- To expedite the launch of Innovative medicines for the peoples in Asia –

E-Labeling Implementation in Japan and Asia
- from industries perspective -

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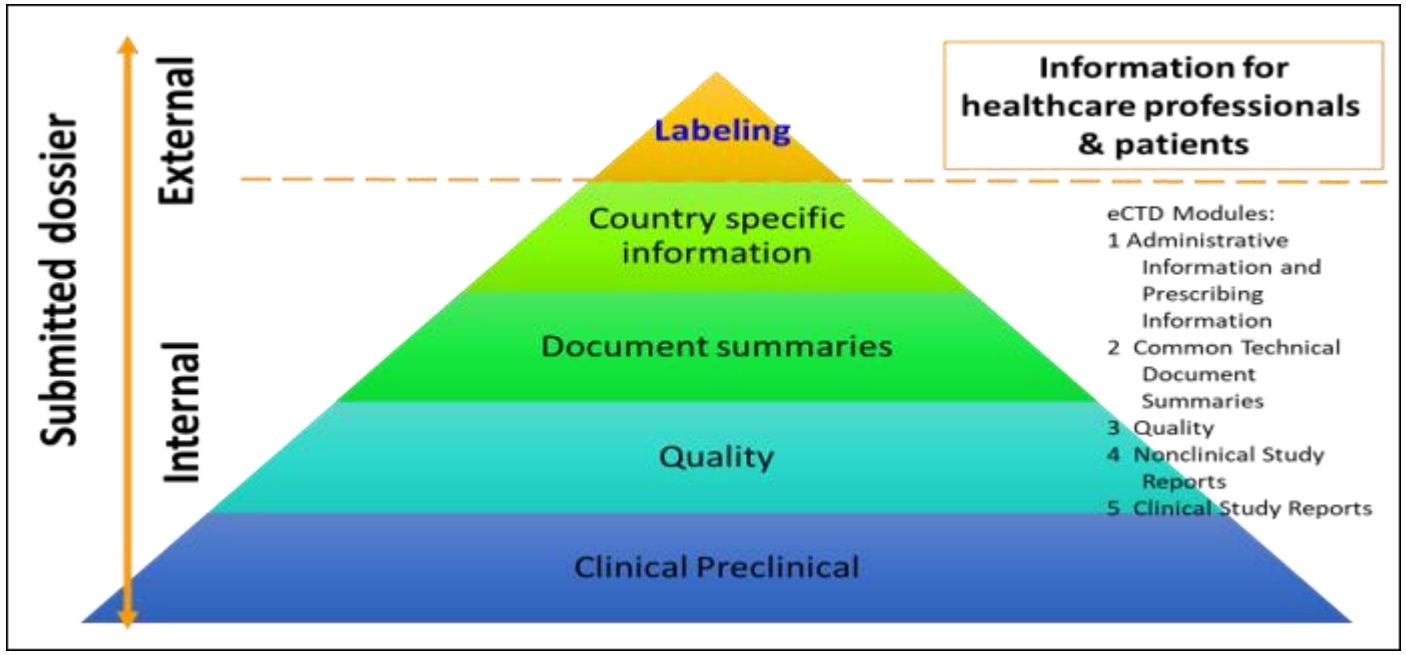
Agenda

1. Product Information (the “Labeling”)
2. What is e-labeling?
3. E-labeling implementation in Japan
4. Outlook of e-labeling Initiatives in Asian markets
5. Summary

The Role of Product Information (the “Labeling”)

The product information (aka the “labeling”) is a key component of the submitted dossier

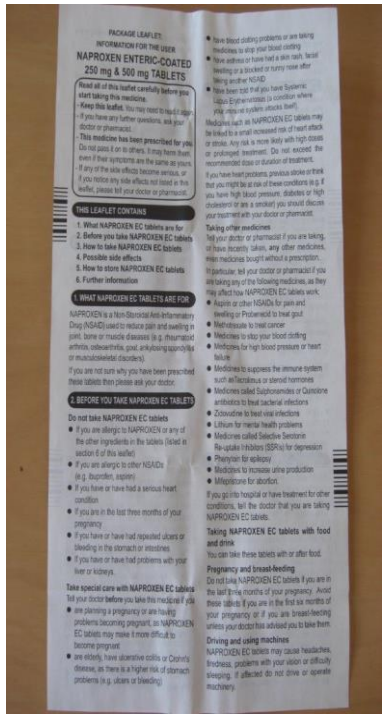
“Labeling is a communication tool.”

