



“Enhancing access to innovative medicines for the people in Asia”

**Asia Partnership Conference of Pharmaceutical Associations
E-labeling EWG meeting**

21-April-2026
APAC e-labeling EWG



Chih-Kang Chiang Ph.D.

Director-General, Taiwan FDA
Ministry of Health and Welfare Taiwan

PERSONAL EXPERIENCES

- 2025/2/27~ Director General, TFDA, MOHW, Taiwan (R.O.C.)
- 2022/8~2025/2/26 Attending Physician and Director, Hemodialysis Division, Department of Integrated Diagnostic and Therapeutics, National Taiwan University Hospital
- 2024/8~2025/2/26 Professor and Director, Graduate Institute of Toxicology, College of Medicine, National Taiwan University
- 2023/8~2025/2/26 Deputy Vice President, Office of Academic Affairs, National Taiwan University
- 2023/8~2025/2/26 Director, Center for Teaching and Learning Development, National Taiwan University
- 2023/2~2025/2/26 Member, Food Safety Board, Executive Yuan, Taiwan

EDUCATION

- Ph.D. Graduate Institute of Toxicology
- M.S. College of Law, National Chengchi University
- M.S. Graduate Institute of Clinical Medicine, National Taiwan University
- M.D. School of Medicine, Chung Shang Medical University

Dr. Chiang has been the Director General of the Taiwan Food and Drug Administration (TFDA) since February 27 2025. He oversees the regulation of food, drugs, medical devices, and cosmetics. Prior to the DG of TFDA, Dr. Chiang was a highly accomplished professional serving as the Director and attending Physician in the Section of Blood Purification, Department of Integrated Diagnostics & Therapeutics at NTUH, and a Professor and Director at the Graduate Institute of Toxicology at NTUH. With a distinguished academic background, Dr. Chiang obtained his PhD from the Graduate Institute of Toxicology at NTU in 2006. He further pursued postdoctoral training at the University of Tokyo, focusing on endoplasmic reticulum stress and hypoxia-related cellular mechanisms. Dr. Chiang's professional interests primarily revolve around internal medicine, kidney diseases, metabolic syndrome, pharmacology, toxicology, and risk analysis of food safety. With extensive expertise in these areas, he contributes significantly to the related fields.



Rie Matsui

APAC e-labeling-EWG leader
Senior Director, Regional Labeling Head for APAC
International Labeling and Artwork, Pfizer R&D Japan

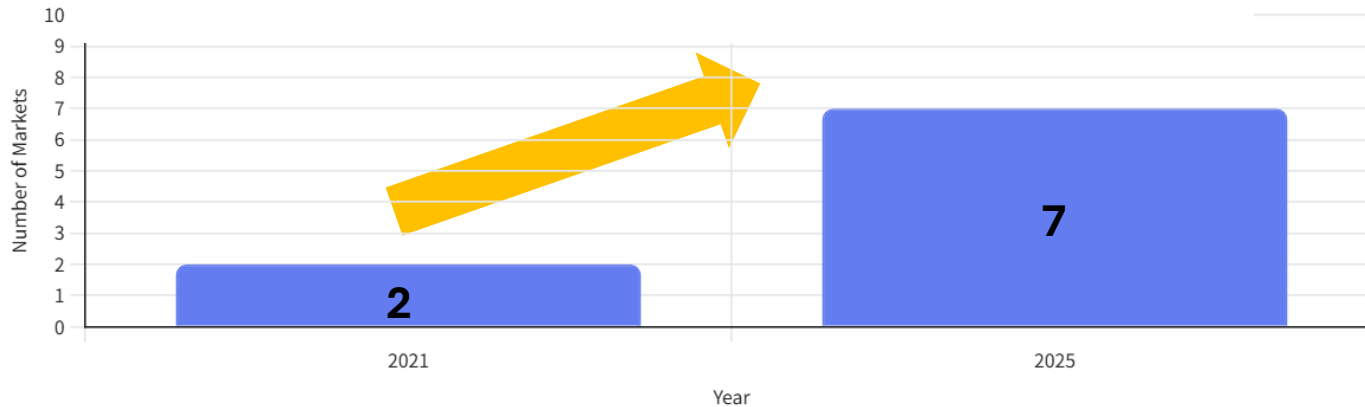
Rie Matsui is Senior Director, Regional Labeling Head for APAC, International Labeling Group, Global Regulatory Science, Pfizer Japan. She is also the Head, External Engagements for ILG and the co-chair for Pfizer E-labelling Centre of Excellence (ELCOE). She is the founder of Asia Labeling Hub at Pfizer that has created various local label updates for more than 25 countries in Asia. She is the lead for the APAC e-labeling Expert Working Group and the program chairperson for DIA Global Labeling Conference in 2025. She received the DIA Japan Regional Award in 2015. Her papers were published in scientific journals such as Therapeutic Innovation & Regulatory Science. She was the vice chair of the 2021 DIA Japan Annual Meeting Program Committee and is the vice chairperson for the DIA Advisory Council of Japan since July 2024. She received DIA Global Inspire Award Connector in 2022. She teaches at Keio University and Chiba University and is a pharmacist.

