

# E-Labeling : Current Status and Next Steps In Japan

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# Disclaimer



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- English translation of Japanese words are mostly done by the presenter and should not be regarded as an official translation.

# Information Provision from PMDA

## PMDA website

Search for  
**Product information**  
and related documents



Link to the list of safety information

- The urgent safety information Letter
- Revisions of PRECAUTIONS
- MHLW Pharmaceuticals and Medical Devices Safety Information
- PMDA Medical Safety Information
- PMDA Alert for Proper Use of Drugs

etc.

PMDA's electronic mailing list service

## PMDA medi-navi



- ✓ Keeps HCPs informed of the **most up-to-date safety information** regarding drugs and medical devices, etc.
  - ✓ Notifies HCPs when new safety information is posted on the PMDA website
- ✓ **Free** to register/use
- ✓ Items can be selected



# PMDA Drug Information Search Page for the General Public

“Search by prescribed medicine name”  
→ *patient-oriented information*

Released in October 2025



The screenshot shows the PMDA homepage with the search bar containing "XXX錠". The page features a navigation menu on the left with links such as "副作用かな、と思ったら" (If you have side effects), "救済制度について知りたい" (I want to know about the relief system), "使っている薬について相談したい" (I want to consult about the medicine I am using), "ジェネリック医薬品とは?" (What are generic medicines?), "臨床試験(治験)を探す・調べる" (Find/Check clinical trials), and "PMDAってなあに?" (What is PMDA?). The main content area displays the search results for "XXX錠", including the text "処方された薬の情報を調べられます" (You can check the information of the prescribed medicine).

The screenshot shows the search results for "XXX錠". The page includes a QR code, the drug name "XXX錠", and the general name/ingredient name "一般名/成分名: XXXX". Below this, there are three expandable sections: "くすりの概要について知りたい (使い方や副作用など)" (I want to know about the overview of the medicine (usage, side effects, etc.)), "さらに知っておいていただきたいこと" (Additional things you should know), and "副作用がでたときの対応は" (What to do when side effects occur). A blue bear mascot is visible at the bottom of the page.

