

# E-Labeling Implementation Experience and Future in Japan

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# Package Inserts (PIs) in Japan

## Regulatory positioning:

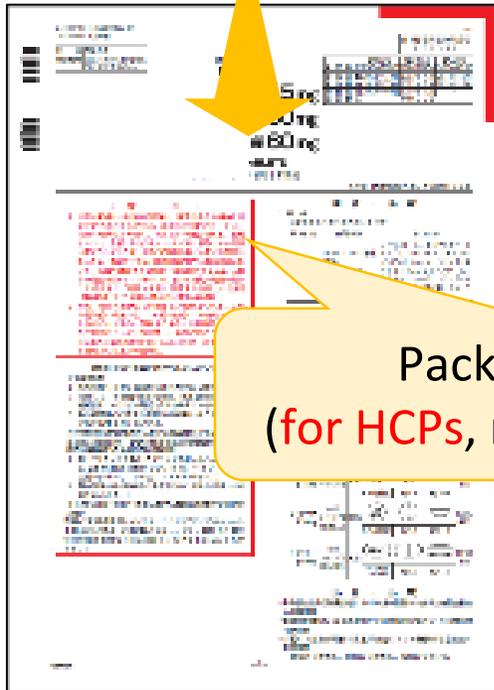
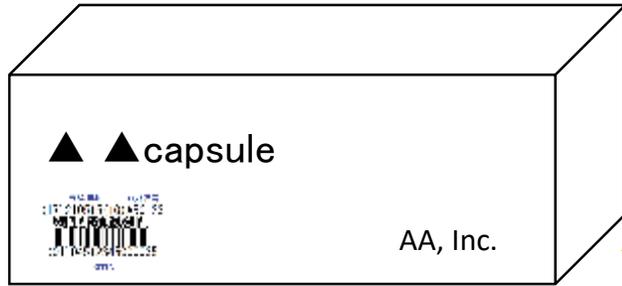
- Official document prepared pursuant to the PMD Act

⇒ It is necessary to have the latest scientific knowledge as the basis of information.

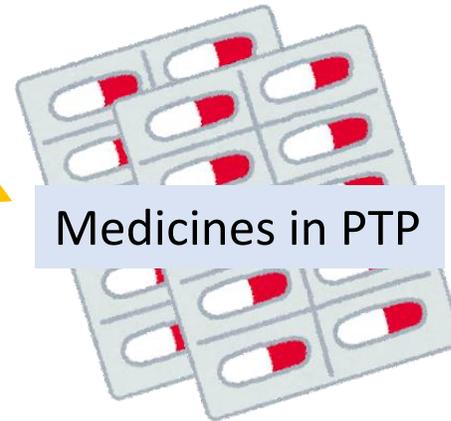
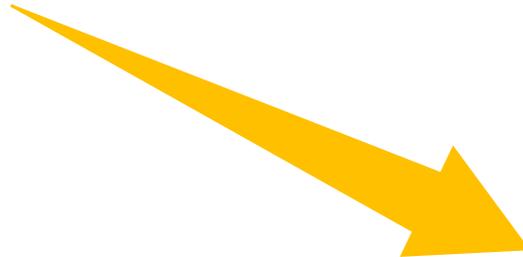
Basic information for HCPs about medical products

# Prescription Drugs in Japan

Package

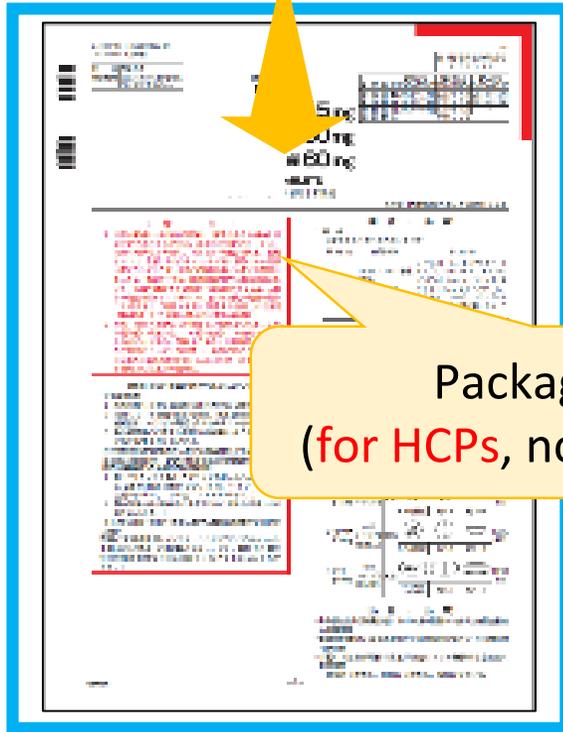
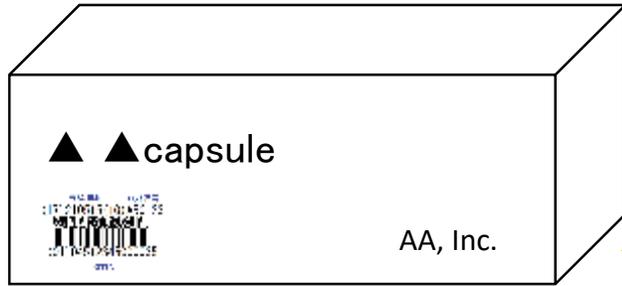


