MEDINFO23

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ePI/eLabeling landscape in the Asia/Pacific

@twitterhandle

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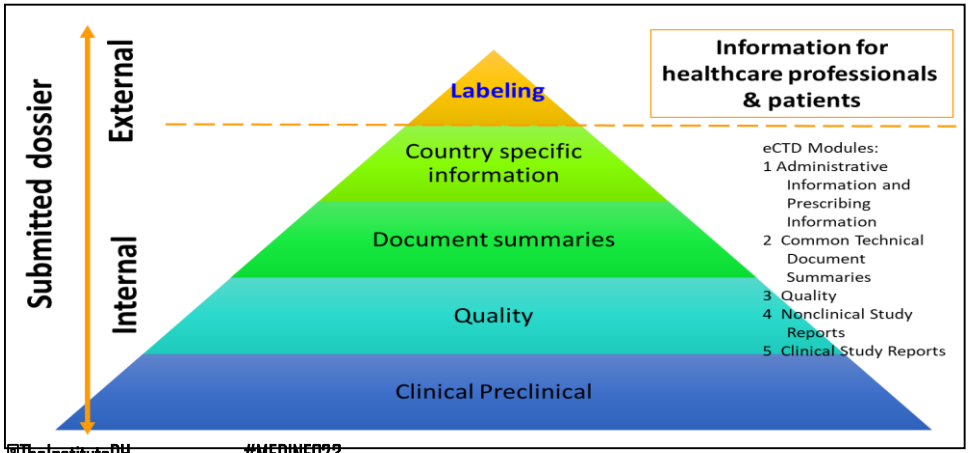
The Role of Product Information (the "Labeling")

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

"Labeling is a communication tool."

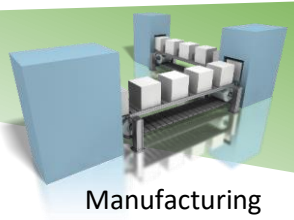


A variety of formats (paper, electronic) and types (patient, HCP) distributed according to national requirements

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

A Shift in Thinking

Health Authority



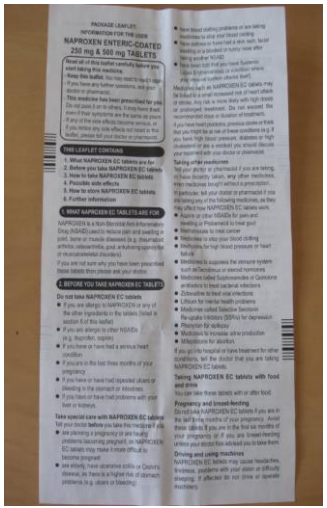
Manufacturing

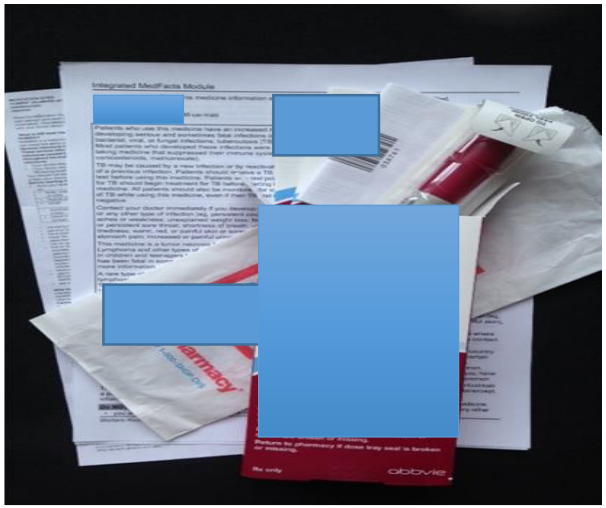
Much of the current focus on labeling is around negotiation of the content and maintenance of the product information post-approval

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 "**patient experience**"

Labeling Documents in the Commercial Pack





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

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. XML
- Interoperability between systems, e.g. share product information across wearable, e-Prescription, and e-Health record

https://link.springer.com/epdf/10.1007/s43441-022-00462-5?sharing_token=cjw66MHpy8y3u5eY0FRbk_e4RwlQNchNByi7wbcMAY4i0rWXuCGMKTqz0bt1IxPWS-llSMdQFzc1SY-1yhS5ssT5V6sNwHX_bcksgE_2q1M_6IAh2EGCLEWAAKNR6laKsS5-l4TQTfPbyrk1L6snNSvRhr_N75os6GDzg4wyXh4=

