

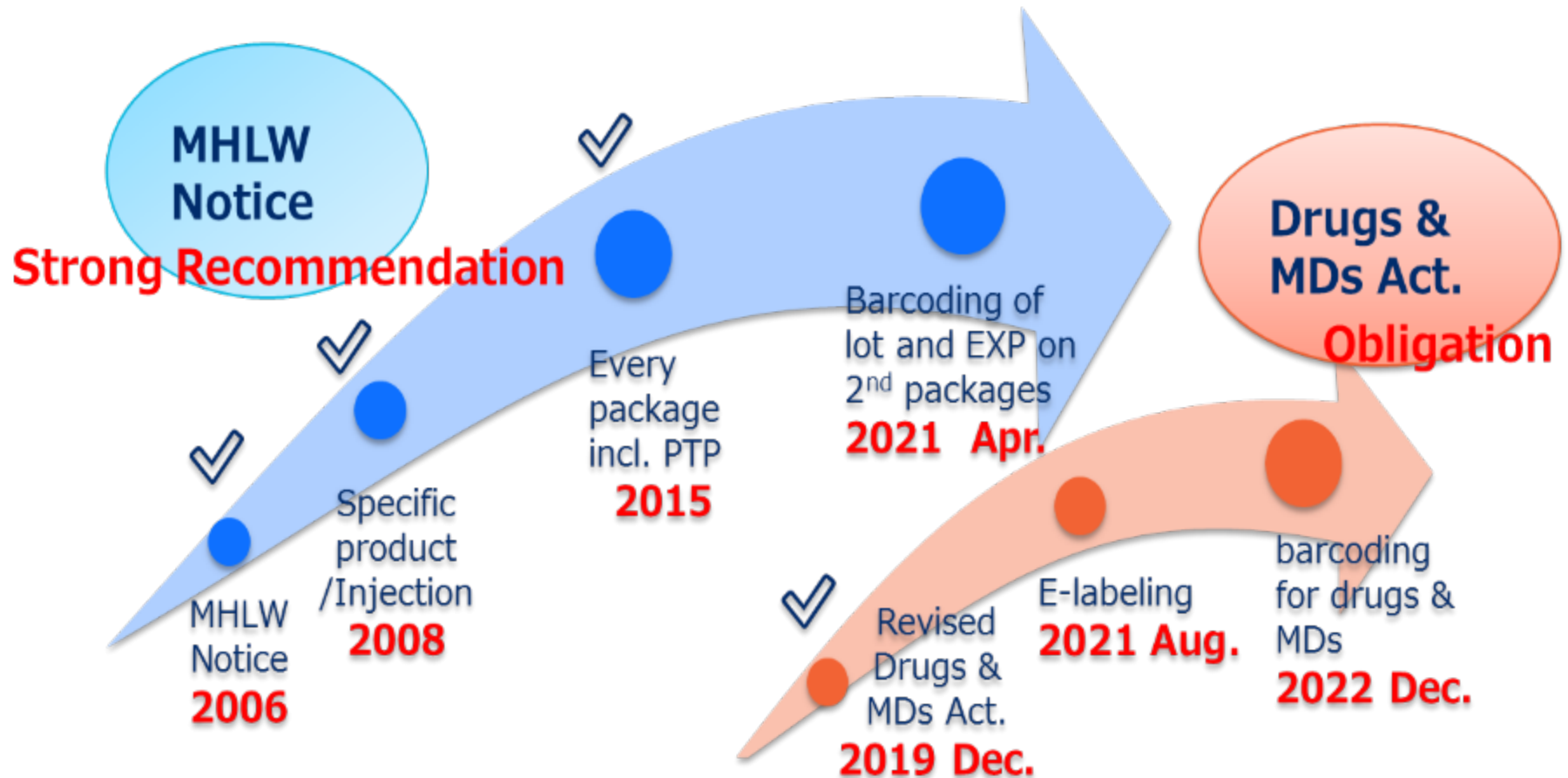
Barcoding of pharmaceuticals in Japan

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Barcoding of pharmaceuticals in Japan



Background and Main Theme of Revision of PMD Act

Background

Pharmaceuticals and Medical Devices Act (PMD Act)*: the regulation of medical products in Japan

* The Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical devices

- Mandatory review of the Act after the 5-years implementation (PMD Act was implemented in 2013)
- The review examines the results of the previous revision, trend of demography, innovation and future vision.
- Expert Committee in the Health Sciences Council started review discussion from April, 2018.
- The committee formulated the review report in December, 2018.