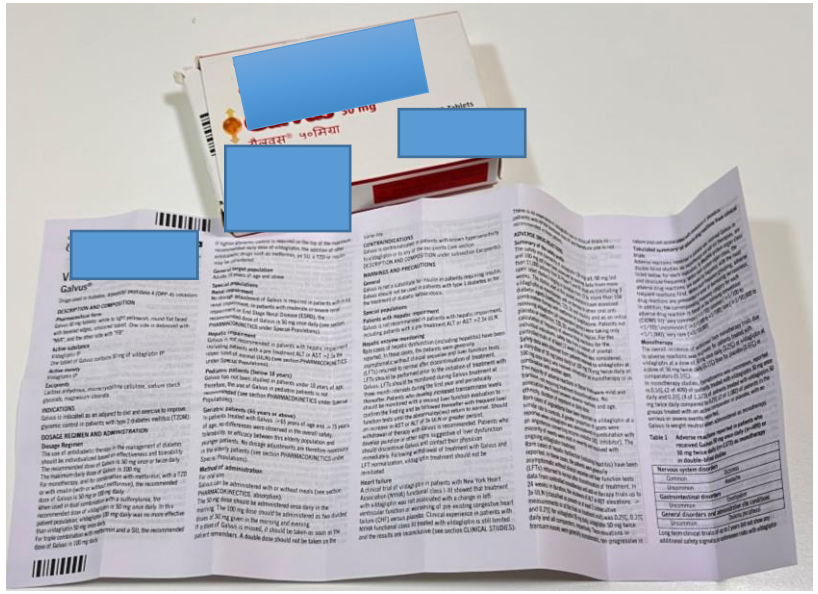


A variety of formats (paper, **electronic**) and types (**patient,** HCP) distributed according to national requirements

A critical risk-minimization measure communicating benefit/risk and usage instructions

Labeling Documents in the Commercial Pack

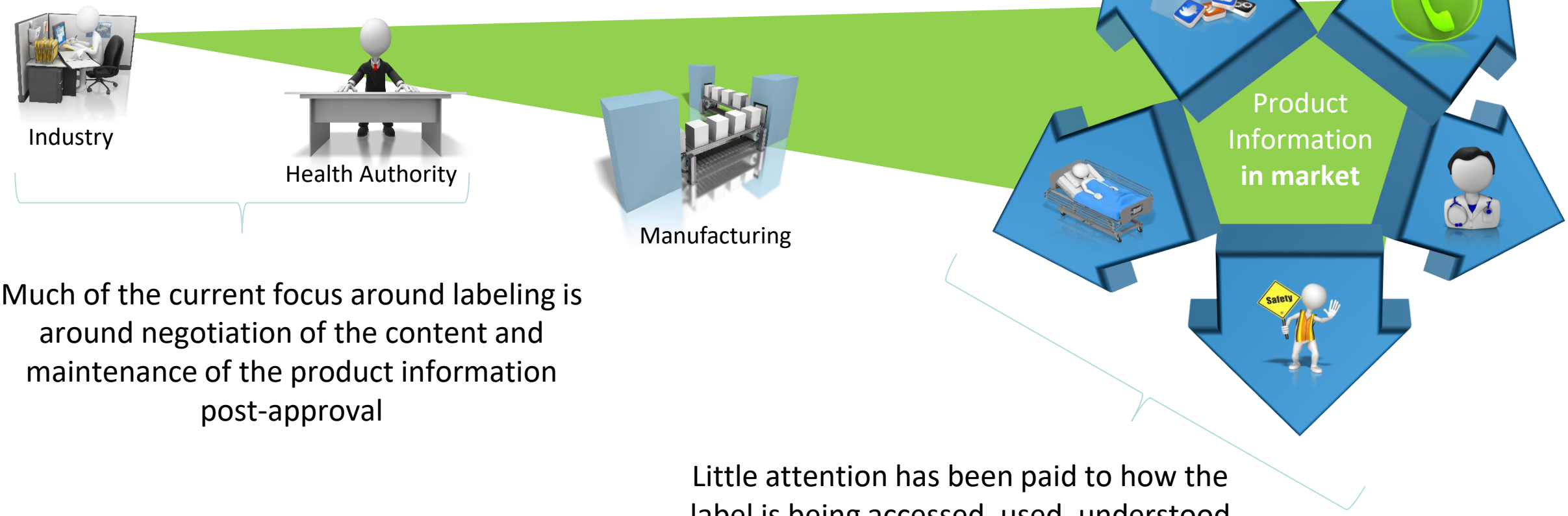




Depending on the country, the pack may contain Healthcare Professional Information (e.g. U.S., **Japan and India**) or patient information (e.g. EU)

In Asia, mostly labeling for HCPs is inserted in a commercial pack.

A shift in thinking



Much of the current focus around labeling is around negotiation of the content and maintenance of the product information post-approval

Little attention has been paid to how the label is being accessed, used, understood and adhered to in real life settings.

In other words the "**customer experience**"

What is e-labeling?

- Availability of the latest labeling on a publicly accessible website (product information is easily accessible online)
- Accessible, reader friendly format, e.g. scanning a code; resizable text; multiple languages; searchable content
- Eliminating paper labeling from commercial pack
- Structured content, e.g. FHIR XML
- Interoperability between systems, e.g. share product information across wearable, ePrescription, and eHealth record

Why is important?