Benefits of e-labeling

For Regulators

- Faster Sharing of New Information
- Assurance of Accurate Information

For Health care professionals and patients

- Accessibility & Customizable Information
- Better Readability & Searchability

For Industry

- Reducing effort
- Reducing Lead Times To Launch New Products
- Potential to Address Drug Shortages
- Reducing Waste & Environmental Footprint

- Digital Health: interoperable with healthcare system

Concerns:

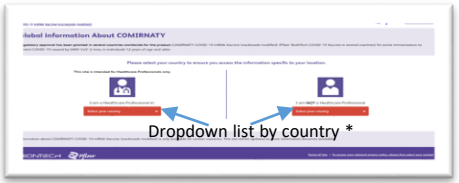
- Low digital literacy level: individuals who have lower levels of digital skills, such as an elderly people, may face difficulties accessing product information in an electronic way
- Lack of internet access: Rural areas or emergency situations where they have problems with internet access (download) or no internet connections

Regulatory Agility:
Case of e-labeling for COVID-19 Vaccines

Instead of inserting a paper labeling, "*e-labeling*" has been introduced for COVID-19 vaccines

- QR code is located on the product carton box
- Scanning of the QR code brings users to the company COVID-19 landing page
- There is a dropdown list* by country and options available for each country page (depending on local requirements)
- Direct to PDF (labeling)
  - Link to an external webpage e.g., HA website, company product page
  - Provide option to add local specific information/documents as requested by local HA

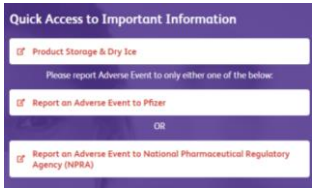
www.cvdv[redacted]om and/or
https://ww[redacted]irnatyglobal.com



Dropdown list by country *

* There is a separate website for Japan.

- **Around 70 markets' labels are available on the website**
- **Labeling has been updated approx. 1-3 times/month for the first 6 months**



The code and website are just a part of e-labeling elements; i.e., makes it easy to access the e-label. The next step is to make the *e-label itself personalized/more useful.*

E-labeling Is a Hot Topic Across Regions

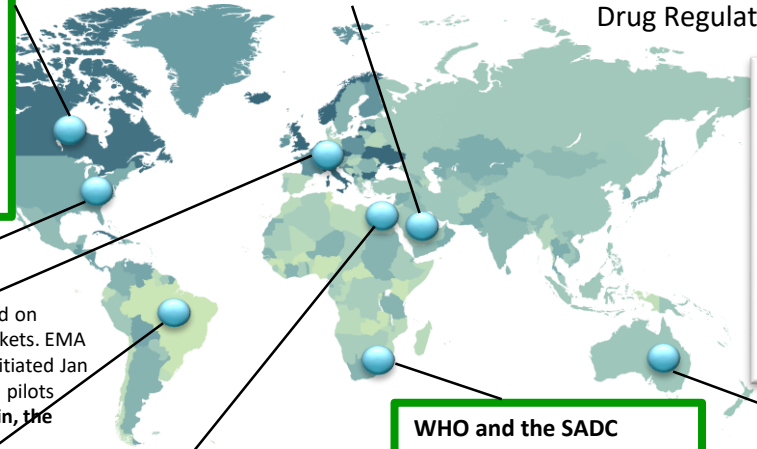
In Canada, a Notice of Intent was issued in Apr 2019 advising of a transition from Product Monographs (in pdfs) to an XML Structured Format (in line with HL7 SPL standards); whereby they communicated the structured information would increase the level of detail available to the public for search and more interactive. Some products have been approved to remove the physical copy of the paper in the pack. In Apr 22 – Interim implementation measures were adopted by Health Canada.

In US, US SPL (an XML format) is available post FDA approval and is posted to DailyMed to enable advanced searching.

In EU, Regional (EMA) and national e-labels commonly published on websites, with enhanced information are available in some markets. EMA ePI 'key principles' published Jan 2020 and ePI Set-Up Project initiated Jan 2021. There are also several national initiatives, such as hospital pilots [illegible] **Spain, the**

In Brazil, ANVISA have made proposals in their Packaging Materials RDC 47/09 guidance that will allow PI to be made available via a digital mechanism. ANVISA also temporarily allowed some paperless packs for hospital destination to be used to support the COVID pandemic.