Main Theme

Three themes were discussed:

1. Ensuring early access to innovative pharmaceuticals & medical devices, and enhancing the safety measures
2. The role of community pharmacies and pharmacists, and the secure access to medicines
3. Enhancing the systems to ensure legitimate manufacturing, distribution and sales of pharmaceuticals & medical devices (Qualification and dismissal of officers, levy surcharge for company)

Main Points of Revised PMD Act

(1) Streamline of Approval Process for early patient access

- ① “Conditional Early Approval System” and “SAKIGAKE Review Designation” should be legislated to clarify process and raise transparency.
- ② New Approval system for Medical Devices to reflect the characteristics of medical devices (considering innovative technologies; Big Data, AI etc.,)
- ③ Clarification of clinical trials process and ensuring safety of subjects

(2) Introduction of new Quality Management System

- ① Introduction of GMP and GCTP inspection per manufactory
- ② Revision of current QMS inspection
- ③ Introduction of Change Management Method for approved products concerning Quality using PACMP

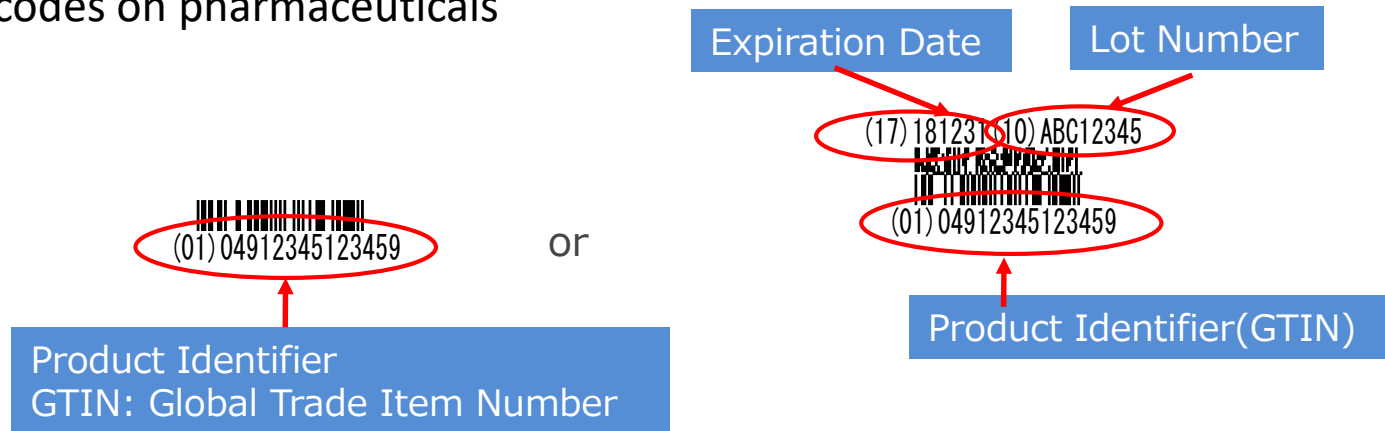
(3) Strengthen Safety Measures

- ① Provide electronic information of Package Inserts
- ② Increase traceability of pharmaceuticals and medical devices
- ③ Utilize Patient Registry Data For safety measure

