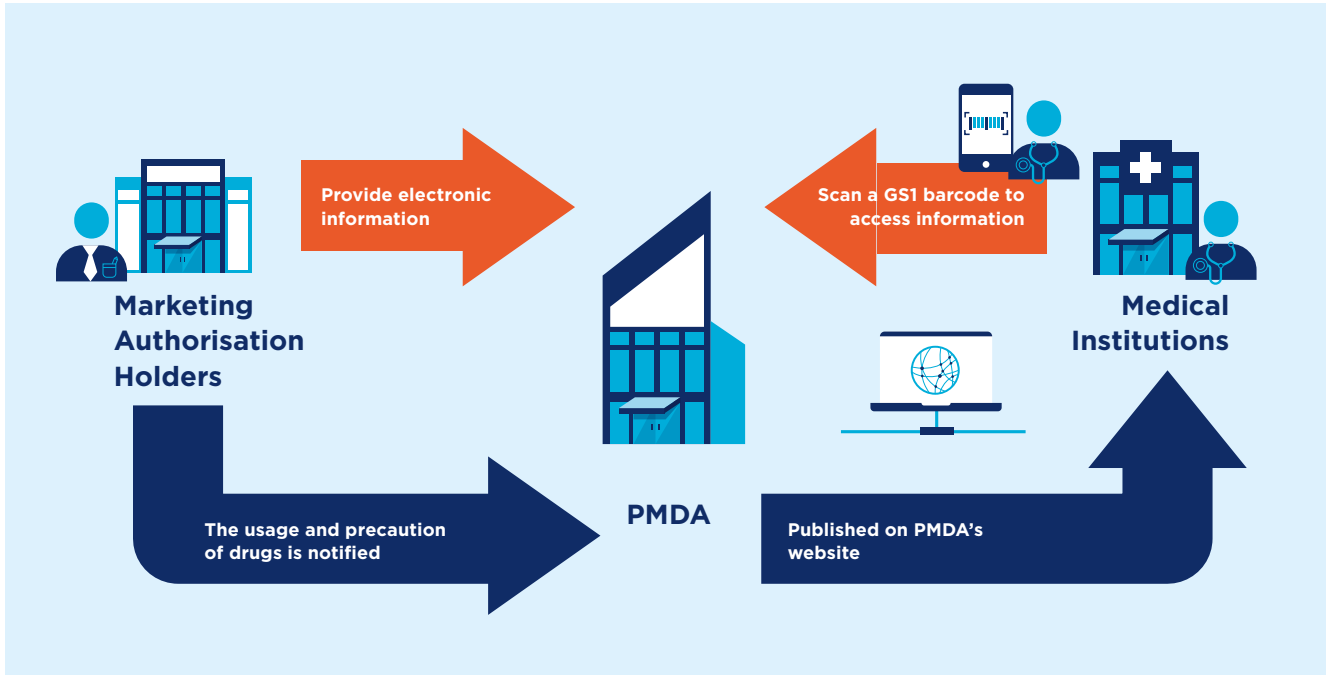
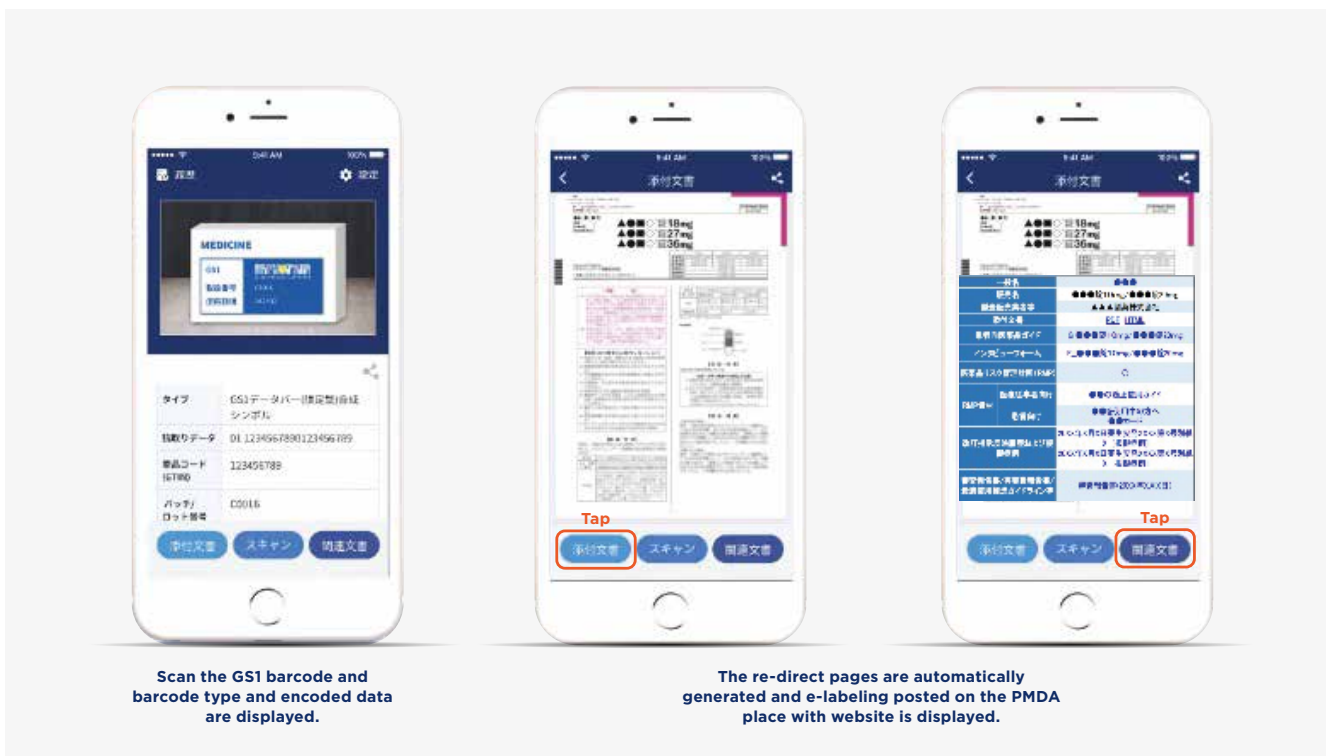