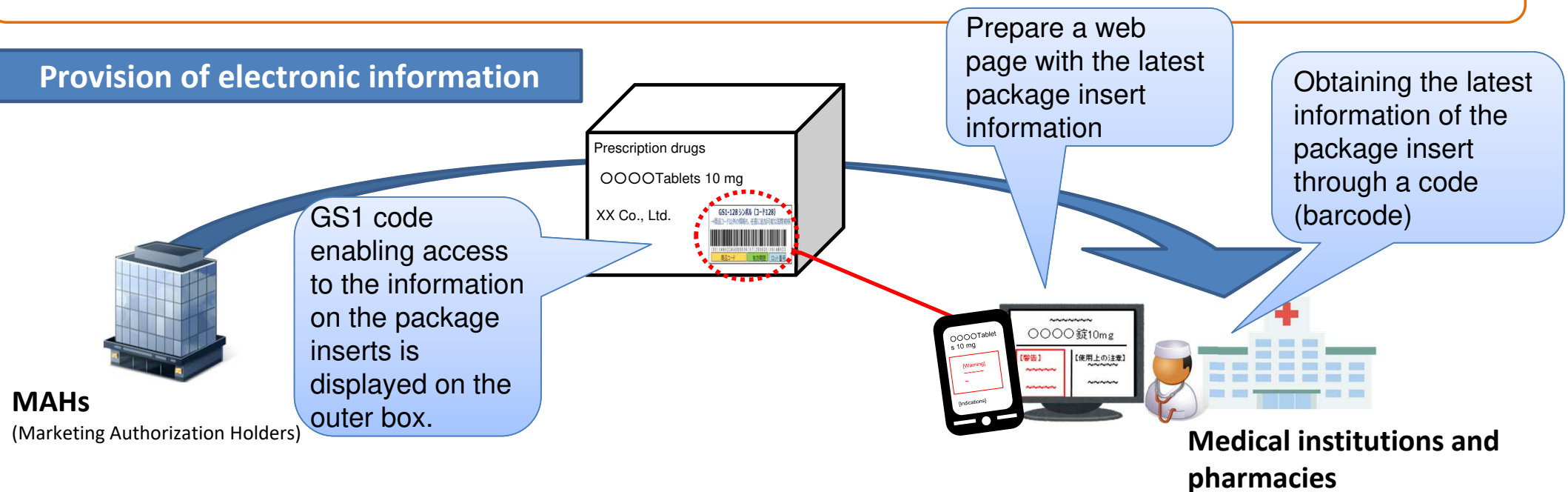
Drug Guide for Patients

RMP Materials

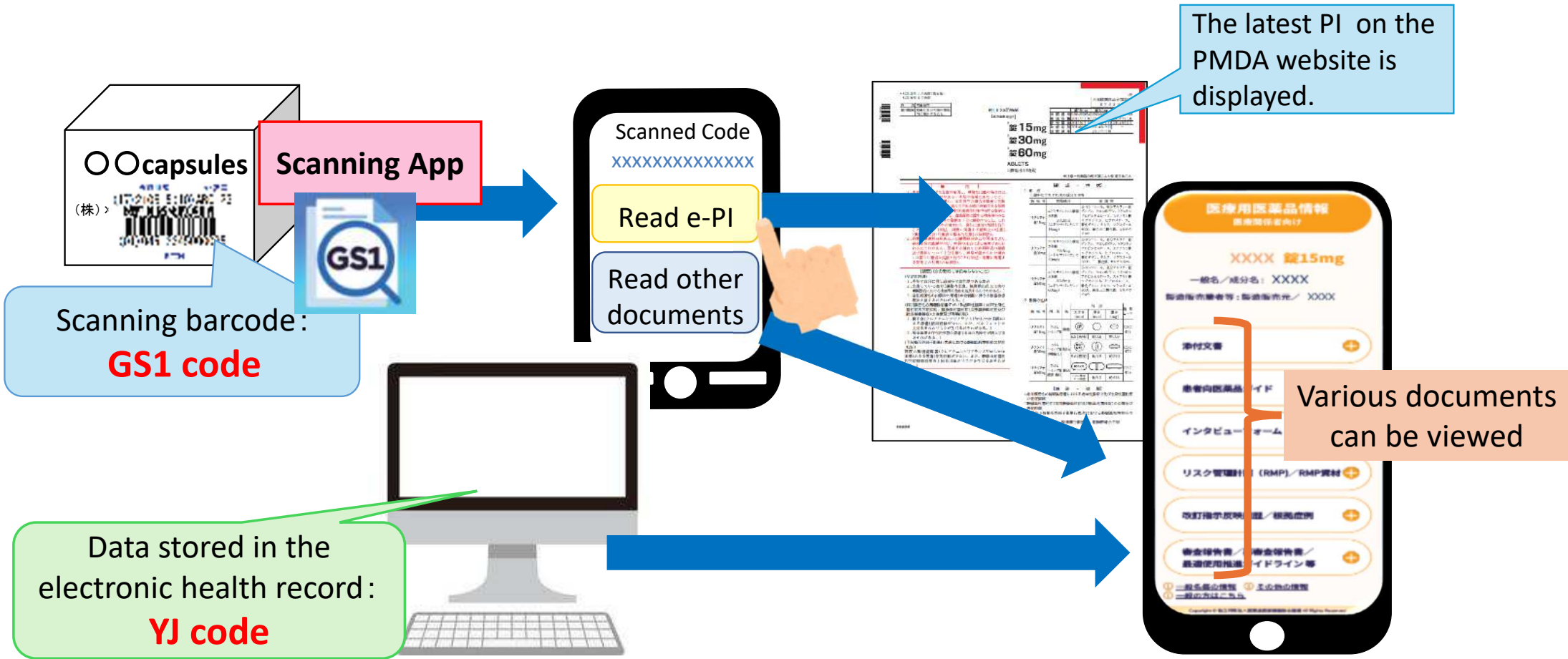
Manuals for the Management of Individual Serious Adverse Drug Reactions

# Electronic provision of package insert information

- Paper package inserts enclosed in the products have been discontinued (August 2021) and are now provided electronically.
- We can access to the latest information through the barcode displayed on the product package.



