



APAC

Asia Partnership Conference
of Pharmaceutical Associations

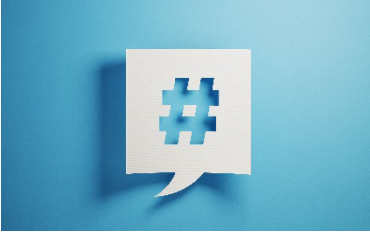
To expedite the launch of innovative medicines
for the peoples in Asia.



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



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.

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	



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

研究の全体像



Achievement (2)

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



Gravitate Health | APAC
Asia Partnership Conference
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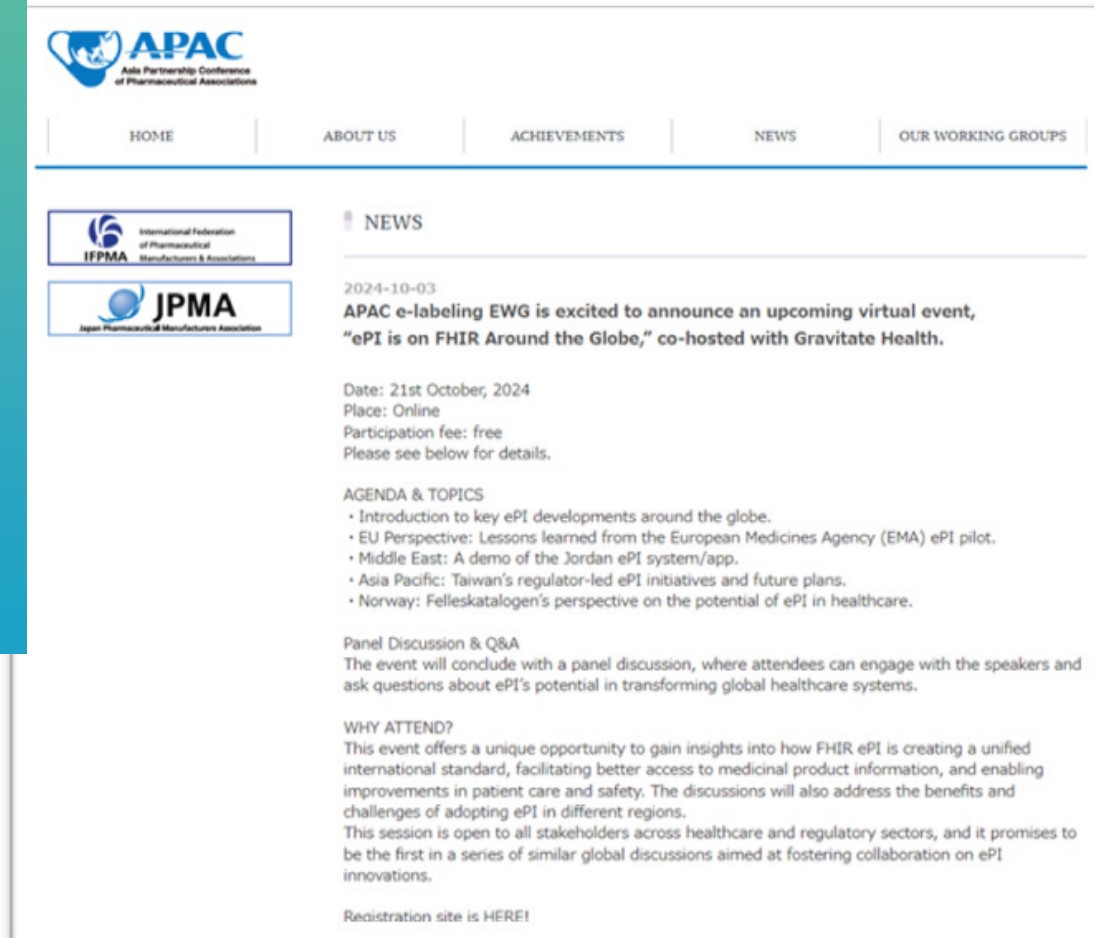
JOINT SESSION ON:
ePI is on FHIR around the globe

WHEN? 21 October 2024
09:00-11:00 CET | 10:00-12:00 Jordan | 16:00-18:00 Tokyo

WHERE? Virtual

Register now!

Logos at the bottom: European Union, efpi*, imi (innovative medicines initiative), and Datastream.



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IFPMA International Federation of Pharmaceutical Manufacturers & Associations
JPMA Japan Pharmaceutical Manufacturers Association

NEWS

2024-10-03
APAC e-labeling EWG is excited to announce an upcoming virtual event, "ePI is on FHIR Around the Globe," co-hosted with Gravitate Health.

Date: 21st October, 2024
Place: Online
Participation fee: free
Please see below for details.

AGENDA & TOPICS

- Introduction to key ePI developments around the globe.
- EU Perspective: Lessons learned from the European Medicines Agency (EMA) ePI pilot.
- Middle East: A demo of the Jordan ePI system/app.
- Asia Pacific: Taiwan's regulator-led ePI initiatives and future plans.
- Norway: Felleskatalogen's perspective on the potential of ePI in healthcare.

Panel Discussion & Q&A
The event will conclude with a panel discussion, where attendees can engage with the speakers and ask questions about ePI's potential in transforming global healthcare systems.

WHY ATTEND?
This event offers a unique opportunity to gain insights into how FHIR ePI is creating a unified international standard, facilitating better access to medicinal product information, and enabling improvements in patient care and safety. The discussions will also address the benefits and challenges of adopting ePI in different regions.
This session is open to all stakeholders across healthcare and regulatory sectors, and it promises to be the first in a series of similar global discussions aimed at fostering collaboration on ePI innovations.

Registration site is [HERE!](#)

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		

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 CDSC O
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.

Let's work together for patients in Asia