Empowering Patients Through e-labeling: Bridging Digital Health and Accessible Information

Time	Presentation	Speaker
13:00-13:05	Opening	Rie Matsui , JPMA
13:05-13:15	Presentation	Mrs. Erlina Widianty Pratiwi , Senior Pharmaceutical and Food Safety Specialist, Indonesia FDA, BPOM
13:15-13:25	Presentation	Mr. Kobu Thiruvanackan , Head of ICT Section, NPRA
13:25-13:35	Presentation	Ms. Miao-Ju Chien , Associate Researcher, Taiwan FDA
13:35-13:45	Presentation	Ms. Miki Ota , Director, Office of Informatic and Management for Safety, PMDA
13:45-14:45	Panel Discussion & Slido	The above speakers and the following panelists Dr. Dorothy Toh , Assistant Group Director, HSA Mr. Nguyen Van Loi , Head of Registration department, DAV Ms. Nada Kim , Assistant Director, MFDS Mr. Kharlo De Guzman , Food-Drug Regulation Officer III, FDA Philippines Ms. Worasuda Yoongthong , Director of Medicines Regulation Division, Thai FDA Dr. Shimon Yoshida , International Advisory Board member for IMI Gravitare Health Pfizer.
14:45-14:50	Closing	Dr. Chih-Kang Chiang , Director General, Taiwan FDA

2026 Update: APAC e-Labeling Position Paper

Number of APAC Markets with e-labeling Guidance




- Please visit our poster for the APAC e-labeling Position Paper, located in front of the conference room.
- The position paper can be accessed from here.



APAC e-Labeling Position Paper 2026
- Advancing Digital Product Information in Asia -
APAC e-Labeling EWG

Abstract:

- E-labeling is gaining momentum across Asia as part of the broader digital transformation in healthcare. However, implementation remains uneven, with markets at different stages of maturity.
- This position paper presents APAC's updated 2026 stance and strategic recommendations to support a more consistent, patient-centered approach to e-labeling across the region.
- We synthesized recent developments, regulatory experiences, and implementation trends across APAC to identify key focus areas and formulate practical guidance.
- Five strategic priorities are proposed: (1) reliable availability of labeling on public websites, (2) reader-friendly digital access, (3) a stepwise transition to paperless labeling, (4) adoption of structured content standards, and (5) interoperability through alignment with global data exchange frameworks (e.g., HL7 FHIR).
- A stepwise roadmap is outlined to guide APAC markets toward greater interoperability and digital harmonization.
- Aligning on digital labeling standards will enhance regulatory efficiency, improve patient safety, and support better health outcomes across the region.



Results

Since 2023, e-labeling implementation has advanced across the APAC region, with several markets moving from discussion to pilot or full-scale adoption. A regional review of 12 APAC markets revealed a clear shift toward digital labeling, though implementation models, timelines, and scope vary.

- Progress has been observed across **five key elements of e-labeling**:
 - Availability:** More markets are publishing HCP and patient labeling on HA websites. Japan, Taiwan, and Thailand have fully implemented centralized platforms, while others like Malaysia and Indonesia are in transition.
 - Accessibility:** QR codes are now widely used across the region, with GS1 barcodes gaining traction for dual use in labeling and supply chain traceability.
 - Paperless:** Japan has fully removed paper leaflets from prescription drug packaging. Other markets are piloting or planning phased removal with transition periods.
 - Structured Content:** Japan and Taiwan have adopted custom XML schemas. Taiwan has announced a phased XML implementation by 2025.
 - Interoperability:** HL7 FHIR is gaining international momentum. While not yet implemented in APAC e-labeling, several markets are exploring its future use.