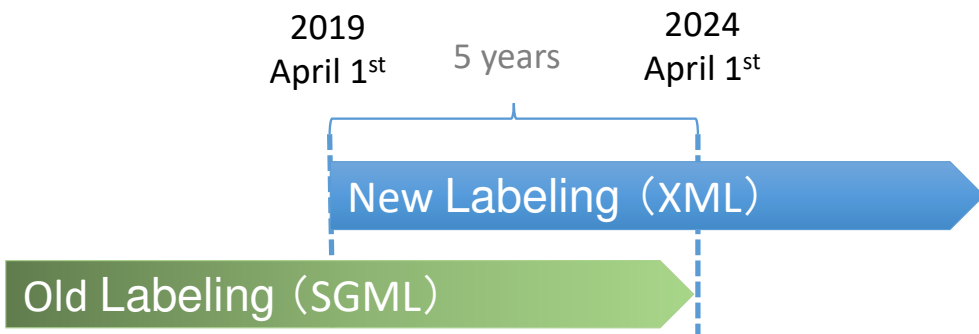
# A Mechanism for accessing the Latest e-PI and Related Documents



GS1 and YJ codes enable access to the latest information !

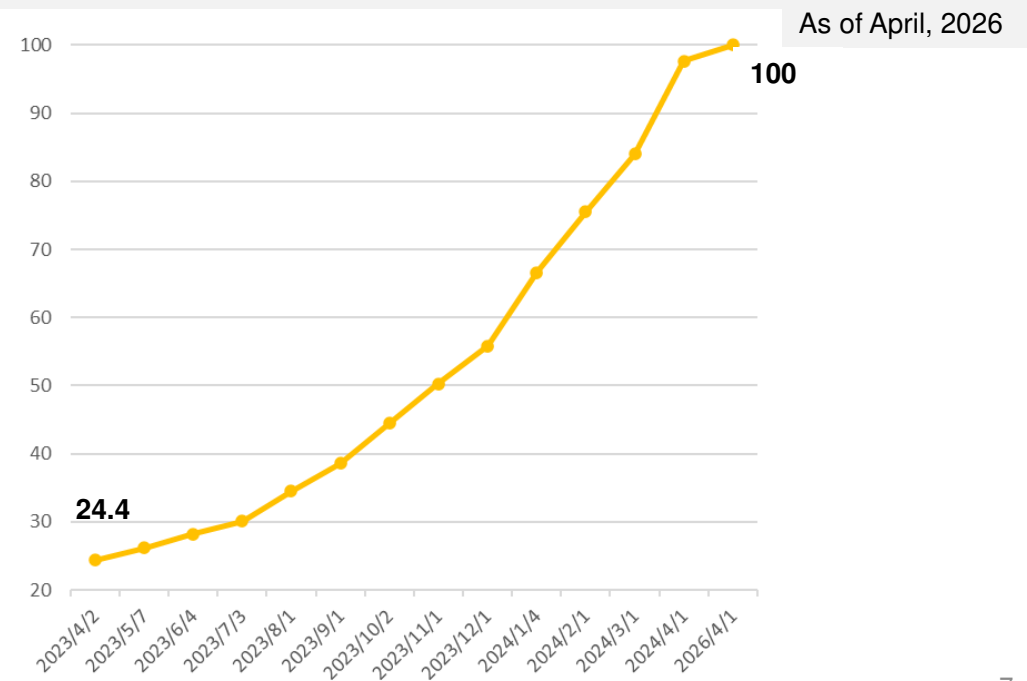
# Conversion of e-PI of Prescription Drugs into XML Format

- The XML format for e-PI was introduced in FY2019, and all e-PIs have been converted to XML.
- Number of cases published in XML format : 11,509 (100%) as of April 1



※ For FY2023 and 2024, system modification is underway to transform the format of package inserts of medical devices into XML format.