Package insert  
(for HCPs, not for patients)

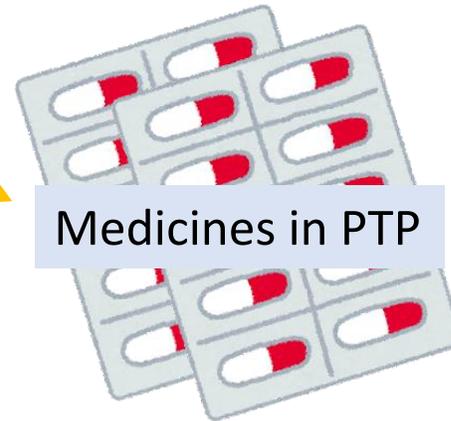
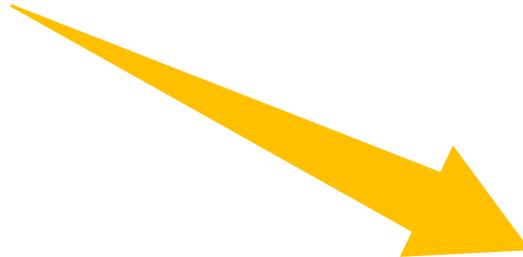


# Prescription Drugs in Japan

Package

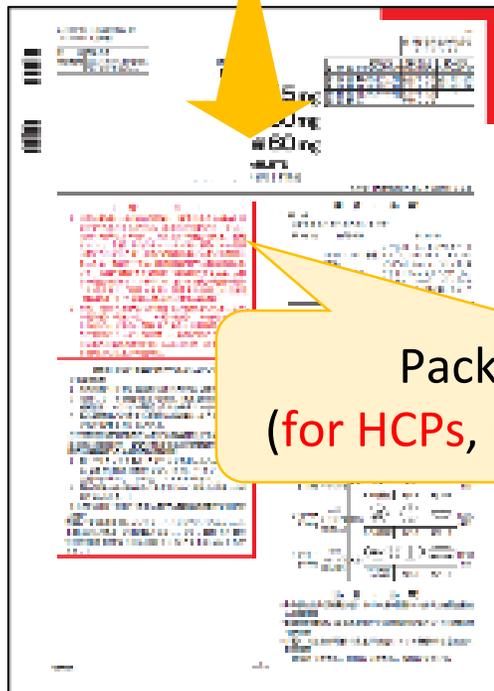
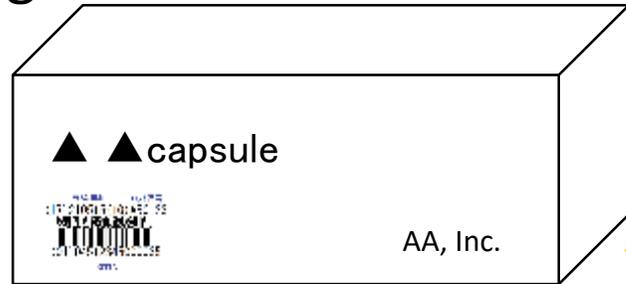


Package insert  
(for HCPs, not for patients)



# Prescription Drugs in Japan

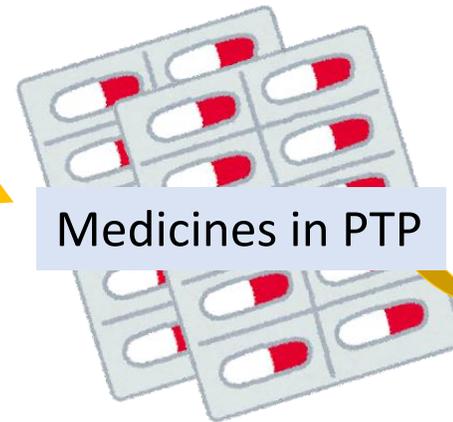
Package



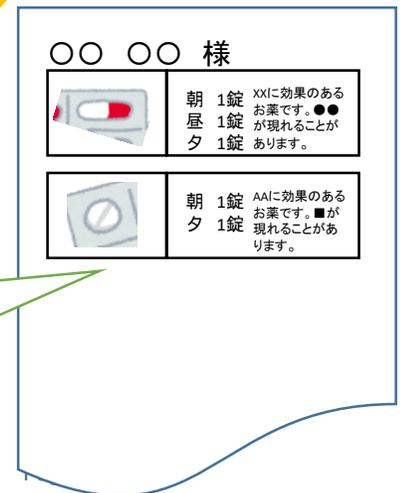
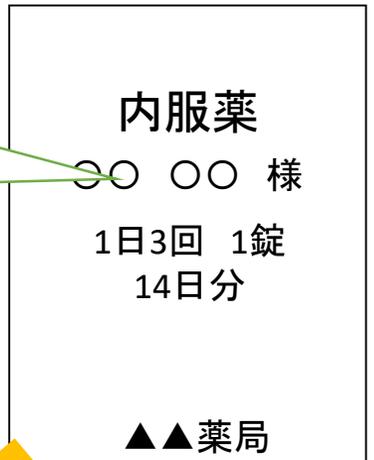
Package insert  
(for HCPs, not for patients)