Figure 3: Now, healthcare providers and patients alike can scan a pharmaceutical package's barcode and the Digital Link's URI directs them to the PMDA website that then directs them to the product's e-leaflet.

Ease of scanning with a smartphone app

GS1 Japan in cooperation with the Federation of Pharmaceutical Manufacturer's Association of Japan (FPMAJ) and the Japan Federation of Medical Devices Association (JFMDA) developed a smartphone app called "Tenbun-Navi."

Available on the Apple App Store and Google Play, Tenbun-Navi is free to download and makes accessing e-leaflet information even easier. With the app, healthcare providers can use their smartphones and tablets (versus specialised scanning equipment) to scan barcodes and browse e-leaflets on the PMDA website.



Scan the GS1 barcode and barcode type and encoded data are displayed.

The re-direct pages are automatically generated and e-labeling posted on the PMDA place with website is displayed.

Figure 4: The Tenbun-Navi app makes e-leaflet information easily accessible via a smartphone or tablet. (<https://www.dsri.jp/standard/healthcare/tenbunnavi/app/index.html>)

Accessing COVID-19 vaccine information

The fact that all primary packages have GS1 barcodes, such as vials, ampules and blisters, provides significant benefits for healthcare providers. Now, healthcare providers can check e-leaflets via these GS1 barcodes at all points of care: pharmacies, hospital wards, theatres or nursing homes. Access to e-leaflet information is also expected to be beneficial during the COVID-19 pandemic. One of the vaccines supplied to Japan has a GS1 barcode on the primary package (vial), which can be scanned by healthcare providers to be directed to the e-leaflet and other related information.

On the path to patient safety

In Japan, the use of GS1 standards to identify, label and barcode healthcare products has been promoted by the Ministry and GS1 Japan and implemented by manufacturers for more than a decade.

Thanks to this promotion, most healthcare products have GS1 barcodes on many levels of packaging, even on primary packages. This foundation of GS1 standards helped make the change from paper to e-leaflets a much more efficient transition.

“With GS1 barcodes on the primary packages of pharmaceutical products and medical devices, GS1 standards are increasingly being recognised in Japan’s healthcare system as highly useful for improving patient safety as well as increasing operational efficiencies,” says Mr. Muraoka. “With the introduction of the GS1 standards, especially GS1 Digital Link, to support ease of access to e-leaflets, we anticipate that healthcare stakeholders like electronic health record companies will become more and more interested in the use of GS1 standards for benefits like traceability.”

Looking to the future, the Ministry along with manufacturers and healthcare providers will continue to leverage GS1 standards for the health and well-being of Japan’s people.

About the author



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Masayuki Muraoka is the Deputy Director, Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau with the Ministry of Health, Labour and Welfare. He is responsible for leading Japan’s barcoding strategy of pharmaceuticals and medical devices. Since 2012, Mr. Muraoka has held numerous government positions, most recently the Deputy Director of the Forestry Agency Administration and Deputy Director to the Assistant Chief Cabinet Secretary.

About the organisation



The Ministry of Health, Labour and Welfare (MHLW) is responsible for health policies and safety practices across Japan. MHLW functions also include labour standards, environmental policies and social assistance for children, families and the elderly.

www.mhlw.go.jp