Percentage of Electronic Package Inserts Posted in XML format (%)



# Research on FHIR-based ePI (Health and Labor Sciences Research Grant)

Research for establishing an Infrastructure to Utilize ePI using International Standards FY2024-2026

Principal Investigator : **Daisuke Koide, PhD** (*Graduate School of Medicine, The University of Tokyo*)

## [Objectives]

The transition of ePI from XML format to HL7 FHIR format by :

- Analyze HL7 FHIR ePI documentation
- Identify difference between Japanese and Overseas PI form international harmonization perspective, using AI technologies



**Development of a Converter to HL7 FHIR-based ePI**

With the promotion of healthcare DX in Japan, interoperability is expected between FHIR-based ePI and HL7 FHIR-compliant standard EMR systems

# Survey on the Use of Drug Safety Information

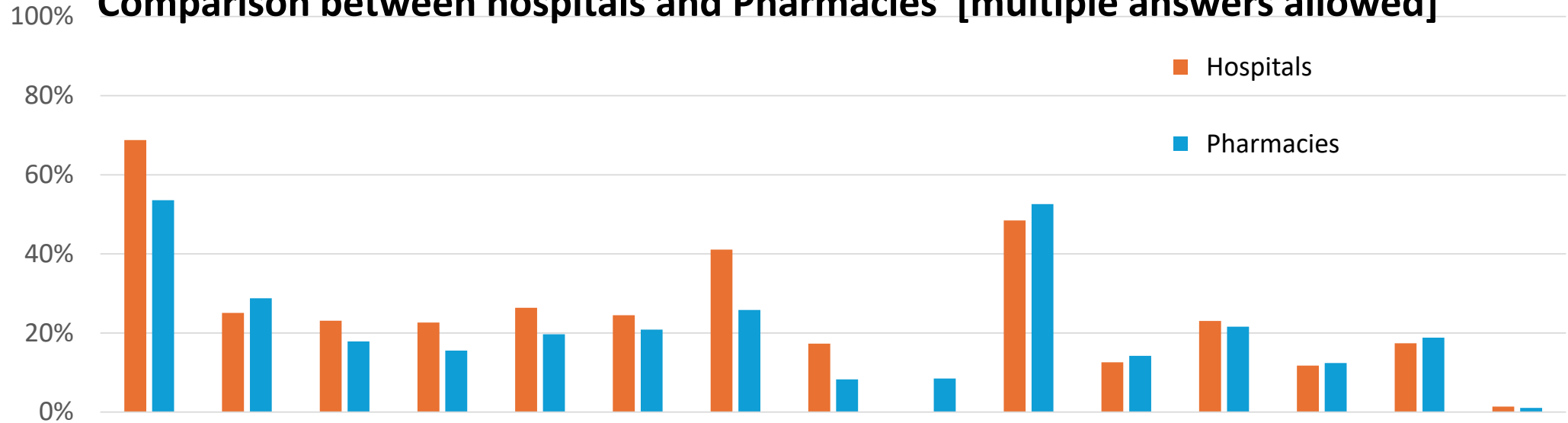
Since FY 2010, the PMDA has been conducting surveys to understand the status of acquisition, communication, and use of safety information at medical institutions, etc. and to consider measures to promote the use of safety information for the purpose of ensuring steady implementation of the safety measures taken and further patient safety.