For patients

Paper bags to provide medicines, prepared at pharmacies

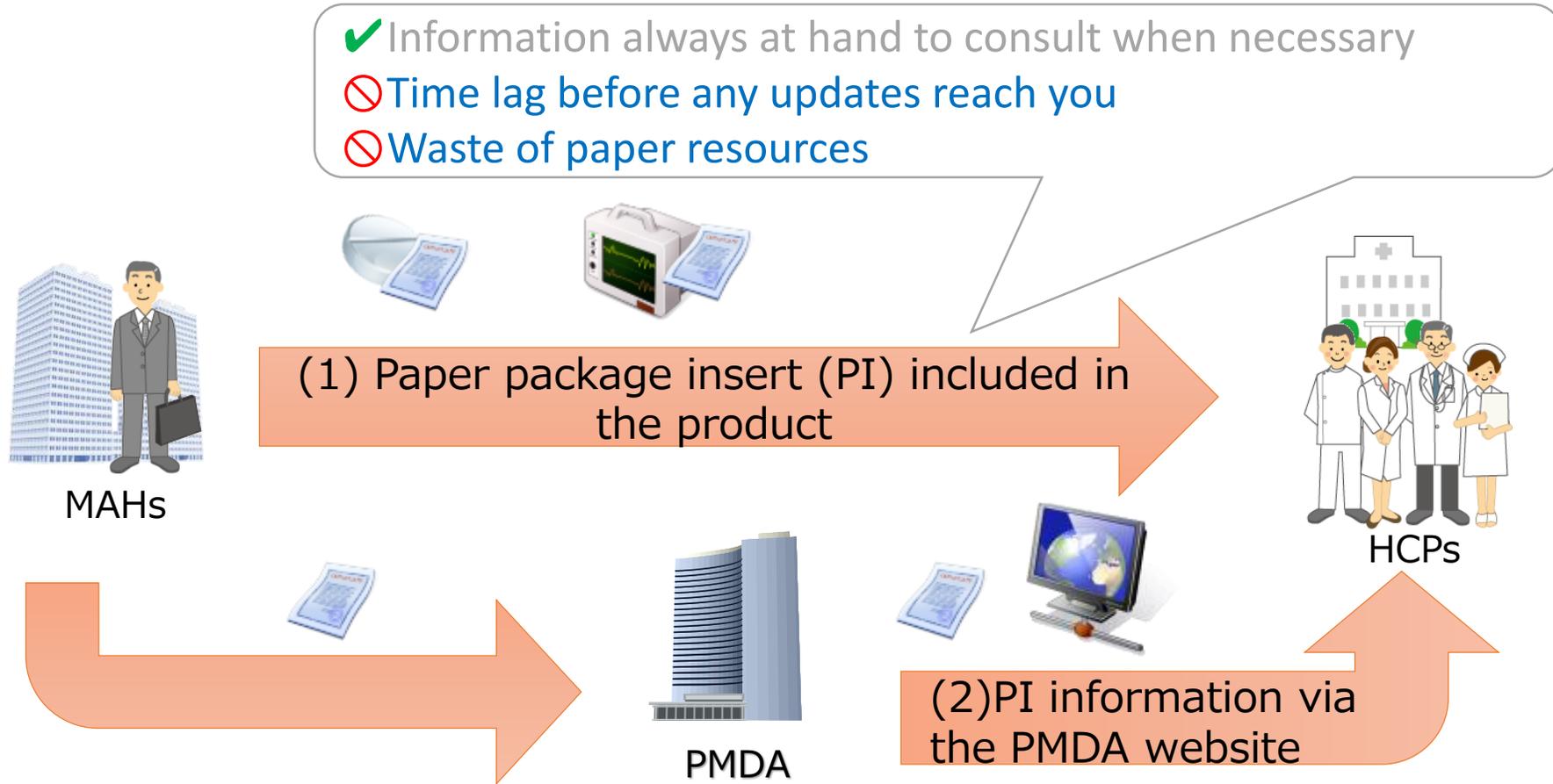


Directions on how to take medicines and precautions, prepared at pharmacies



# Previous Method of Browsing PIs

Before the Amendment of the Pharmaceuticals and Medical Devices Act (PMD Act)



- ✓ Information always at hand to consult when necessary
- ✗ Time lag before any updates reach you
- ✗ Waste of paper resources

