14th APAC “e-labeling Session”
Accelerate e-labeling initiatives, interoperability across digital health platforms, as part of health data ecosystem for patients

22-April-2025

Asia Partnership Conference of Pharmaceutical Associations（APAC）
E-labeling Expert Working Group

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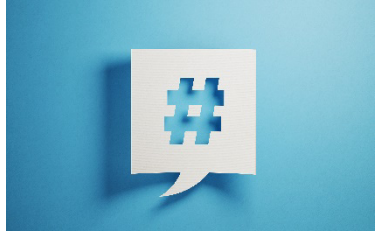

Conclusions and Next Steps from APAC e-labeling session in 2024

✔ ◆ Dynamic progress for e-labeling initiatives such as issuing an e-labeling guidance in Asian region has been made through 2023. It was an amazing year for APAC e-labeling EWG after the EWG has been established since 2021. However, e-labeling initiatives are implemented on a voluntary basis in many markets in Asia. It was agreed upon encouraging the increased uptake in the availability of e-labeling – more markets, more companies, more products, and more e-labeling for patients.

✔ ◆ The discussion on the structured contents of labeling based on international electronic common standard for digital health has just started in a few markets. It was agreed to discuss further on the introduction of structured content of labeling based on international electronic common standard at the 3rd APAC e-labeling regulators workshop. The adoption of HL7FHIR for the healthcare system has been progressing in many markets in Asia and should be in mind for e-labeling initiatives.

✔ ◆ 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. It was agreed to encourage the important introduction of patient centric e-labeling.

✔ ◆ The results of APAC e-labeling survey targeting 12 Asian economies has been conducted to monitor the progress of e-labeling initiatives in the Asian region. It was confirmed for past 3 years and will be continued.

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Achievement (1)

Collaboration between APAC e-labeling EWG and Asian markets

- Discussed e-labeling at the India-Japan symposium.
- Collaboration on e-labeling workshop/session with IPMG in Indonesia, IRPMA in Taiwan and PReMA in Thailand.

12:15-13:00	(4) E-Labeling Implementation in Japan and Asia - from industries perspective -	Ms. MATSUI Rie Pfizer R&D Japan, JPMA
	(5) Revised G (Schedule –	
	(6) Q&A	

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Submission for the MHLW Research Application

- Submitted the MHLW research application for the FHIR e-labeling project in August 2024.
- Was not accepted
- Will try to find the next opportunities

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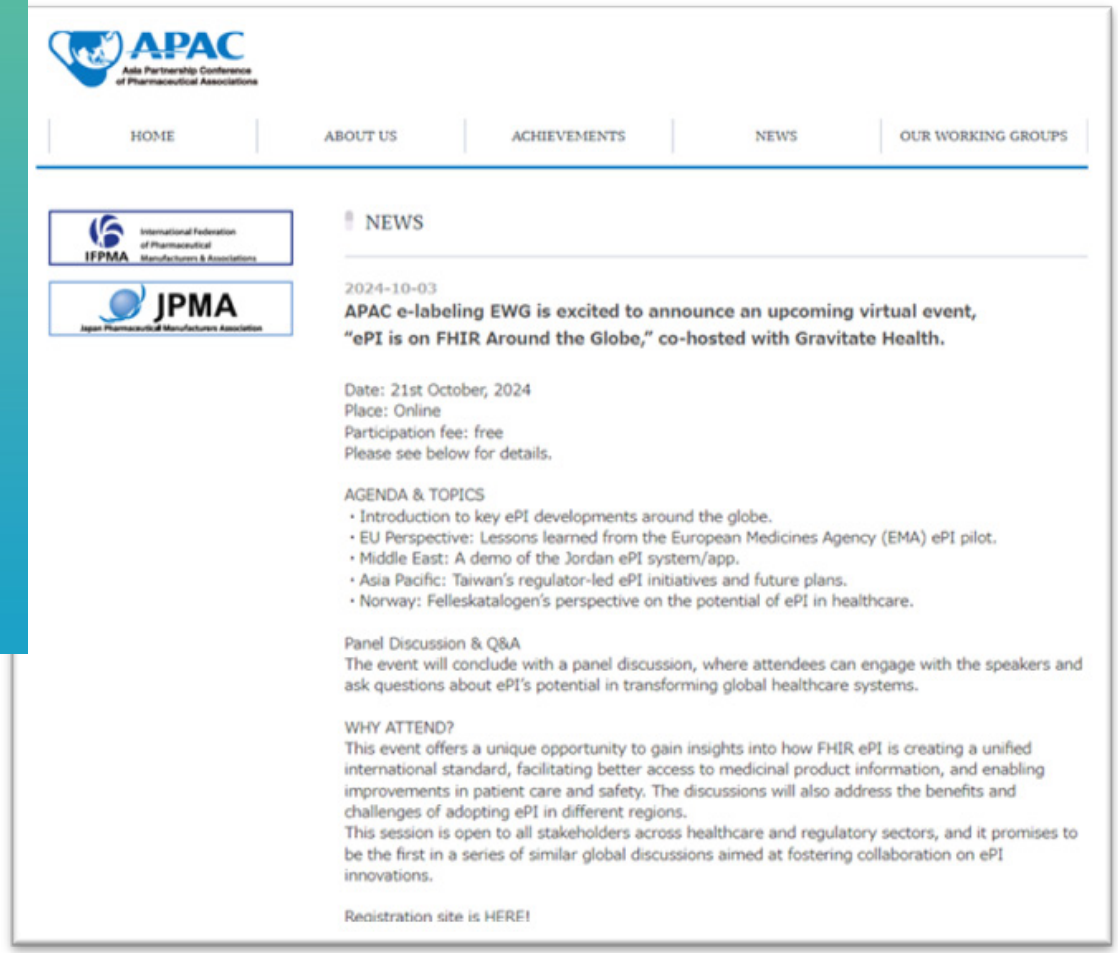
Achievement (2)

