Share and agree to the APAC EWG position paper

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Outline of Presentation

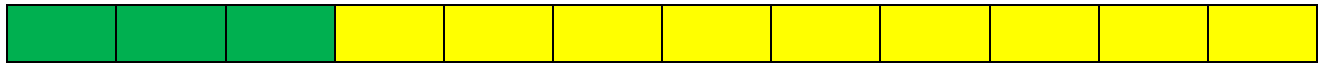
1. Introduction
2. Factors
   - Availability of the latest labeling on publicly accessible website
   - Accessibility through a reader-friendly format
   - Eliminating paper labeling from commercial pack
   - Common electronic standard for efficient information flow
3. Conclusion
4. Acknowledgments

Introduction

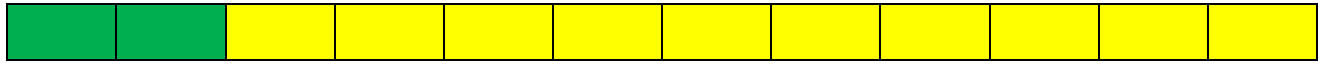
Status of e-labeling implementation in APAC markets

1) Availability of the latest labeling on a publicly accessible website (product information available online)

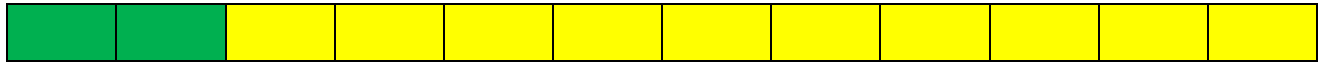
2) Accessible, reader friendly format, e.g., scanning a code



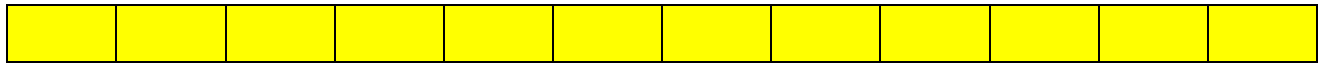
3) Eliminating paper labeling from commercial pack



4) Common electronic standard, e.g., structured contents



5) Efficient information flow, e.g., interoperability between systems



Implemented
Not implemented

- There are different levels of e-labeling initiatives in Asia, although most of the markets have started to discuss e-labeling initiatives.
- The discussion on e-labeling initiatives is still at early stage in majority of markets, and there is a challenge due to a variety of approaches in the region.
- This position paper proposes how to proceed with e-labeling initiatives to have a consistent approach in Asia.

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Introduction

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.

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Availability of the latest labeling on publicly accessible website

Option	Pros	Cons
Health Authority (HA) Website	• Reliable and secure, single source of information • Facilitates the comparison of product information of various drugs • Centrally-managed platform	• Less flexibility in terms of controls, features and ownership from MAH perspective • Increase burden in rolling-out and maintaining the website from HA perspective
Company Website	• Internally updated and managed by MAH who has full control and accountability • Real-time uploading and implementation of labeling	• Need to establish reliability and security of information • Need to ensure consistency in the management of e-labels
External Vendor Website	• Resources may be shared by industry • More centralized platform for HCPs and patients	• Need to establish reliability and security of information • Need to ensure consistency in the management of e-labels

Proposed Position (Using Company or External Vendor as a platform)

For Company Websites:

- The e-label should be managed internally by MAH for document version control.
- The newly approved/registered e-label is published and available with PDF or structured format of labeling (XML) on the company website in a timely manner agreed with HA.
- The company is responsible for ensuring compliance with local law and regulation, importantly the accuracy of the approved/registered version and timeline until publishing completion.

For External Vendor Websites:

- The e-label is managed by the MAH for document version control.
- The newly approved/registered e-label is transferred from the MAH to the external vendor via the secured platform in a timely manner and then published and available with PDF or structured format of labeling (XML) on the external vendor website in a timely manner as agreed.
- The MAH is still the owner and responsible for ensuring compliance with local law and regulation, importantly the accuracy of the approved/registered version and overall timeline until publishing completion on the external vendor website.
- Monitoring and evaluation as a tool for oversight of the external vendor operation is essential to ensure compliance.

“Each local market should base their decision on how to make labeling information publicly accessible in consideration of their available resources while referring to the pros-cons for each approach.”

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Accessibility through a reader-friendly format

It is ideal that there should be a single, reader-friendly accessibility code format printed on the packaging of a pharmaceutical product

http://www.example.com/filename.html

Scan QR code for more product information

GS1 DataMatrix

(01)09521101530001
(17)210119(10)AB-123

GS1-128

(01) 1 9521101 53000 8 (17) 210704 (10) AB-123

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Accessibility through a reader-friendly format

A stepwise approach should be considered by adopting markets after carefully assessing the pros and cons of the available code formats and the markets' varying levels of capacity, available technology, internet connectivity and end-user's preference, among other factors

Format	Benefits/Pros	Risks/Cons
URL http://www.example.com/filename.html	• No need for specific devices or applications.	• It takes some time to reach to the e-labeling due to manual encoding. • Challenging to print if long text or packaging has limited space.
QR Code	• Almost all mobile devices can scan the code without specific applications. • It can be scanned anytime, anywhere using mobile devices.	• Need additional printing of QR code to the packaging with prior codes for other purposessuch as serialization , which may cause confusion for end-users. • Some people are not too familiar with mobile devices.
GS1 Barcodes 	• Existing GS1 barcode for serialization on the secondary packaging can be utilized for e-labeling as well. • It can be scanned anytime, anywhere using mobile devices.	• Need specific application for scanning. • Some people are not too familiar with mobile devices.