(1) Paper package insert (PI) included in the product

MAHs

HCPs

PMDA

(2) PI information via the PMDA website

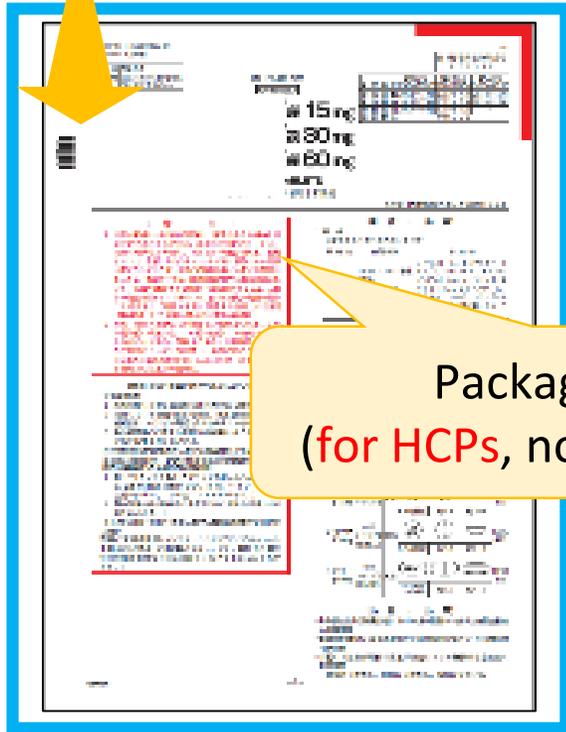
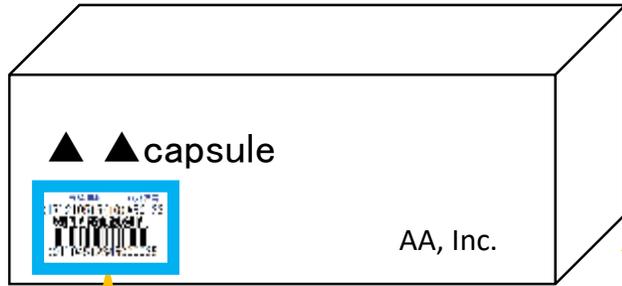
- ✓ Latest versions always available
- ✗ You have to search for specific PIs.

# Summary of the Amendment of the PMD Act

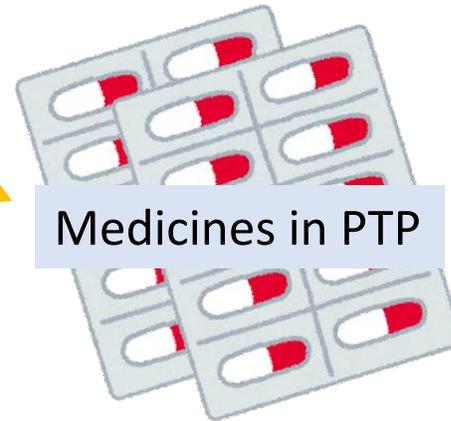
- Inclusion of Paper PIs in the products is abolished in principle, and PIs are **provided by electronic method**.  
(except for guidance-mandatory or OTC drugs and medical devices for home use)
- **Indication of GS1 code for accessing the latest PIs on the package of products is required**. It is necessary to arrange a mechanism to notify medical institutions and pharmacies, etc. of any updates through paper media or other means in case that they cannot be provided by electronic method.
- In addition to an electronic method, paper PIs are provided at the initial delivery of drugs or medical devices by MAHs in cooperation with wholesalers, if necessary.

# Prescription Drugs in Japan

Package



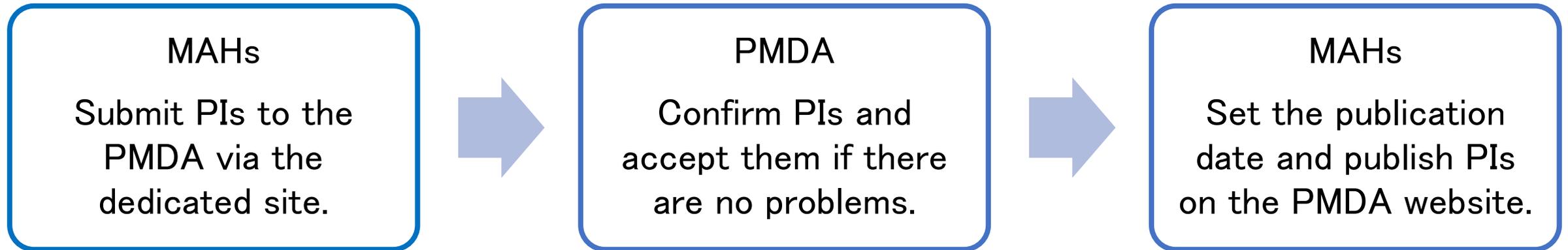
Package insert  
(for HCPs, not for patients)



# Notification and Publication of PIs



< Flow from notification of PIs to publication >



- “Notification” means that MAHs submit PIs to the PMDA via the dedicated site.
- “Publication” means publishing PIs on the PMDA website.