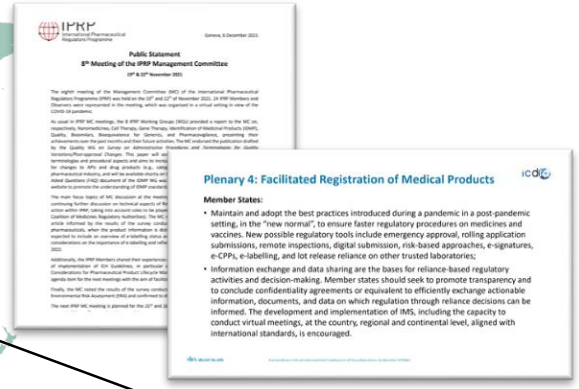
In Saudi Arabia, a Saudi Drug Information (SDI) website has been developed which holds all PILs and SmPCs for registered products in XML format. A Tammeni app has also been launched.



In Egypt, The EDA have issued a guidance th[illegible] the availability of a e-label on their platform[illegible] accessible via a QR code added to secondar[illegible] support easier access of PI to users. They ha[illegible] announced the possibility to remove paper[illegible] hospital products.

WHO and the SADC markets have completed some e-labeling pilots in South Africa and Zimbabwe linking the packs to PI.

E-labeling is also a current focus for organizations such as the International Pharmaceutical Regulators Program (IPRP) and the International Conference of Drug Regulatory Authorities (ICDRA)


IPRP
International Pharmaceutical Regulators Programme

Public Statement
8th Meeting of the IPRP Management Committee

Plenary 4: Facilitated Registration of Medical Products

Member States:

- Maintain and adopt the best practices introduced during a pandemic in a post-pandemic setting, in the "new normal", to ensure faster regulatory procedures on medicines and vaccines. New possible regulatory tools include emergency approval, rolling application submissions, remote inspections, digital submission, risk-based approaches, e-signatures, e-CPPs, e-labelling, and lot release reliance on other trusted laboratories;
- Information exchange and data sharing are the bases for reliance-based regulatory activities and decision-making. Member states should seek to promote transparency and to conclude confidentiality agreements or equivalent to efficiently exchange actionable information, documents, and data on which regulation through reliance decisions can be informed. The development and implementation of IMS, including the capacity to conduct virtual meetings, at the country, regional and continental level, aligned with international standards, is encouraged.

In Australia, a 3rd party website (the Pharmacy Guild) hosts e-labeling for many years now, with just-in-time printing available at the Pharmacy.

	E-labeling platform	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
EU	✔ (HA)	In discussion		Will start a pilot	Will start a pilot
U.S.	✔ (HA)			✔	✔
Japan	✔ (HA)	✔ GS1 barcode	✔	✔	
Singapore	✔(Company or 3rd party)	✔Voluntary (company choice)	✔ Voluntary		
Korea	✔(Company or 3rd party)	Pilot underway (QR)	Pilot underway	✔	
Taiwan	✔ (HA)	Pilot underway (QR)	Pilot underway	Pilot underway	
Malaysia	✔(HA)	✔Voluntary (QR)	✔ Voluntary		
Thailand	✔ (HA)	✔Voluntary	✔(HCP labels) Voluntary		
Indonesia	Will start a pilot (HA)	Will start a pilot	Will start a pilot		

E-labeling initiatives in Asia

In Singapore, HSA pub
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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
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-labeling is linked
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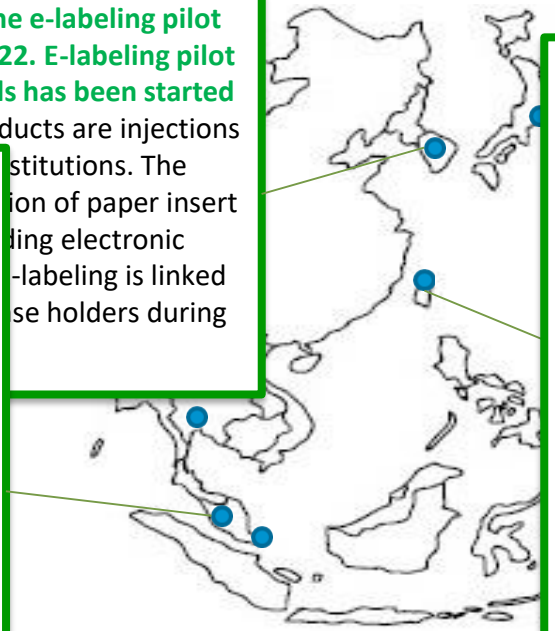
In Malaysia, both HCP and patient labeling are published on Malaysia HA (NPRA) website. **NPRA issued the Guideline on Electronic Labelling (e-Labelling) for Pharmaceutical Product in April 2023 and it was effective since May 1**, 2023. The provision of an approved product information that includes the package insert (PI) and/or Consumer Medication Information Leaflet (RiMUP) electronically via a machine readable QR code on the outer carton/inner label of the product that links to the NPRA QUEST3+ system. It is voluntary for companies to implement e-labeling where physical labels need not be distributed with the pack.