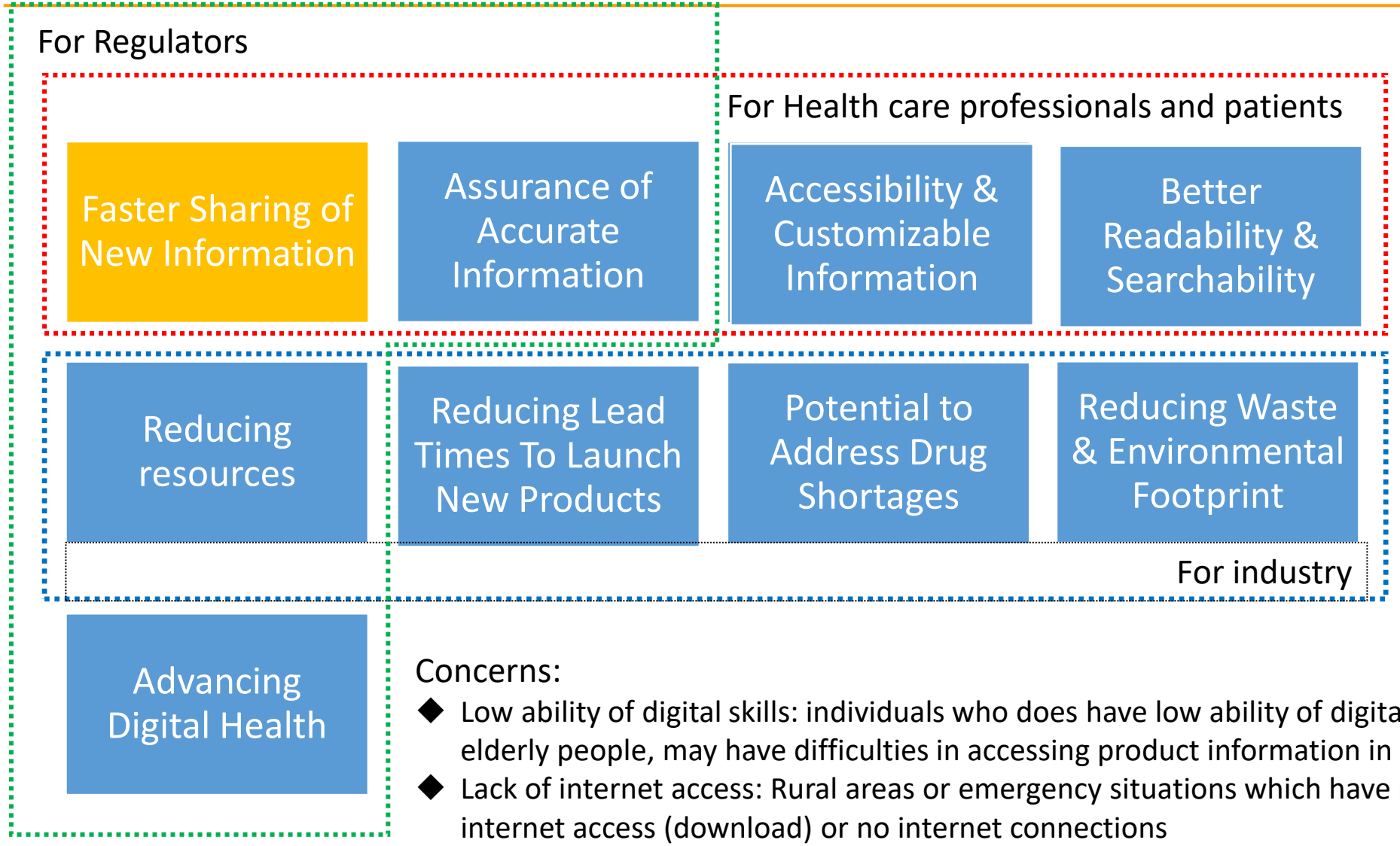
E-Labeling can improve:

- Accessibility & understanding of most recent product information for patients & HCPs
- Adherence
- Patient outcomes
- Improve efficiency and reduce paper waste

E-labeling is the availability of the latest approved product information electronically on publicly accessible website via smart devices. E-labeling would be in a common structured format using global standards to allow efficient and seamless information flow amongst manufacturers, regulators, HCPs, and patients. E-labeling would eventually replace the paper product information leaflet that are placed within commercial packs. (*From the APAC e-labeling position paper.)*

https://link.springer.com/epdf/10.1007/s43441-022-00462-5?sharing_token=cjw66MHpy8y3u5eY0FRbk_e4RwlQNchNByi7wbcMAY4i0rWXuCGMKTqz0bt1IxPWS-lISMdQFzc1SY-1yhS5ssT5V6sNwHX_bcksgE_2q1M_6IAh2EGCLEWAAKNR6laKsS5-l4TQTfPbyrk1L6snNSvRhr_N75os6GDzg4wyXh4=