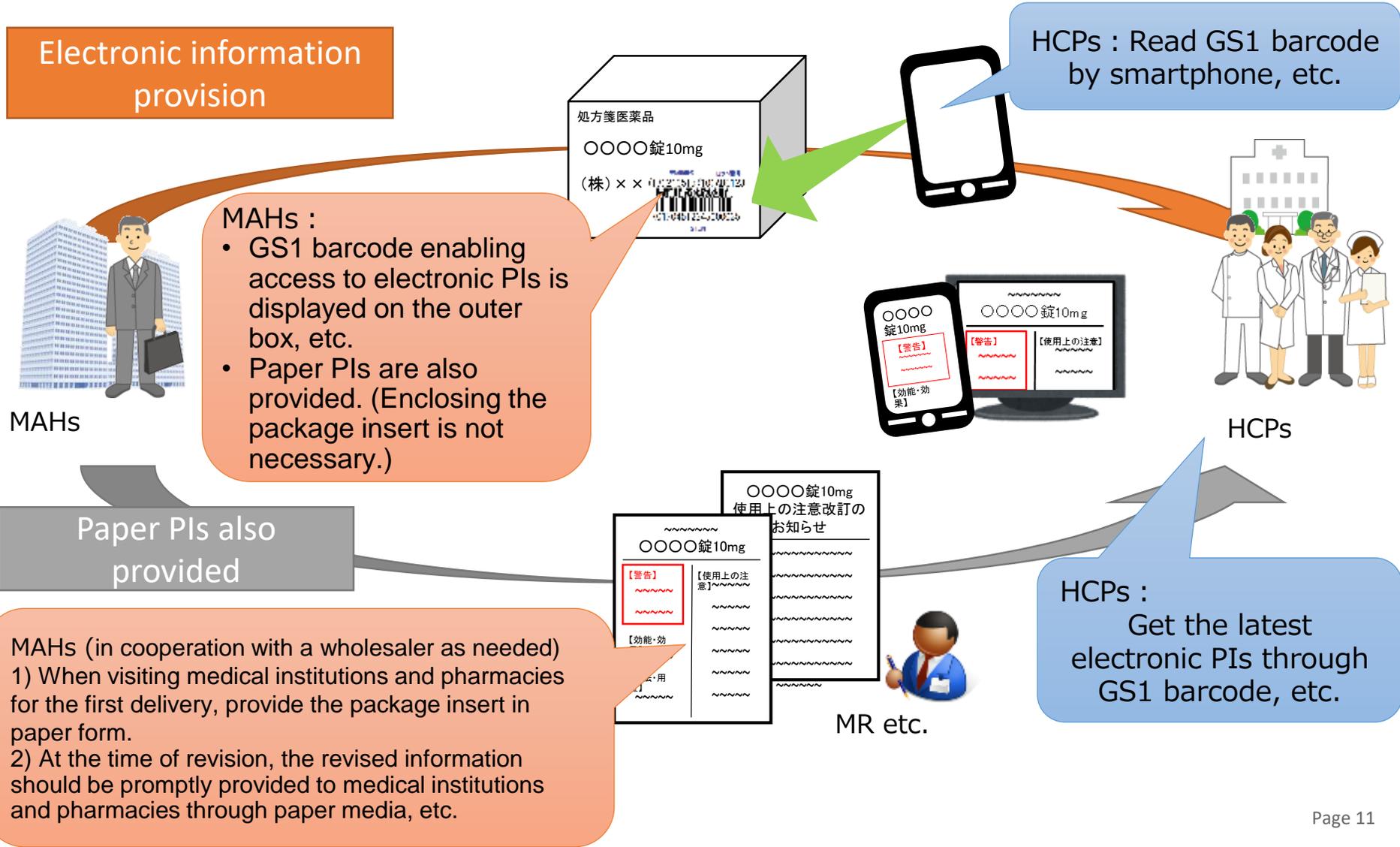
# Registration and Linking of GS1 Codes

GS1 code registration, etc. is operated as follows.

- When the GS1 code is registered to the PMDA, the website is designed so that the users can check if the GS1 code has any defects.
- The PMDA regularly checks any defects in GS1 codes in cooperation with GS1 Japan, which issues GS1 codes in Japan.
- MAHs are responsible for the link between the GS1 code and PI number, and MAHs, not the PMDA, confirm if the link is correct.