In Japan, 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
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In Chinese Taiwan, Taiwan FDA and the trade association completed a 6-month phase 1 pilot study for selected HCP labels. The objective was to test the e-labeling platform constructed by TFDA in order to transform to XML format in the future. **Taiwan FDA issued a notification to conduct a 2-year phase 2 pilot studies for injectable product** used in hospital for selected HCP labels, restrict to vaccine/blood products/Botox, anticancer **to remove a paper labeling from the commercial pack**. Barcode must be registered on the website. The format must use standard labeling format, and upload to the TFDA website

In Thailand, e-labeling has just been implemented in June 2023.

E-labeling System in Japan

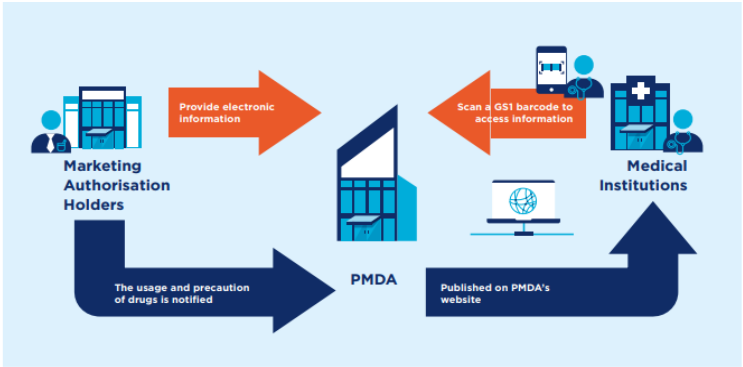


Figure 3: Now, healthcare providers and patients alike can scan a pharmaceutical package's barcode and the Digital Link's URI directs them to the PMDA website that then directs them to the product's e-leaflet.

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 to medical institutions/pharmacies without delay.

- Several educational materials were created by the industry association.

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)

- An app for HCP has been developed by the Federation of Pharmaceutical Manufactures' Associations of Japan, the Japan Federation of Medical Devices Association and GS1 Japan.

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

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.

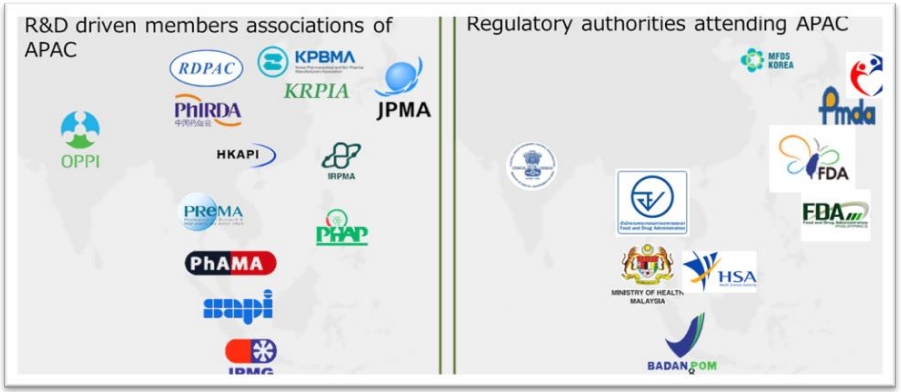
GS1HC-Reference-Book-2021-2022-FINAL.pdf

Integrated Labeling of the Future

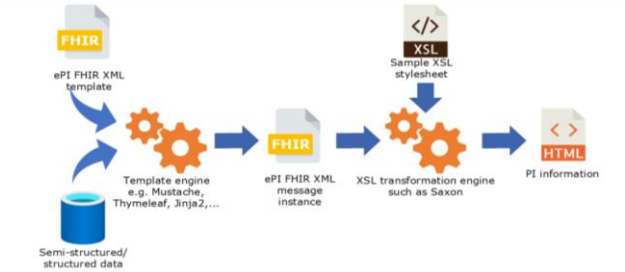
In Japan, a pilot study on the use of J-PI in the format that complies with HL7FHIR, which is an international standard, is planned by the consortium*.

APAC Asia Partnership Conference of Pharmaceutical Associations

* One of the Asia Partnership Conference of Pharmaceutical Associations (APAC) initiatives.



- 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 Medical Records
  - Production of tailored (personalised) labels
  - Automated creation of other materials
  - Provision of real world evidence possible



https://github.com/EuropeanMedicinesAgency/EU-ePI-common-standard/tree/master/XML%20templates

Thank you

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