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Paperless

Implementation

- Paper PI co-exist (during interim period)
- Remove paper PI (with on-demand printing)

Operational

- Change control and QC
- Communication to HCP
- Packaging redesigning?

Regulatory

- Guidance document
- Access security (cyber security)

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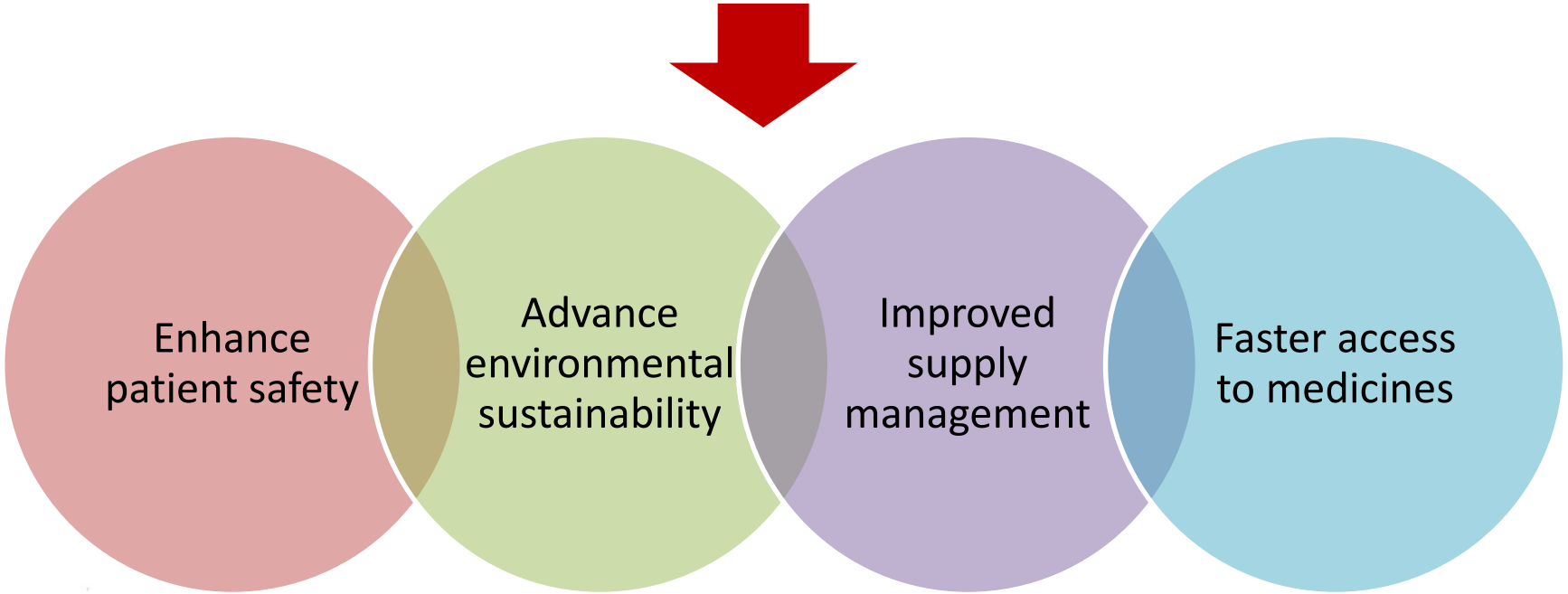
Paperless

Conduct survey/ seek feedback *to assess the readiness to implement e-labeling*

Communicate to all stakeholders *to create awareness*

Conduct pilot *to assess feasibility and identify challenges for continuous improvement*



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Common electronic standards

A common electronic standard for ePI should be adopted in the creation, submission, and review process to allow searching, reuse, and potential integration with other digital health platforms **i.e., interoperability**.