## 2025 Survey

	<u>Hospital</u>	<u>Pharmacy</u>
<b>Target</b>	<b>40%</b> of <b>hospitals</b> nationwide ⇒ 3248 institutions	<b>5%</b> of <b>pharmacies</b> nationwide ⇒ 3146 institutions
<b>Respondents</b>	<b>The drug safety management supervisors physicians</b>	<b>Supervising pharmacists or persons in charge of DI in pharmacies</b>
<b>Contents</b>	<ul style="list-style-type: none"> <li>• Basic facility information</li> <li>• Method for accessing e-labeling information</li> <li>• Understanding and Use of Risk Management Plans (RMPs) and Patient</li> <li>• Utilization of GS1 barcodes</li> </ul>	

# Sources of e-PI used by Healthcare Professionals

## Comparison between hospitals and Pharmacies [multiple answers allowed]



	Number of facilities	PMDA website	PMDA Medinavi	MHLW Safety Information	Drug Safety Update (DSU)	Pharmaceutical Representatives (MR/MS)	Company Direct mail (DM)	Pharmaceutical company websites	Wholesalers websites	Central DI	EMR/Pharmacy system	GS1 barcodes Appr	Medical websites/E-mail/Appr	Books	General search engines	Others
Hospitals	1224	68.8%	25.1%	23.1%	22.6%	26.4%	24.5%	41.1%	17.3%	-	48.4%	12.6%	23.0%	11.8%	17.4%	1.4%
Pharmacy	2200	53.6%	28.8%	17.9%	15.5%	19.7%	20.9%	25.8%	8.3%	8.5%	52.6%	14.2%	21.6%	12.4%	18.8%	1.0%

### Hospitals

1. PMDA website **68.8%**
2. EMR (Hospital systems) **48.4%**
3. website of the pharmaceutical company **41.1%**

### Pharmacies

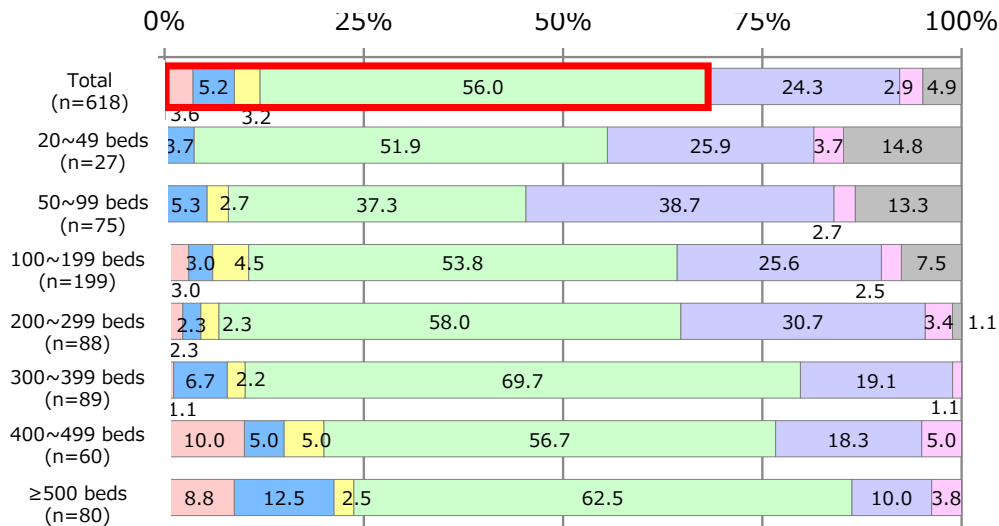
1. PMDA website **53.6%**
2. Pharmacy systems (e.g., dispensing computer systems) **52.6%**
3. PMDA medi-navi **28.8%**

# Frequency of Information Updates within the System

How frequently is drug information updated in in-house systems such as electronic medical records (EMR)?