Benefits of e-labeling



Concerns:

- Low ability of digital skills: individuals who does have low ability of digital skills, such as elderly people, may have difficulties in accessing product information in electronic way
- Lack of internet access: Rural areas or emergency situations which have problems with internet access (download) or no internet connections

E-labeling implementation in Japan

Regulation/ guidance issued	E-labeling platform	Type of products	Easy accessibility to e-label (e.g. via bar code)	Eliminating paper labeling from a commercial pack	Structured contents of labeling such as XML	Interoperable e-labeling
Feb 2021	✔ (HA)	Rx	✔ GS1 barcode App is used	✔All Rx	✔	NA

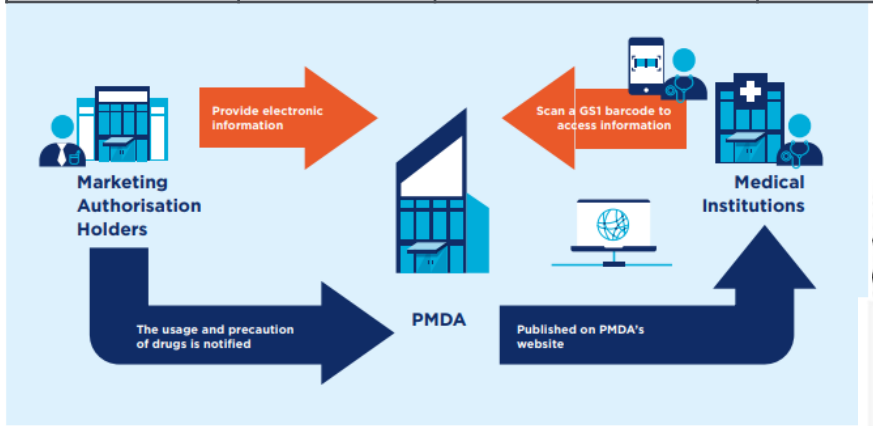


Figure 3: Now, healthcare providers and patients alike can scan a pharmaceutical package's barcode and the Digital Link's URI directs them to the PMDA website that then directs them to the product's e-leaflet.

MAH (in cooperation with a wholesaler, if needed)

- Provide package inserts in paper format to medical institutions/pharmacies at the initial delivery of the products.
- Provide revised information in paper media, etc. to medical institutions/pharmacies without delay.