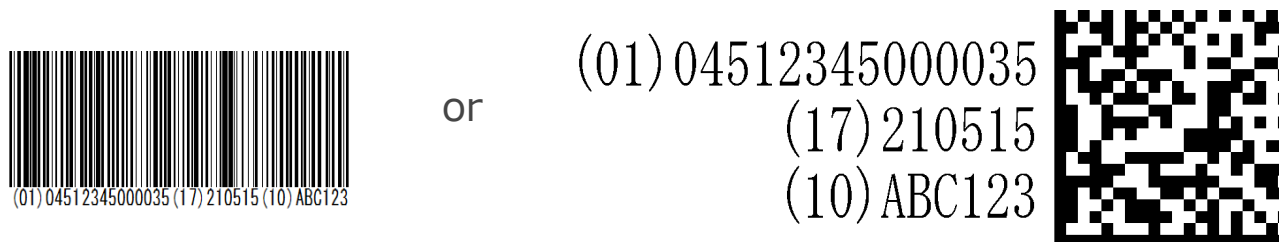
GS1 barcodes for patient safety

- A GS1 barcode is marked on every primary and secondary package
- The barcodes are used for the patient safety at medical facilities
 - To prevent medication errors
 - To make a secure traceability
 - To improve efficiency of dispensing, recording and accounting

○ Barcodes on pharmaceuticals



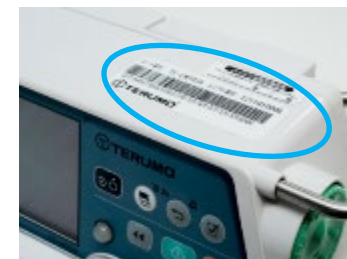
○ Barcodes on medical devices



Barcodes on pharmaceuticals and medical devices



For patient safety as well as efficiency of distribution



Barcodes for pharmaceuticals in Japan

Primary and Secondary packages Barcode: GS1 DataBar



Tertiary packages Barcode: GS1-128



Barcoding ratio of pharmaceuticals

		Barcoding ratio		
		primary	secondary	tirtiary
Specified biological products	GTIN	100.0%	100.0%	100.0%
	Attributes (lot & Exp)	100.0%	100.0%	100.0%
Biological products	GTIN	100.0%	100.0%	100.0%
	Attributes (lot & Exp)	22.3%	100.0%	100.0%
Oral medicines	GTIN	100.0%	100.0%	93.0%
	Attributes (lot & Exp)	0.6%	67.2%	90.0%
Injection	GTIN	100.0%	100.0%	94.4%
	Attributes (lot & Exp)	1.9%	72.8%	92.4%
Topical medication	GTIN	100.0%	100.0%	83.2%
	Attributes (lot & Exp)	0.9%	41.6%	76.8%

Surveyed on 2019 by MHLW
<https://www.mhlw.go.jp/content/10807000/000552688.pdf>

Barcoding ratio of medical devices

In addition to GTIN, the expiration date and lot are displayed as barcodes.
Barcodes are displayed in accordance with UDI regulations around the world.

	Primary	secondary
Medical devices (total)	88.9%	95.8%
Highly controlled MD	81.1%	97.6%
Specified medical materials	95.7%	97.7%
In vitro diagnostics	99.6%	99.8%

Surveyed on 2019 by MHLW

<https://www.mhlw.go.jp/content/10807000/000552712.pdf>

Barcode Scanning in Hospitals and pharmacies



Picking and checking of medicines



Mixing of infusion at wards

Preparation of anti-cancer drugs or vaccines



Barcode Scanning in Hospitals and pharmacies

Operating room



- GS1barcode are putted on most of items at the operating room.