APAC and Gravitate Health joint event & APAC e-labeling Regulators Meeting 21st October 2024



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APAC Regulators-Industry Joint Workshop for e-labeling was held on April 21, 2025

14:30	-	18:00	210			
14:30	-	14:35	5	1. Opening Remarks	APAC e-labeling Leader	
14:35	-	15:20	45	2. FHIR e-labeling (1) What FHIR e-labeling is, what we should prepare, how to introduce FHIR e-labeling	Craig Anderson	HL7 VULCAN Electronic Product Information
15:20	-	15:30	10	(2) Advancing E-Labeling in Taiwan: Implementation Journey and Future Plans	Mei-Chen Huang	Taiwan FDA
15:30	-	15:55	25	(3) Q&A for the session 2	All	
15:55	-	16:05	10	Break		
16:05	-	16:15	10	3. Patient Centric Product Information (Paperless-FHIR use case) (1) Overview of Patient Centric Product Information	Rie Matsui	JPMA
16:15	-	16:30	15	(2) PMDA initiatives for Patient Centric Product Information	Miki Ota	PMDA
16:30	-	16:45	15	(3) Q&A for the session 3	All	
16:45	-	17:30	45	4. Group discussion on Use cases	All	
17:30	-	17:35	5	Break		
17:35		17:55	20	Share the group discussion (3 minutes x 4 groups) (Options: HCP labels, patients labels, Potential use FHIR: Type 2, 3, 4) Personalized labels	All	
17:55	-	18:00	5	5. Closing remarks		
18:00	-			Reception		

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2025 APAC e-labeling session:

Accelerate e-labelling Initiatives, Interoperability across Digital Health Platforms, as Part of Health Data Ecosystem for Patients

Time	Presentation	Speaker
13:00-13:06	Opening	Rie Matsui, JPMA
13:06-13:21	FHIR ePI and the Future of Electronic Labeling and Digital Health	Craig Anderson, Co-lead, HL7 VULCAN Electronic Product Information Project, International Labeling, Pfizer
13:21-13:29	e-Labeling Progression - Thailand	Worasuda Yoongthong, Thai FDA
13:29-13:37	The Future of Pharmaceutical Labeling: Updates on Malaysia's e-Labeling Initiative	Maslinda Mahat, NPRA
13:37-13:45	Advancing E-Labeling in Taiwan: Implementation Journey and Future Plans	Mei-Chen Huang, Taiwan FDA
13:45-14:35	Panel Discussion	All Speakers plus Miki Ota, PMDA YeonHae Han, MFDS Nova Emelda, BPOM Maria Cecilia Matienzo, PH FDA Annam Visala, CDSCO
14:35-14:40	Closing	Miki Ota, PMDA

2025 Quick Survey Results: Which areas would you like to move forward in the next 3-5 years?

	IDN BPOM	JPN PMDA	KOR MFDS	MYS NPRA	PHL PFDA	TWN TFDA	THA Thai FDA	IND CDSCO
1) Availability of the latest labeling on a publicly accessible website (e.g. product information available online)			✓	✓	✓		✓	✓
2) Accessible, reader friendly format (e.g. scanning a machine readable code)			✓	✓	✓		✓	✓
3) Eliminating paper labeling from commercial packs	✓		✓	✓		✓	✓	
4) Common electronic standard (e.g. structured contents such as FHIR e-labeling)	✓		✓			✓	✓	✓
5)-Interoperability between systems (e.g. share product information across wearable, e-prescription, and eHealth record)		✓			✓	✓	✓	✓

E-labeling Session Conclusions:

Accelerate e-labelling initiatives, interoperability across digital health platforms, as part of health data ecosystem for patients

- **Session summary**

• Cooperating between APAC regulatory authorities and APAC e-labeling EWG, e-labeling initiatives have significantly advanced by revising e-labeling regulation and issuing e-labeling guidance.

• In Europe and US, discussion on e-labeling have been made for interoperability across digital health platforms and FHIR e-labeling. They are shifting towards implementation. When introducing structured contents of e-labeling in APAC region, we have discussed the benefits/risks of implementing FHIR (International electronic common standard).

• In APAC region, only around 30 % of the markets prepare and provide patient labeling for prescription drugs. We reaffirmed the importance of providing e-labeling for patients.

- **Session Conclusions**

• Accelerate implementation of e-labeling in APAC region for more products and more markets.

• Consider implementing FHIR and utilizing interoperability across FHIR e-labeling and digital health platforms when introducing structured contents of e-labeling in APAC region.

• Promote the provision of e-labeling for prescription drug to patients in APAC region and discuss further utilization as a part of the health data ecosystem.

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Let’s work together for patients in Asia

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