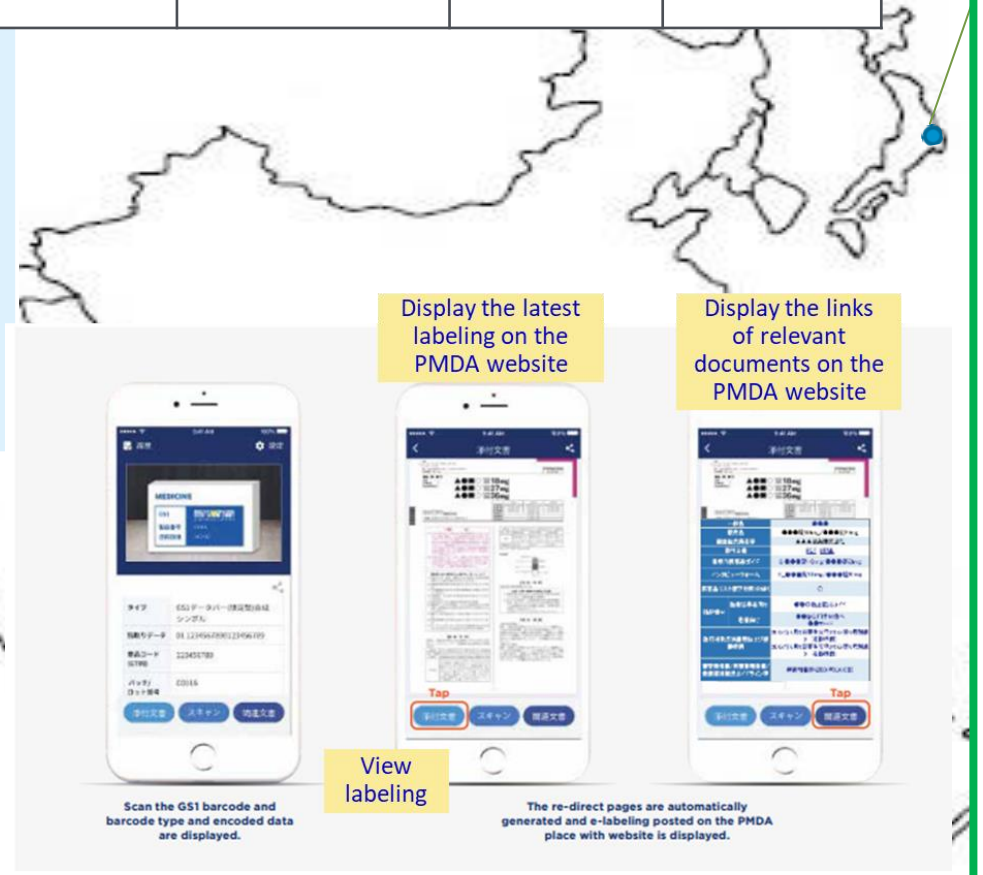
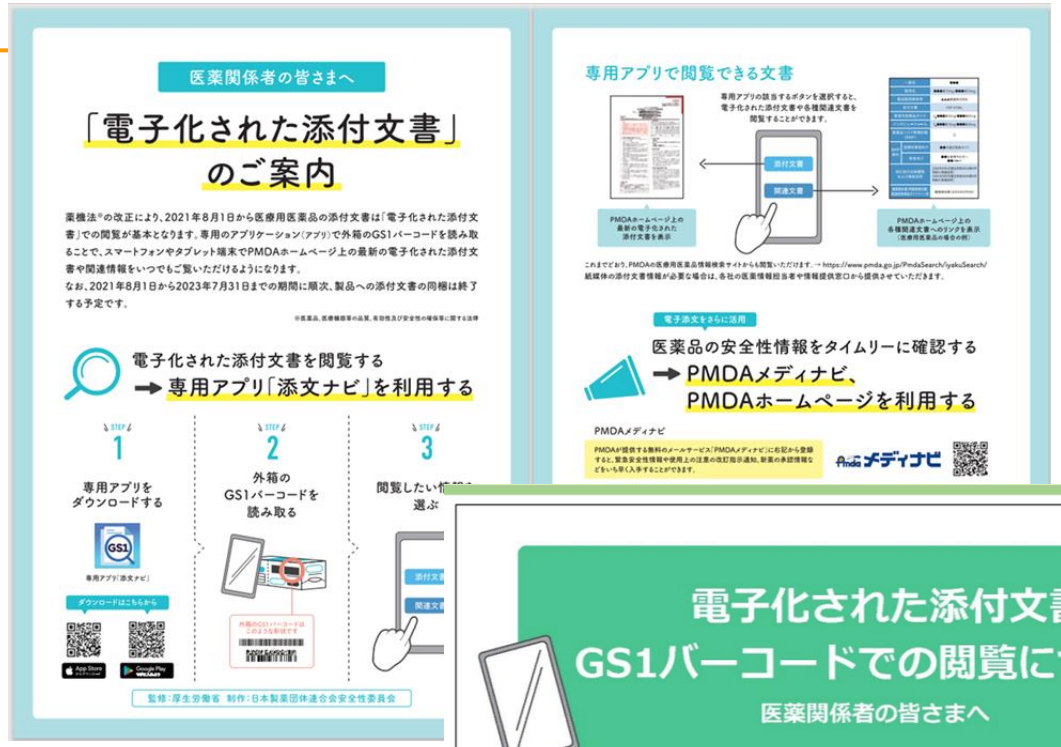


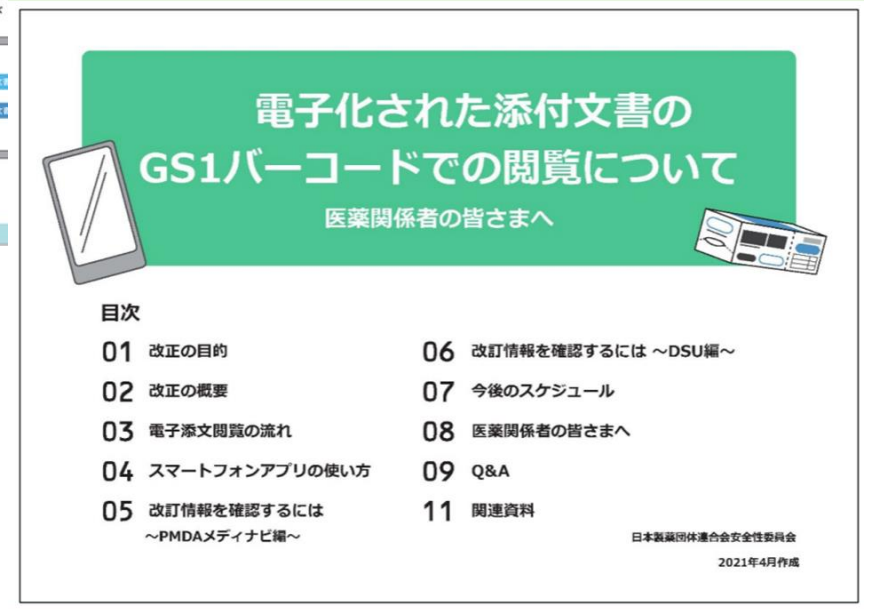
Figure 4: The Tenbun-Navi app makes e-leaflet information easily accessible via a smartphone or tablet. (https://www.dsri.jp/standard/healthcare/tenbunnavi/app/index.html)