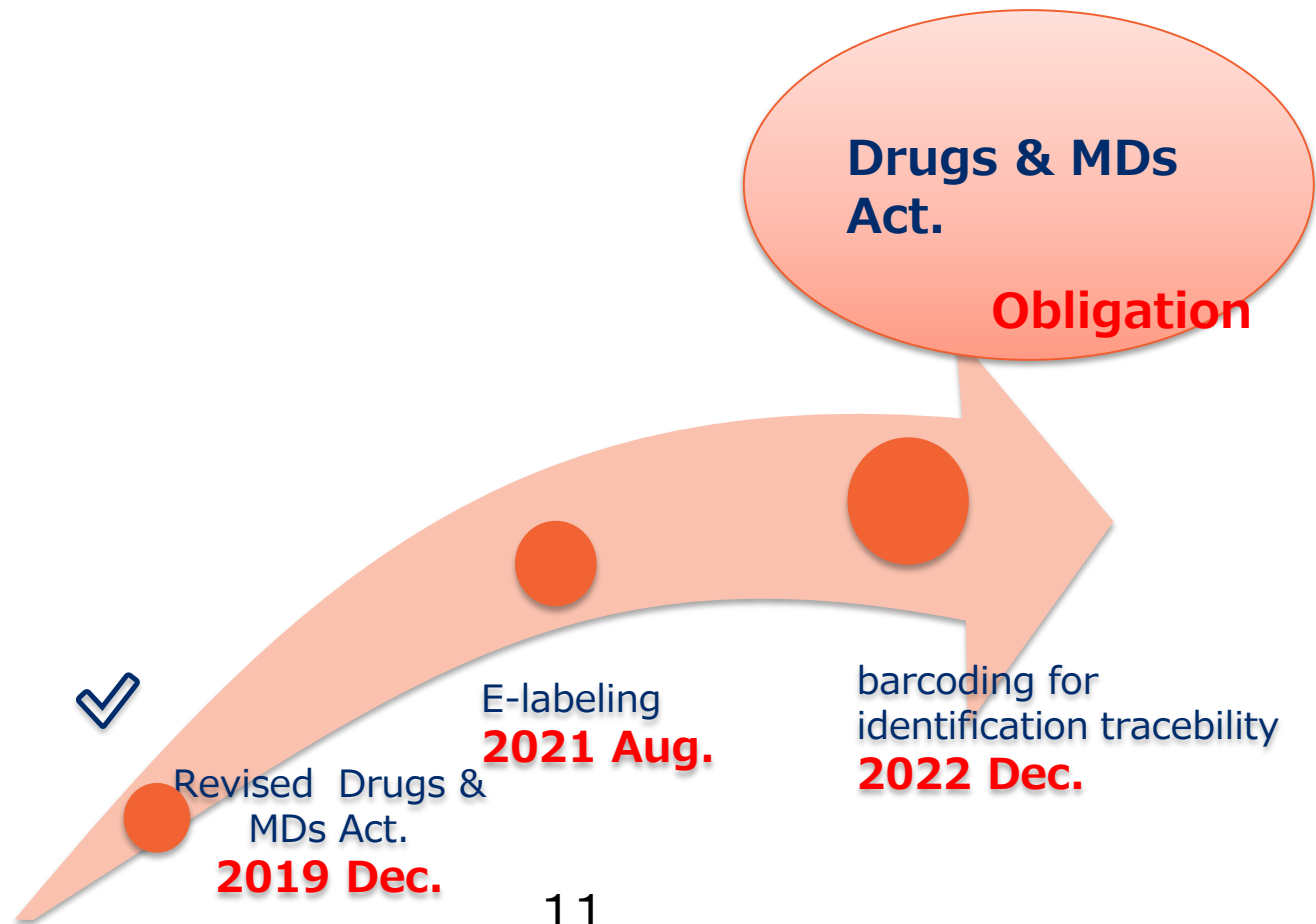
Medical center



- GS1 barcode are putted on most of items at the medical center.