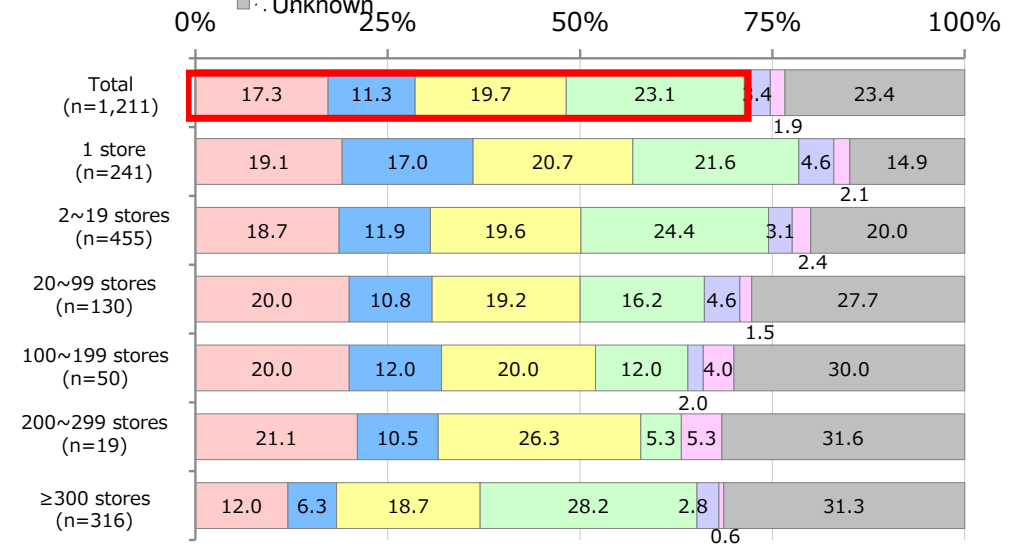
## Hospitals 【Number of beds】

- Real-time
- Daily
- Weekly
- Monthly
- Every 2-3 months
- Other
- Unknown



## Pharmacies 【Number of pharmacy stores per Ownership】

- Real-time
- Daily
- Weekly
- Monthly
- Every 2-3 months
- Other
- Unknown

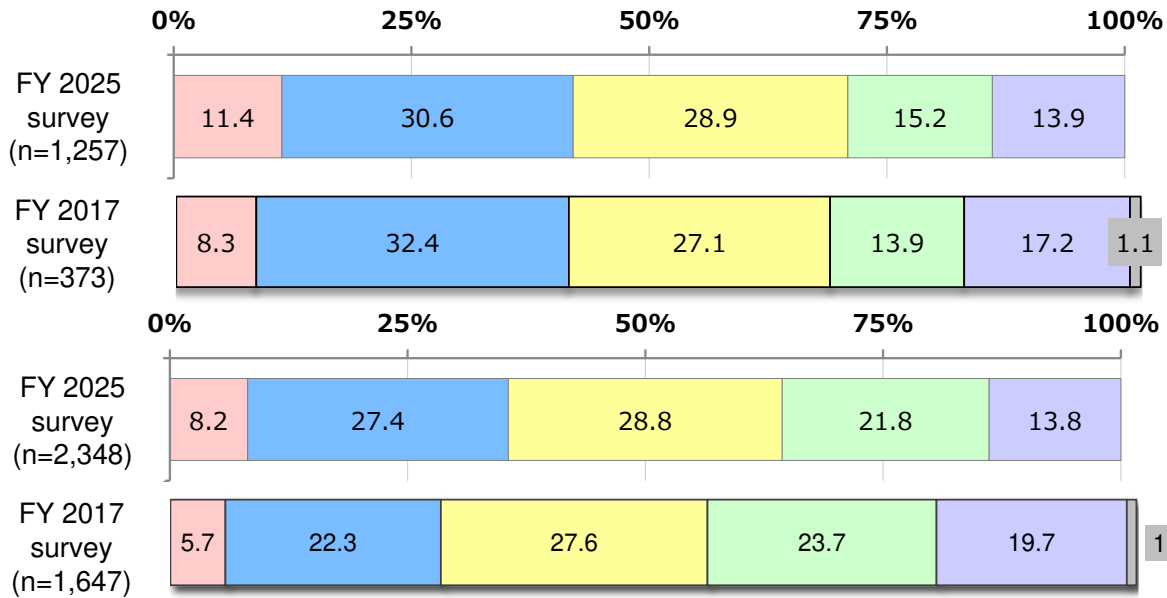


Approximately 70% of both hospitals and pharmacies reported an update frequency of once a month or more, suggesting that the latest information is generally being accessed.

# Status of understanding of Drug Guide for Patients

## Are you familiar with Drug Guide for Patient?

Well Understood    Some understanding    Seen  
 Heard of    Not aware



### Facilities with an understanding of Drug Guide for Patients

**Hospitals** : 40.7% ⇒ **42.0%**

**Pharmacies** : 28.0% ⇒ **35.6%**

FY 2017 survey    FY 2025 survey

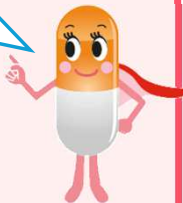
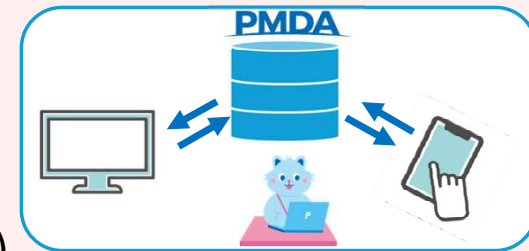
# Promoting the Further Utilization of Drug Safety Information

## Strengthen System-Level Access

- ◆ Promote **integration between hospital IT systems** (e.g. EMR, pharmacy systems) and **PMDA drug safety information**