- PMDA has required SGML versions of the JPI (HCP labeling) for many years and has started to switch to XML in 2019.
- In December 2019, Pharmaceuticals and Medical Devices Act was amended to introduce e-labeling officially, replacing paper labeling and accompanying necessary scheme that enables all healthcare professionals access the up-to-date labeling information.
- The GS1 bar code is required to print on the outer box so that healthcare professionals can access labeling information. A mobile app for reading GS1 barcode became available from May 2021.
- The enforcement of the amendment was implemented on Aug 1, 2021.
- **There is a 2-year transition period and paper labeling has been removed by the end of July 2023.**

Japan case: What industry have done for e-labeling implementation

- Upload labels on the PMDA website
- Complete the linkage between GS1 code and labeling information
- Establish the process including updating SOP to implement e-labeling
- Educate HCPs on how to use e-labeling including the app





http://www.fpmaj.gr.jp/Library/eMC/documents/Leaflet_2P.pdf

What companies have completed: Packaging Impact Assessment for e-labeling

Roles of packaging:

- Protect and preserve products during transportation, storage and distribution from initial containment to the end of the product consumption.

Critical roles of packaging insert:

- Can be served as a tangible packaging functional component
- Aid steadiness of the product in container during transportation
- Can provide some degrees of light protection and thermal insulation

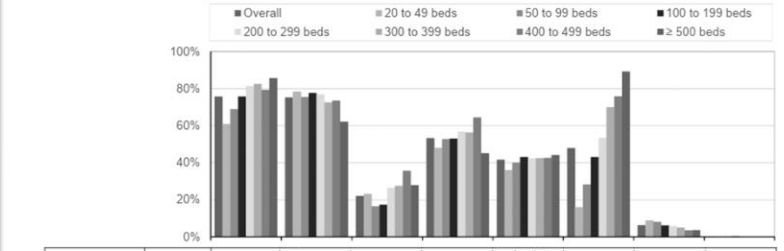
Packaging Risk Assessment is a MUST Prior to ePI Implementation

Japan: Acquisition of the latest information related to the digitization of package inserts (Duration June 17 to July 29, 2022)

- 75.6% of hospitals and 48.1% of pharmacies visit the PMDA website to see the latest package insert information
- 47.9% and 55.0%, respectively of the respondent facilities use their in-house system such as the electronic medical record system and receipt computer system.
- 75.2% of hospitals and 71.4% of pharmacies also refer to paper package insert
- **Only 1.7% of hospitals and 2.7% of pharmacies relay solely on paper package inserts**

https://www.pmda.go.jp/files/000252814.pdf#page=14

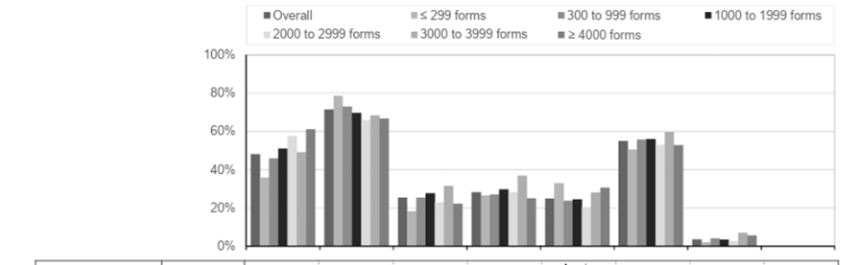
Figure 3-1: Method of browsing the latest package insert information (multiple choices allowed) [hospitals]



	Number of respondent facilities	Search the PMDA website		Read the paper package insert if included with the product.		Read the barcode (GS1 barcode) of the product using an application such as Tenbun Navi.		Check the website of the pharmaceutical company		Acquire information from the medical representatives (MRs) or the marketing specialists (MS)		Use the in-house system such as electronic medical record system.		Other		No answer	
			(%)		(%)		(%)		(%)		(%)		(%)		(%)		(%)
Overall	1441	1090	75.6	1084	75.2	317	22.0	768	53.3	599	41.6	690	47.9	90			
20 to 49 beds	125		60.8		78.4		23.2		48.0		36.0		16.0				
50 to 99 beds	273		68.9		75.5		16.5		52.7		39.9		28.2				
100 to 199 beds	470		75.7		77.7		17.2		53.0		43.0		43.0				
200 to 299 beds	208		81.3		76.9		26.4		56.7		42.3		53.4				
300 to 399 beds	160		82.5		72.5		27.5		56.3		42.5		70.0				
400 to 499 beds	87		79.3		73.6		35.6		64.4		42.5		75.9				
≥ 500 beds	111		85.6		62.2		27.9		45.0		44.1		89.2				