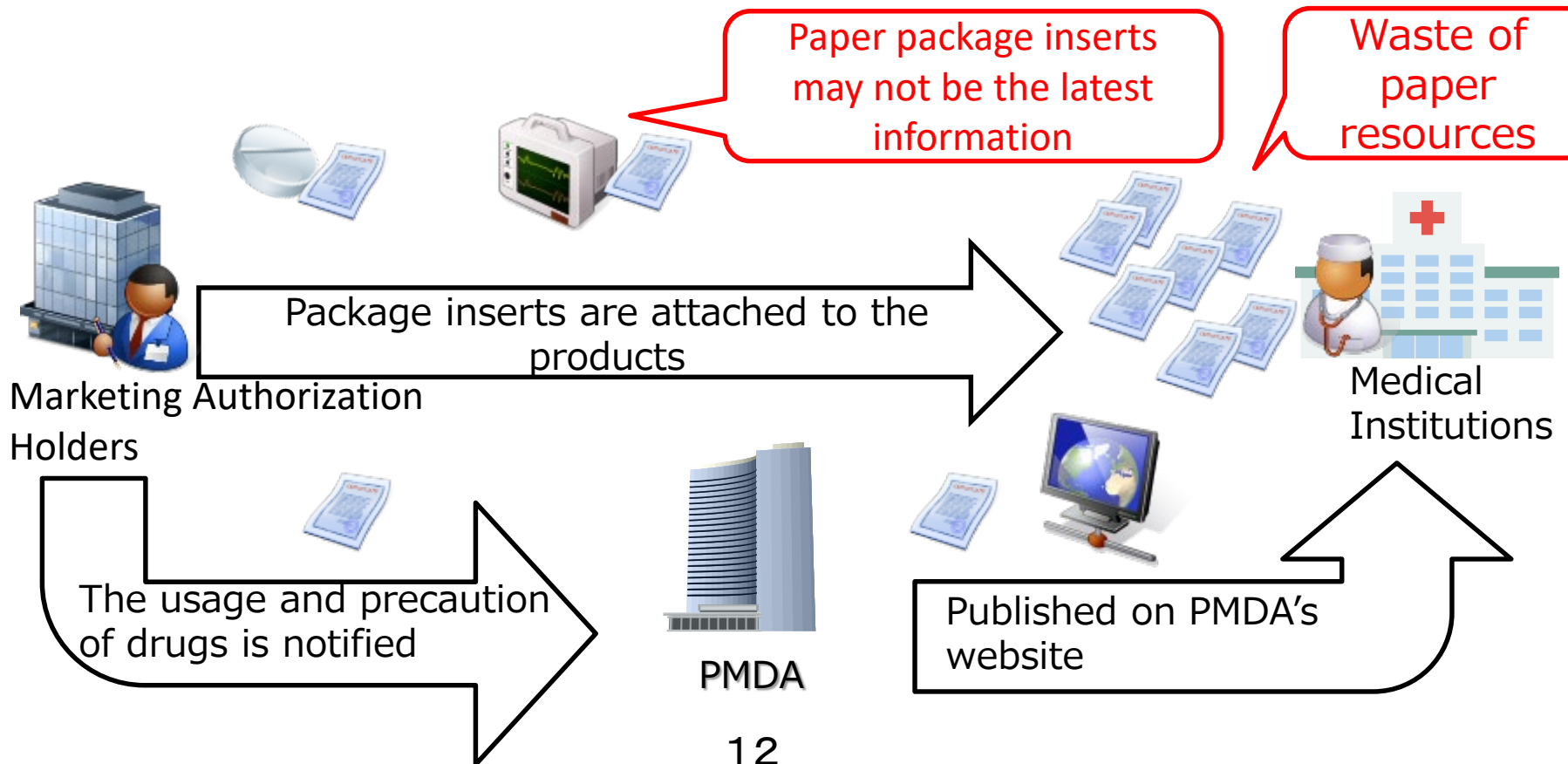
Partial revision of Regulation for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices

- Link to e-labeling on the PMDA database by scanning GS1 barcodes of secondary packages (sales packages) (Enforcement: 2021 August)
- Barcoding on secondary packages (sales packages) that displays lot and EXP for identification traceability on (Enforcement: 2022 December)