## Improve PMDA Website Usability

- ◆ Simplify and clarify **navigation from the PMDA top page** to key risk communication tools (e.g. RMPs, Safety Alerts, Drug Guides)
- ◆ Make it **easy to understand what information is available and where it is located**
- ◆ Ensure **timely, accurate, and user-friendly online access**



## Support External Information Channels

- ◆ Enhance **reusability of PMDA information** by medical websites, e-mail services, and apps
- ◆ Clarify issues related to **access, reuse, and dissemination** of PMDA web content

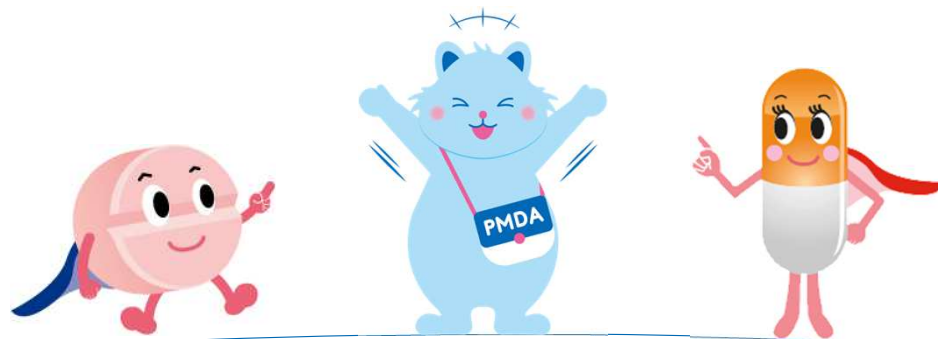
## Foster Awareness and Practical Use

- ◆ Promote **early and correct understanding** of risk communication tools (e.g. RMPs)
- ◆ Encourage organizational frameworks that support **multi-professional sharing and use** of safety information

# Thank you for your attention!

Details of the survey results are available on the PMDA website.

<https://www.pmda.go.jp/safety/surveillance-analysis/0010.html>



**PMDA**

健やかに生きる世界を、ともに

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