Number of beds

Figure 3-2: Method of browsing the latest package insert information (multiple choices allowed) [pharmacies]



	Number of respondent facilities	Search the PMDA website		Read the paper package insert if included with the product.		Read the barcode (GS1 barcode) of the product using an application such as Tenbun Navi.		Check the website of the pharmaceutical company		Acquire information from the medical representatives (MRs) or the marketing specialists (MS)		Use the in-house system such as receipt computer system		Other		No answer	
			(%)		(%)		(%)		(%)		(%)		(%)		(%)		(%)
Overall	2103	1012	48.1	1502	71.4	533	25.3	594	28.2	522	24.8	1156	55.0	76	3.6	0	-
≤ 299 forms	192		35.9		78.6		18.2		26.6		32.8		50.5		2.1		-
300 to 999 forms	855		46.0		73.0		25.4		27.0		23.7		55.8		4.0		-
1000 to 1999 forms	744		51.1		69.6		27.7		29.7		24.5		56.0		3.4		-
2000 to 2999 forms	191		57.6		66.0		23.0		28.3		20.4		52.9		2.6		-
3000 to 3999 forms	57		49.1		68.4		31.6		36.8		28.1		59.6		7.0		-
≥ 4000 forms	36		61.1		66.7		22.2		25.0		30.6		52.8		5.6		-

Number of prescriptions

Outlook of e-labeling Initiatives in Asian markets

	Regulation/ guidance issued	Type of in-scope products	E-labeling platform	Easy accessibility to e-label via machine-readable code	Eliminating paper labeling from a commercial pack	Structured contents of labeling such as XML	Interoperable e-labeling
Japan	Feb 2021	Rx	✔ (HA)	✔ GS1 barcode App is used	✔All Rx	✔	NA
Singapore	Apr 2021	Rx	✔(Company or 3rd party)	✔Voluntary: company choice	✔ Voluntary	NA	NA
Taiwan	Dec 2021 (pilot) Sep 2023 (official)	Some injectables/ Oral administration (vaccine, contrast media)	✔ (HA)	✔Voluntary: QR	✔ Voluntary	✔	In discussion
Korea	Dec 2022 (pilot) Jan 2024 (official)	Hospital Injectables	✔(Company or 3rd party)	✔Voluntary: QR (Pilot ongoing)	✔ Voluntary: Pilot ongoing	NA	NA
Malaysia	Apr 2023	Biologic, New Drug Product, Generic Product Containing Scheduled Poison for Rx	✔(HA)	✔Voluntary: QR	✔Voluntary	NA	In discussion
Thailand	Jun 2023	All products	✔ (HA)	✔Voluntary: company choice	✔Voluntary: Only HCP labels	NA	In discussion
Indonesia	Sep 2023	Vaccines, injectables (1st phase), then other Rx (2nd phase), some OTCs (3rd phase)	✔ (HA) (pilot to be started)	✔Pilot to be started (2D barcode, app from HA)	✔Voluntary: Pilot to be started.	NA	NA

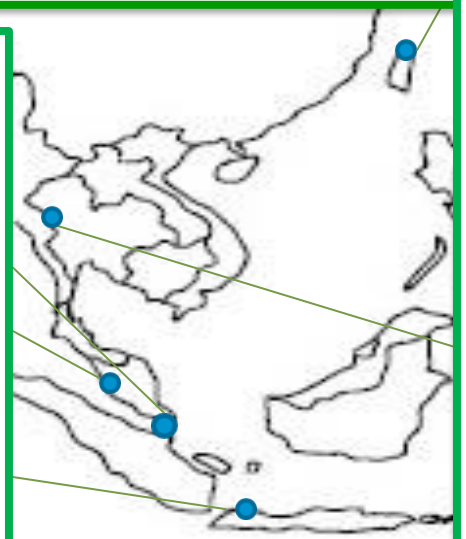
E-labeling initiatives in Asia

In Singapore, HSA published HCP and patient labeling on their website, but their website is not used in connection with e-labeling. **The first Therapeutic Product in April 2023 and it** is voluntary basis.

In Malaysia, both HCP and patient labeling are published on Malaysia HA (NPRA) website. **NPRA issued the Guideline on Electronic Labelling (e-Labelling) for Pharmaceutical Product in April 2023 and it** was effective immediately.

In Indonesia, **BPOM issued the Guidance on Implementation of e-labeling pilot project on September 14, 2023**.
In the Pilot Project, e-labeling will be available on BPOM website via serialization Barcode (QR or GS1 data matrix).
BPOM mobile app will be used for e-labeling purpose too. In Indonesia, GS1 data matrix has been implemented for serialization purpose for some products, for which BPOM has already developed a mobile app and the function of e-labeling will be added. Paper labels can be removed. The pilot will be lasted for 2 years.