Figure summarizes the regional evolution of these five elements from 2023 to 2026, highlighting key milestones and trends.

While each market follows its own path, the region is converging toward a shared vision of structured, interoperable, and patient-centered e-labeling.

Discussion / Key Recommendations

To support consistent, scalable, and sustainable e-labeling implementation across the APAC region, this position paper proposes **four key recommendations**, each aligned with the five core elements of e-labeling.

- Establish a central, authoritative platform for labeling availability.** Where feasible, Health Authorities (HAs) should host the latest approved labeling on their official websites, serving as the "single source of truth." This ensures consistency, version control, and public trust. In markets with limited HA resources, flexibility may be granted to allow company or third-party platforms, provided that HAs define clear requirements for format (e.g., PDF/XML), update timelines, auditability, and security.
- Enhance accessibility** through user-friendly digital formats. Packaging should include machine-readable access points such as QR codes, GS1 barcodes, or short URLs that link directly to the latest labeling. While QR codes are widely used, GS1 barcodes offer the advantage of dual use for both e-labeling and supply chain traceability. Markets should work toward convergence on a single standardized code, while allowing flexibility during transition.
- Support a phased transition to paperless labeling.** Removing paper leaflets from product packs should be done gradually, with pilot programs and transition periods to allow adaptation by healthcare professionals and patients. During this time, both paper and electronic formats may coexist. Clear communication, stakeholder engagement, and legal alignment are essential to ensure a smooth and safe transition.
- Adopt structured content and global data standards** to enable interoperability. Markets should move from PDF to XML and eventually to HL7 FHIR to support data reuse, integration with health IT systems, and cross-border harmonization. Structured authoring tools and standardized templates can reduce duplication and improve efficiency.

Introduction / Background


- The COVID-19 pandemic accelerated digital transformation in healthcare, highlighting the need for timely, accessible, and reliable product information.
- E-labeling has emerged as a key enabler of this transformation, offering a way to deliver the most up-to-date labeling to healthcare professionals (HCPs) and patients.
- Across APAC, countries are at different stages of e-labeling implementation—some have fully transitioned to digital systems, while others remain in pilot or discussion phases.
- This variation creates regulatory complexity, increases burden on industry, and limits the potential for cross-border interoperability.
- To address these challenges, APAC stakeholders must work together to align on key principles and practical steps for advancing e-labeling in a harmonized and sustainable way.

Objective

- This position paper outlines five strategic priorities to guide e-labeling advancement in APAC:
 - reliable availability via public websites,
 - user-friendly digital access,
 - phased paperless transition,
 - adoption of structured content standards, and
 - interoperability through global data alignment.
- Building on progress since 2023, the goal is to support health authorities and industry with practical, harmonized guidance for sustainable implementation.

Methods

- A structured review was conducted across APAC markets to assess the maturity of e-labeling implementation.
- Key focus areas included availability, accessibility, paperless transition, structured content, and interoperability.
- Regulatory frameworks, digital infrastructure, and implementation models were analyzed.
- Findings were synthesized to identify common challenges and best practices.
- The goal was to inform practical, regionally aligned recommendations for sustainable e-labeling.



Scan the QR code to access the full APAC e-Labeling Position Paper 2026

Key Message (Take-Home Point):

Aligning on common digital platforms and data standards—while allowing flexibility in content—will maximize the value of e-labeling across APAC. A clear regional roadmap toward HL7 FHIR adoption will support long-term interoperability and global integration.

Conclusion

- The COVID-19 pandemic accelerated digital transformation in healthcare, and e-labeling has emerged as a key enabler of timely, structured, and accessible product information.
- In the APAC region, many markets have made meaningful progress since 2023, with increasing adoption of digital platforms, QR codes, and structured content.
- However, differences in implementation models, timelines, and technical capacity remain, creating risks of fragmentation.
- To address this, regional collaboration is essential. Sharing best practices, aligning on data standards, and supporting capacity-building will help bridge gaps and accelerate progress.
- HL7 FHIR is gaining global momentum as the next-generation standard for structured, interoperable e-labeling. While not yet widely implemented in APAC, several markets are exploring its feasibility.
- A clear regional roadmap for FHIR adoption—starting with PDF and XML, and progressing toward FHIR—will help avoid future fragmentation and ensure long-term compatibility with global digital health systems.
- The five strategic priorities outlined in this paper—availability, accessibility, paperless transition, structured content, and interoperability—offer a flexible yet aligned framework for action.
- By working together, APAC stakeholders can build a future-ready, patient-centered e-labeling ecosystem that improves safety, transparency, and access to information across the region.