Current Issues

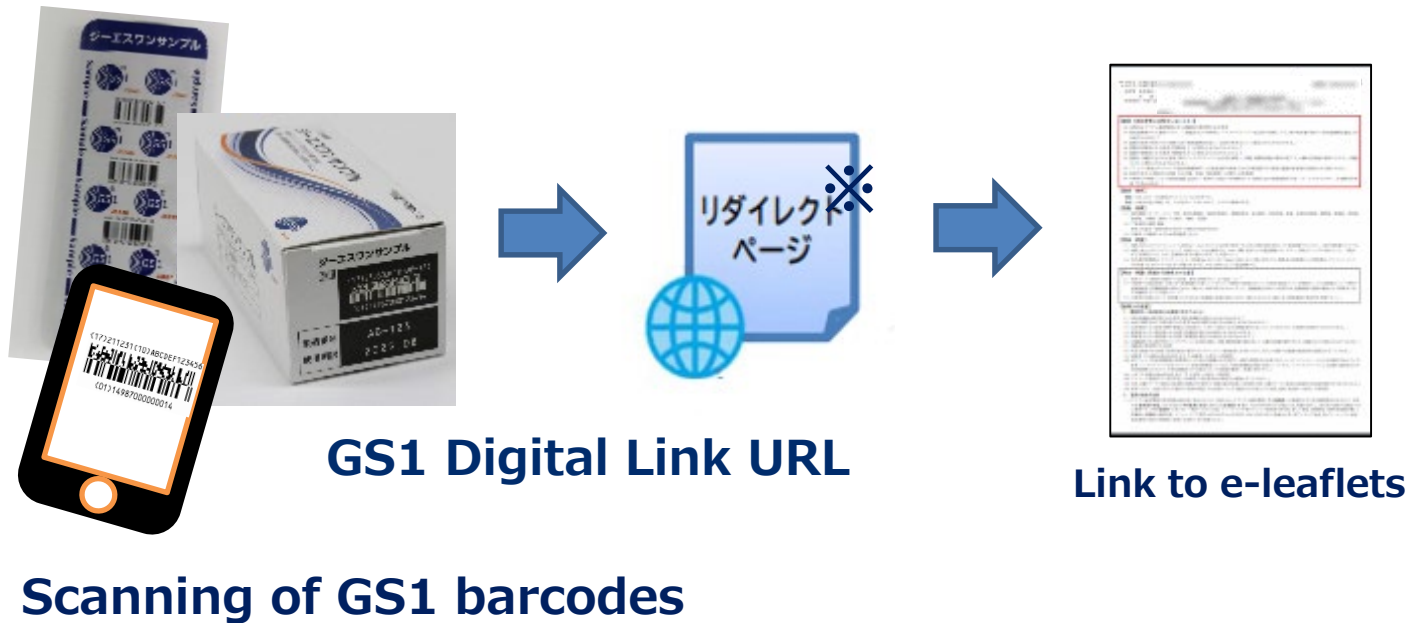
- Package inserts are frequently revised. Therefore, package inserts attached to the products may not be the latest information.
- Information provision with paper package inserts leads to waste of paper resources.



Main Feedbacks from the Council

- It is important to always have the latest information. Digitization should be promoted.
- It is important to provide information on paper at the time of initial and revision in anticipation of a disaster.
- Some doctors are not familiar with digitization. Some people need to have information in paper media.

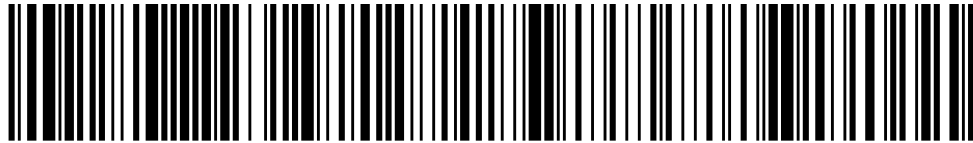
Link to e-labeling on the PMDA database by scanning GS1 barcodes of secondary packages (sales packages) (Enforcement: 2021 August)



Adoption of GS1 Digital Link

GS1 Digital Link format is used for access to re-direct page on PMDA database

Registration of GTIN and e-leaflet to PMDA Database
All pharmaceuticals and medical devices
By August 2021



(01)04912345678904(17)210515(10)ABCDF123456



(01)04912345678904(17)230501(10)ABC1234

GS1 Digital Link format for the redirect website of PMDA

<https://www.pmda.go.jp/PmdaSearch/bookSearch/01/04912345678904>

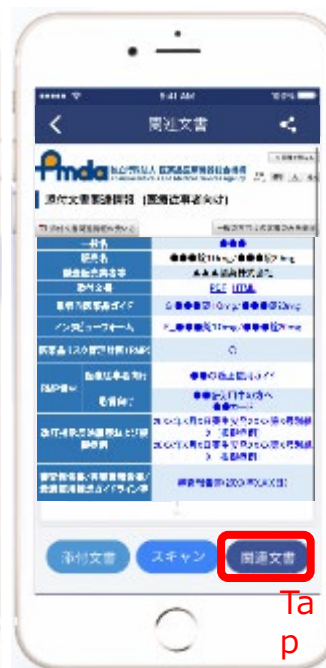
Operation image of the app



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



The re-redirect pages are automatically generated and e-labeling posted on the PMDA database is displayed.