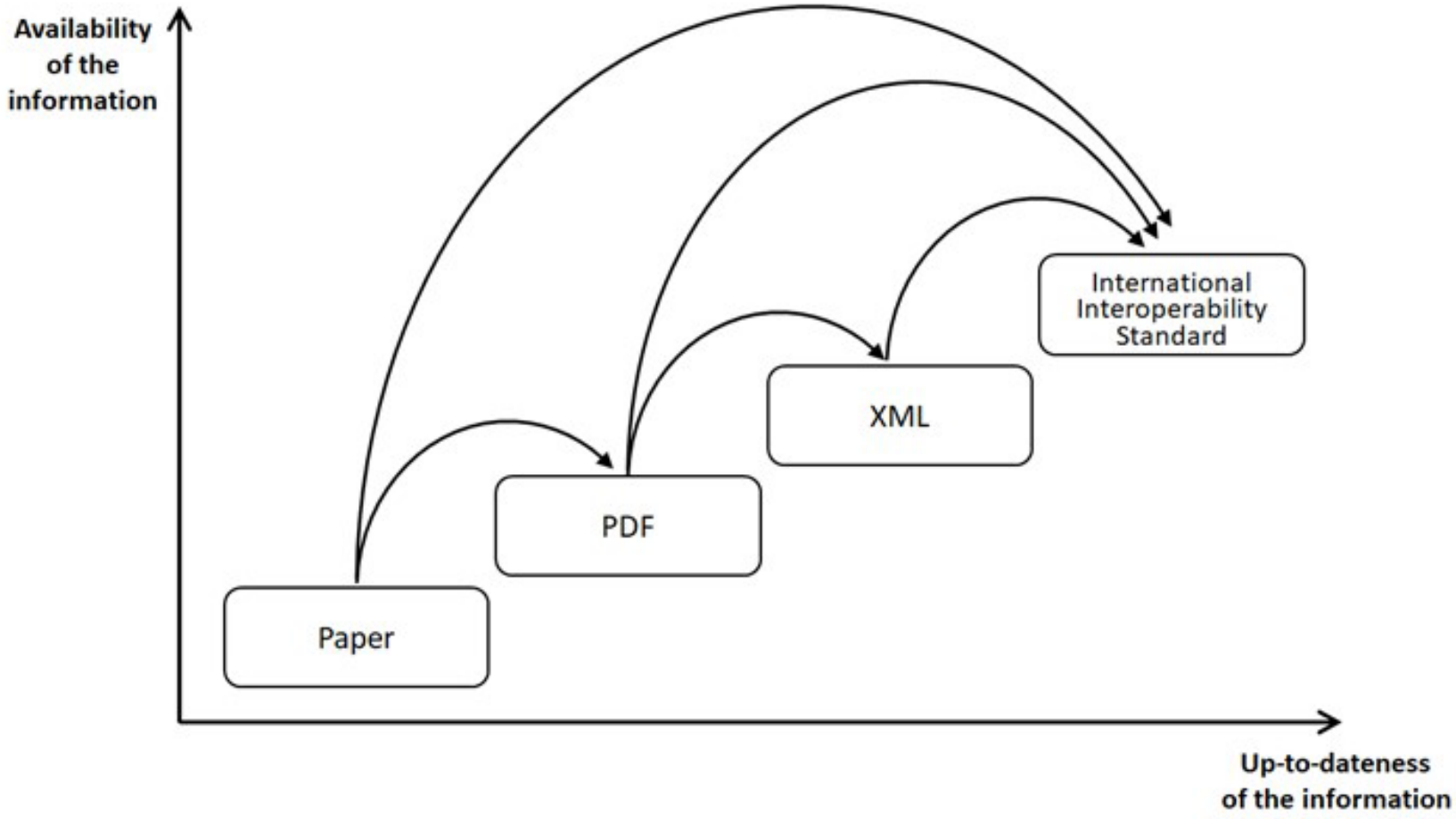
Identification of existing electronic standards

Market	Implementation (Current or Planned)	Electronic Standard for structured contents
USA	SPL (Structured Product Labeling)	HL7 Structured Product Labeling (SPL)
EU	ePI (electronic Product Information)	HL7 Fast Healthcare Interoperability Resources (FHIR)
Japan	PMDA XML PI	PMDA-custom XML Schema

Pros and Cons of Electronic Standards

		Acceptability in APAC	Affordability in APAC	Accessibility in APAC
HL7 SPL (USA)	Pros	• **Interoperable** • A history of over 15 years • Familiar • Flexible	–	• Standard is **freely accessible** • Written in English • Lots of available resources for reference
	Cons	• No backward compatible	• Initial cost might be high • Maintenance cost may increase	• Transition to FHIR • Training required for users familiar with traditional tools (MS Word, PDF, etc)
HL7 FHIR (EU)	Pros	• **Interoperable** • APAC requirements (if any) will be met by either core or extended specification. • Strong support of implementation	• **Low total and long-term cost**	• **Freely accessible** • Written in English • Based on well-accepted technologies
	Cons	• Unfamiliar • **No country/region has implemented yet**	• Initial cost might be relatively high	• Might be tough to catch up
PMDA-custom XML Schema (Japan)	Pros	• Used over 2 years • English labeling is applicable	–	• Specifications for the Schema is already available
	Cons	• Currently only support for Japan e-labeling • Not designed to be interoperable	• Initial cost might be high	• Documentations are written in Japanese

Common electronic standards
- Stepwise Approach -



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Conclusion

- E-labeling is now a global hot topic in regulatory and digital health circles, with rapid progress being made over the last few years.
- As there is no universal standard for e-labeling initiatives, this position paper proposed a regional guidance for Availability, Accessibility, Paperless, and Common standards.
- The close collaboration between agencies, HCPs, patients, and industry associations are important to move the e-labeling initiatives forward in Asia.

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