# Current Method of Provision of PI Information

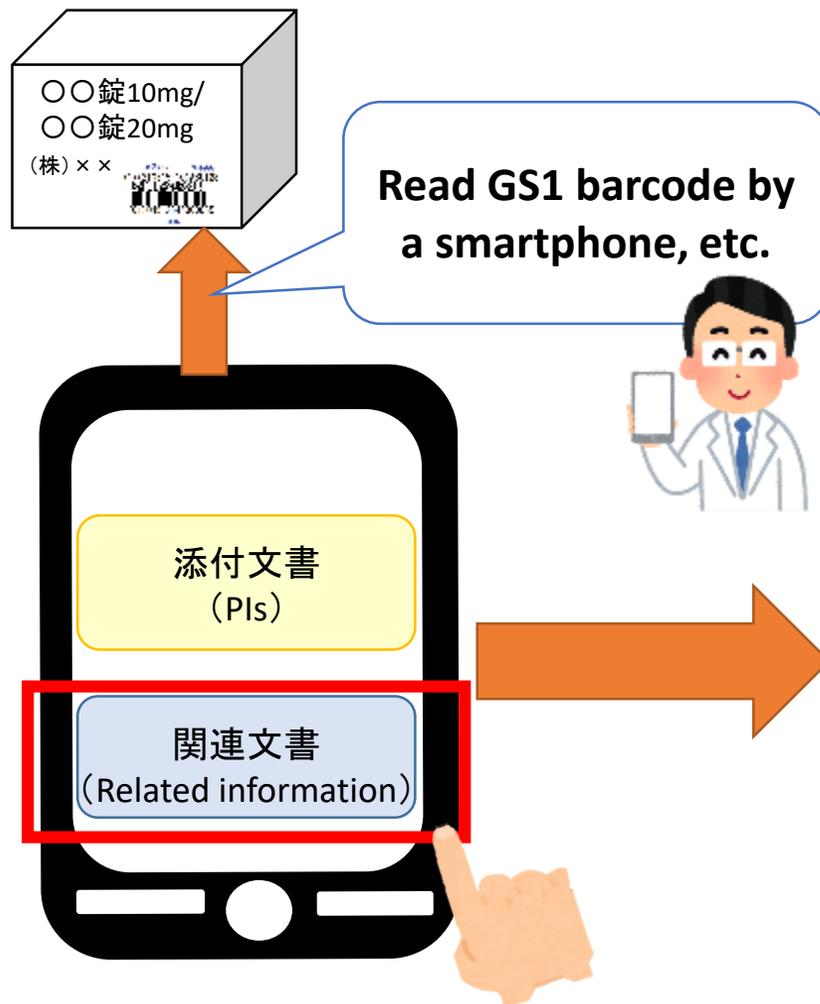
## After the PMD Act Amendment





# Image of Electronic Browsing of Related Information 1

<To display related information for the HCPs>



Review reports, RMPs, etc.

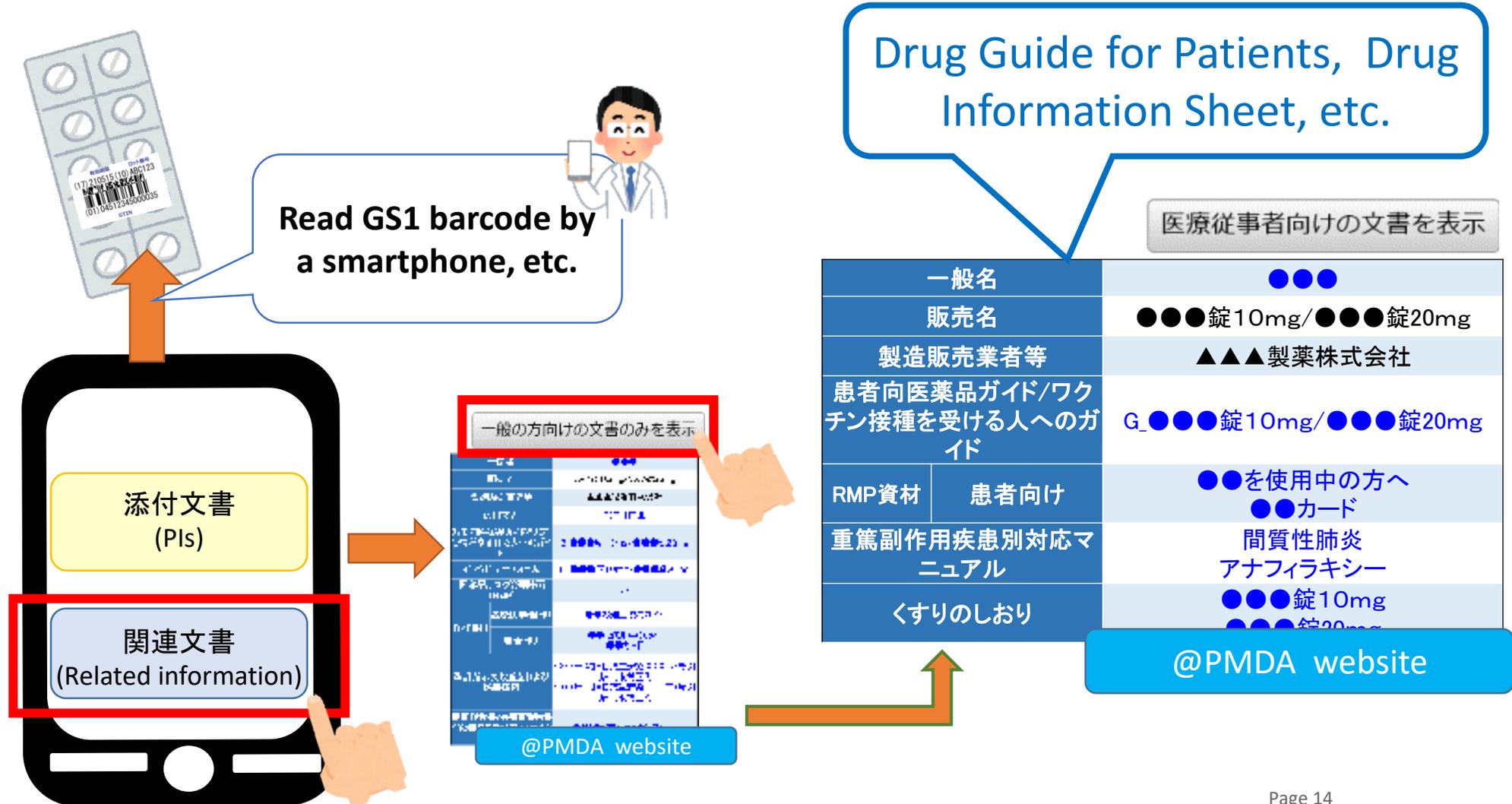
一般の方向けの文書のみを表示

一般名	●●●	
販売名	○○錠10mg/○○錠20mg	
製造販売業者等	▲▲▲製薬株式会社	
添付文書	<a href="#">PDF</a> <a href="#">HTML</a>	
患者向医薬品ガイド/ワクチン接種を受ける人へのガイド	G_●●●錠10mg/●●●錠20mg	
インタビューフォーム	F_●●●錠10mg/●●●錠20mg	
医薬品リスク管理計画 (RMP)	○	
RMP資料	医療従事者向け	●●の適正使用ガイド
	患者向け	●●を使用中の方へ ●●カード
改訂指示反映履歴および根拠症例	20XX年X月X日薬生安発XXXX第X号別紙X [根拠症例] 20XX年X月X日薬生安発XXXX第X号別紙X [根拠症例]	
審査報告書/再審査報告書/最適使用推進ガイドライン等		