In Korea, MFDS issued the e-labeling pilot guidance in December 2022. E-labeling pilot project of pharmaceuticals has been started from 2023.
The target products are injections only used in medical institutions. The exemption from the provision of was made when ectronic information (e-abeling is linked to the he license holders during



In Taiwan, Taiwan FDA and the trade association completed a 6-month phase 1 pilot study for selected HCP labels in 2021. The objective was to test the e-labeling platform constructed by TFDA in order to transform to XML format in the future.

- Currently, the new TFDA e-labeling website (https://mcp.fda.gov.tw/) is open to the public and consumers can search the labeling document in either

In Thailand, the Thai FDA has officially announced e-labeling has been fully implemented for new registration via e-submission since June 23, 2023.
e-labeling implementation is mandatory for new registration application submitted after the announced date.
Accessibility code such as QR code should be indicated on the product carton.
Once the accessibility code is scanned, the product information for HCPs and patients are available as the PDF files from the Thai FDA website.
Paper labeling for HCPs can be removed due to the e-labeling implementation, but PIL is required for physical labeling.

Integrated Labeling of the Future

- Having labeling information only available as .doc (Word) or .pdf files is restrictive as they are “unstructured”. The files cannot be used “digitally”

- Creation of labeling in a common electronic standard (e.g. HL7FHIR) offers huge opportunity for further digital transformation

  - Linkage with Electronic Health Records
  - Production of tailored (personalised) labels
  - Automated creation of other materials
  - Provision of real world evidence possible

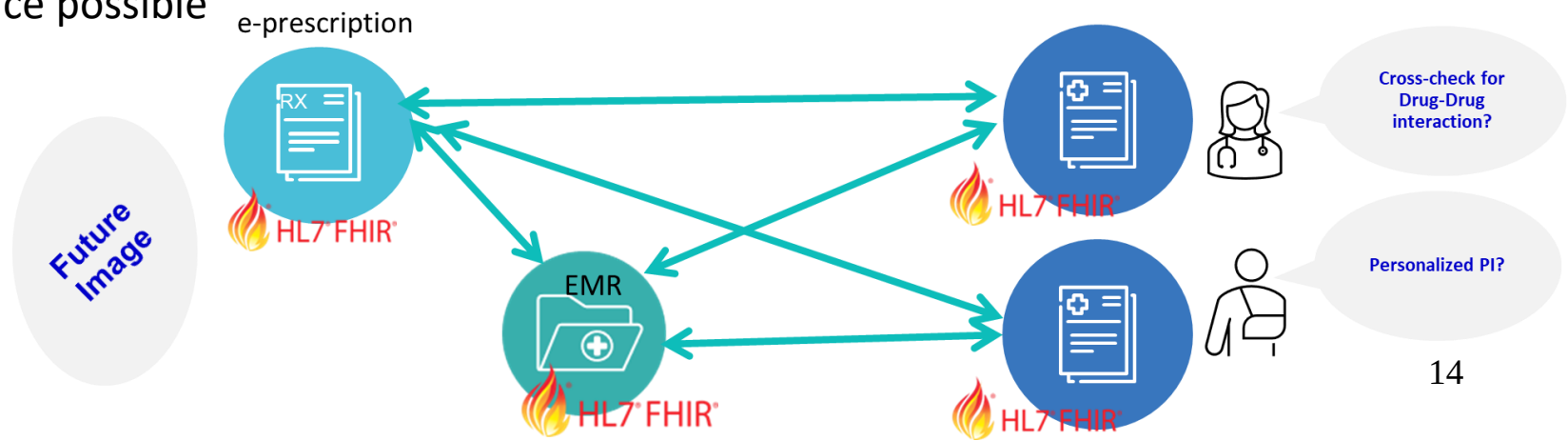
FHIR Adoption in India

- Biggest FHIR based healthcare project in the world (abmd.in) (290MM patients covered)

https://abdm.gov.in/

- ABDM FHIR IG here:

https://nrces.in/ndhm/



Summary

- Japan issued an e-labeling guidance in Feb 2021 and implemented e-labeling as a mandatory by the end of July 2023.
- Also, dynamic progress for e-labeling initiatives in Asian region has been made through 2023. 7 markets have issued an e-labeling guidance to implement or to start pilot for e-labeling initiatives.
  - ➢Issuing e-labeling guidance is the important step for e-labeling initiative.
- The structured contents of labeling based on international electronic common standard offers huge opportunity for further digital transformation. The adoption of HL7FHIR for the healthcare system has been progressing in India.
- The availability of patient centric labeling is only around 30 % of the markets in Asian region. Currently, the adoption of e-labeling is mainly for healthcare professionals, not much for patients.
  - ➢ The introduction of patient centric e-labeling should be encouraged.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go raibh maith agat
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