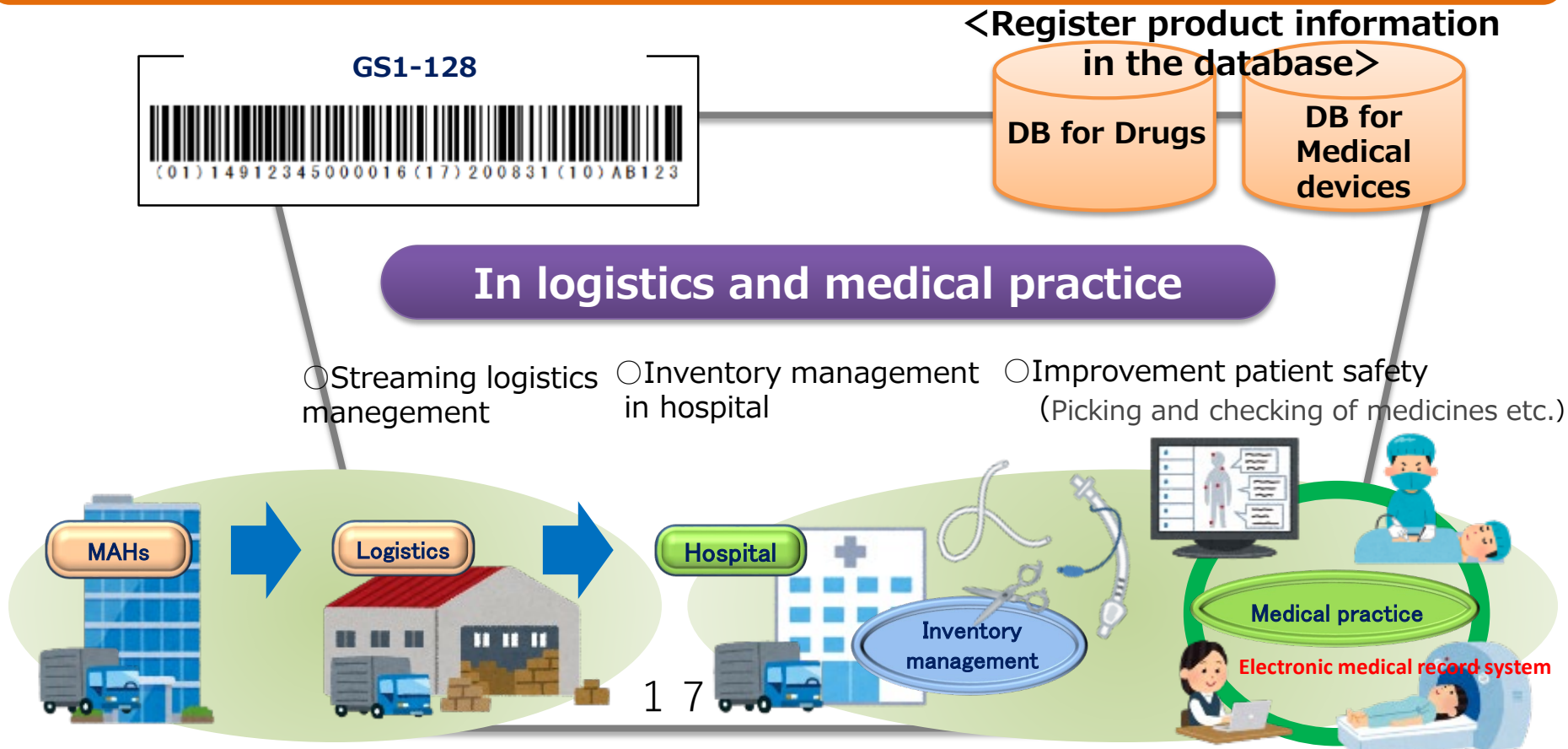


This APP has a function that enables re-access from the history.



Barcoding on secondary packages (sales packages) that displays lot and EXP for identification traceability (Enforcement: 2022 December)

- By putting GS1 barcode on products containers, traceability of products becomes possible, and it is expected to be used in logistics and medical practice.
- In order to further utilize barcodes, putting GS1 barcode on products containers has become a legal obligation of MAHs by partial revision of Drugs & MDs Act.
- The government is currently considering the details of the system.



Let's work together
for patients in the world !

Thank you!