@PMDA website

# Image of Electronic Browsing of Related Information 2

<To display related information for the general public >



# Changes in the Posting of PIs on RA(PMDA) Website

April  
1999

- Posting of SGML PIs on RA website started.
- Target: Prescription drugs with new active ingredients approved after 1989

July  
1999

- Scope of SGML PIs to be posted was expanded.
- Target: Prescription drugs approved after 1979

October  
1999

- In addition to SGML PIs, posting of PDF PIs started.
- Target: Prescription drugs approved after 1979

January  
2000

- Scope of SGML and PDF PIs to be posted was expanded.
- Target: All prescription drugs

July  
2000

- Scope of SGML and PDF PIs to be posted was expanded.
- Target: All prescription drugs and in vivo diagnostics

December  
2000

- Scope of SGML and PDF PIs to be posted was expanded.
- Target: All prescription drugs, in vivo diagnostics, and biological products (vaccines, antivenoms)

April  
2019

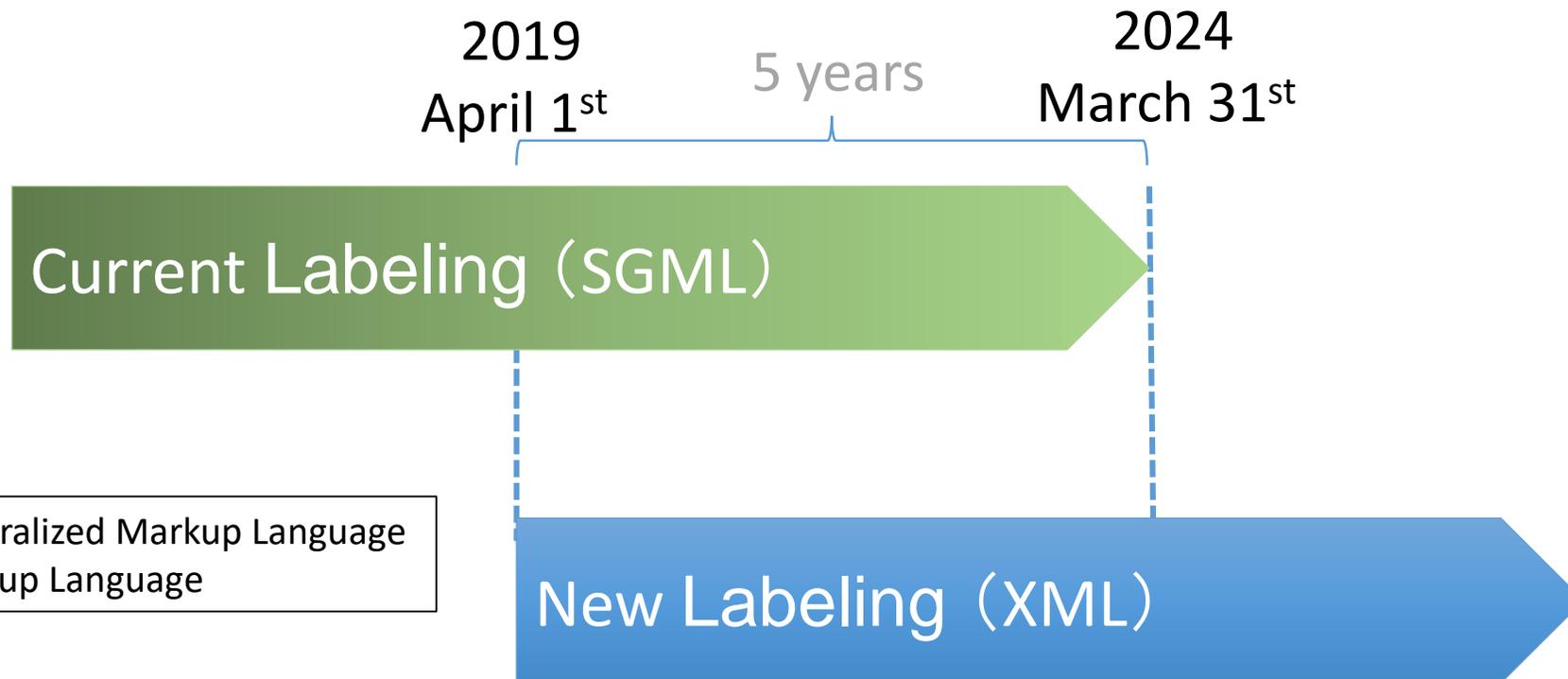
- Changing of the format of PIs from SGML to XML started. The transition period is until March 2024.
- Target: All prescription drugs, in vivo diagnostics, and biological products (vaccines, antivenoms)

November 2014  
Notification and Publication of PIs on the PMDA website are legally required. Target: Prescription drugs, Guidance-mandatory drugs, Medical devices (Class IV), Regenerative medical products

August 2021  
Inclusion of Paper PIs in the products is abolished. The transition period is until July 31, 2023.

# XMLization Schedule of Prescription Drug Package Inserts

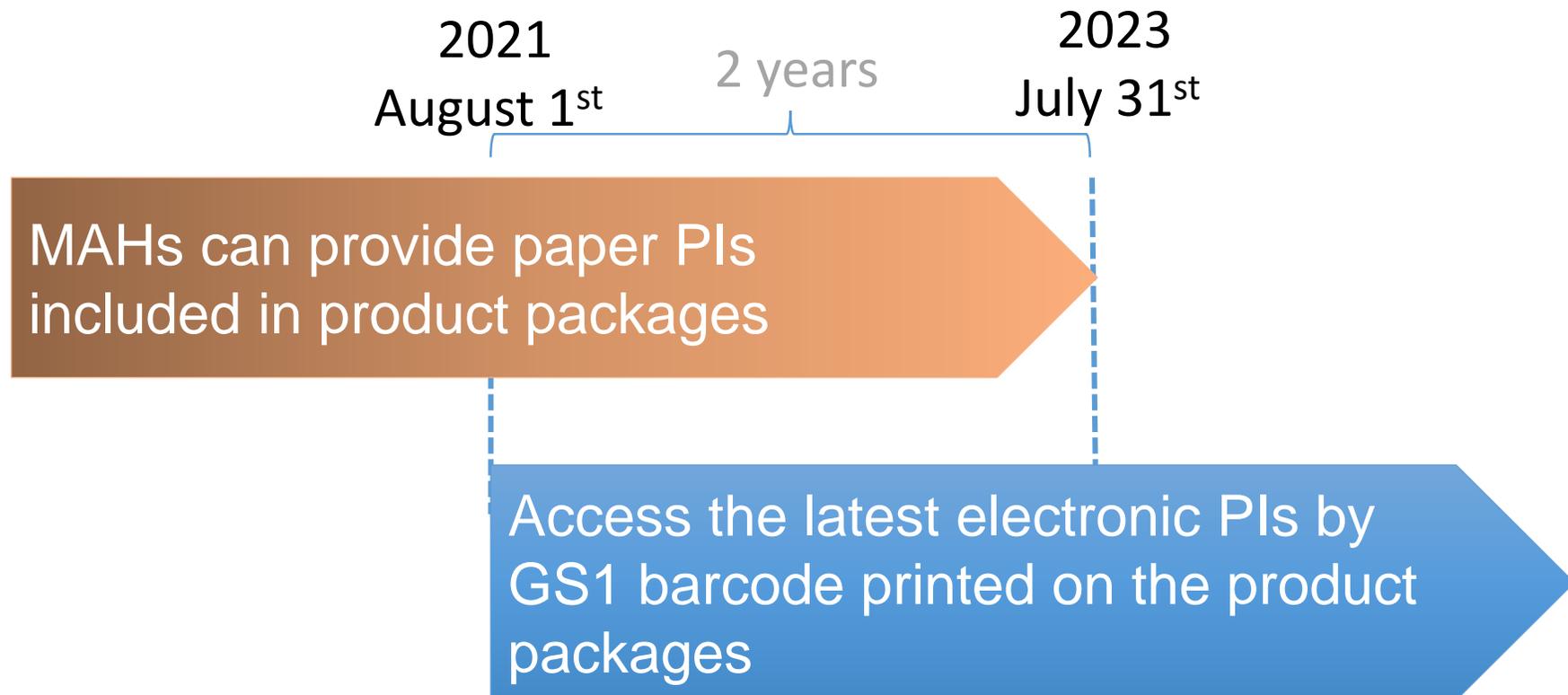
- Posting of PIs in XML format started in FY2019 in line with the revision of instructions for package inserts.
- Full transition to XML formatting of prescription drug PI information is expected by April 2024.



SGML : Standard Generalized Markup Language  
XML : EXTensible Markup Language

# Schedule of the Shift to Electronic PIs

- Transition Period is until July 31st, 2023.
- On and After August 1st, 2023, inclusion of Paper PIs in the products will be abolished and replaced by electronic browsing of PIs.



## In such cases ...

- What if the PMDA server goes down due to a disaster or something?  
→ Automatically switch to the backup site.
- What if the Internet access at a medical institution is unavailable in the event of a disaster or something?  
→ HCPs are recommended to utilize the bulk download function of PIs regularly.
- What if a medical institution, such as that in a remote island, does not have Internet access?  
→ MAHs provide PIs in paper form as necessary.

## Future Tasks

- PIs in Japan is for HCPs. The PMDA is currently considering how information should be provided to patients, including structuring of information to be provided and mutual data linkage.
- The PMDA is also considering the conversion into XML concerning PIs for medical devices and in vitro diagnostics.

Thank you for your attention!