APAC Regulators-Industry e-labeling Workshop(Closed)

Participants	<p>15 regulators from BPOM, CDSCO, HSA, MFDS, NPRA, PMDA, Taiwan FDA, Thai FDA, Philippines FDA(invited), Craig Anderson (Virtual), Shimon Yoshida and APAC e-labeling EWG members (in total 31 participants)</p>
Program	<ol style="list-style-type: none"> 1. Opening Remarks (5 min) 2. FHIR e-Labeling (95 min) <ol style="list-style-type: none"> (1) Progress of FHIR ePI: Global Landscape and Opportunities for APAC (30 min) – Craig Anderson, Co-lead HL7 VULCAN Electronic Product Information Project (2) Q&A for Session 2 (20 min) (3) Updates on FHIR ePI Discussions (APAC Regulators) (15 min + 5min Q&A) (4) Outcomes of the Gravitare Health Project in Europe (20 min + 5 min Q&A) – Shimon Yoshida, International Advisory Board member for IMI Gravitare Health 3. Break (15 min) 4. Patient-Centric Product Information (30 min) <ol style="list-style-type: none"> (1) Updates on Drug Guide for Patients: PMDA Initiatives for Patient-Centric Product Information (15 min) – PMDA (2) Q&A for Session 4 (15 min) 5. Group Discussion (60 min) <p>Exercise: Creating a Roadmap for FHIR ePI (45 min)</p> <ul style="list-style-type: none"> • What will be achieved through digitalization using the future e-labeling FHIR format? • What milestones and action items should be defined for FHIR ePI use cases in Asia? <p>Sharing of Group Discussion Results (15 min: 3 min × 4 or 5 groups)</p> 6. Closing Remarks (5 min)

Erlina Widianty Pratiwi

Senior Pharmaceutical and Food Safety Specialist, Indonesia FDA (Badan POM)



Erlina Widianty Pratiwi is a Senior Pharmaceutical and Food Safety Specialist at the Indonesia FDA (Badan POM). She has extensive experience in pharmaceutical regulation, focusing on improving access to medicine information and strengthening regulatory systems.

She is actively involved in digital health initiatives, including the e-labeling pilot project in Indonesia, supporting the adoption of international standards to enhance interoperability across healthcare systems.

Through her role, she contributes to improving patient access to reliable information and promoting the safe and effective use of medicines. She is also responsible for monitoring drug information, including the evaluation of medicine advertisements and labeling in the market.

Presentation Title:

Update E-labeling Pilot Project in Indonesia



Kobu Thiruvanackan

Head of ICT Section, National Pharmaceutical Regulatory Agency, Malaysia

1. Professional background

- B.Pharm (Hons) University of Malaya, M.I.S. (Hons) National University of Malaysia (Faculty Outstanding Achievement Award).
- Certified Google Workspace Trainer.
- Gemini AI@Work Champion & AI Aware Badge (AI untuk rakyat).
- Google Cloud Technical Series (App Dev & Infrastructure Ed.) – Google Cloud APAC.
- Google & AWS Cloud Fundamentals Certified.

2. Notable roles or achievements

- Spearheaded NPRA ICT Section for 8 years. (22 years in Public Service)
- Led NPRA to win the Google Workspace Highest Uptake Usage award among Government Sector Agencies in 2023.
- Vast pharmacy background: Government Health Clinics (Sabak Bernam, Shah Alam Sec 7 & 19), Klang General Hospital, Pharmacy Practice & Development (Quality Use of Medicine), and NPRA (ICT Section).
- Extensive experience in digital transformation initiatives.
- Involved in major initiatives/policies: DUNAS, PTTs, MDC, Medicine Shortage & Discontinuation, ARPA, e-Labeling, and Patent-linkage.
- Publications/Speaking: Participated at the 77th FIP World Congress (Korea, 2017). Co-authored studies on { MTM (2007), Generic Medicine Awareness Guideline (2013), mHealth Evaluation (2017), Halal Capsule Shells (2018), and Generic Product Application Deficiencies (2024)}.

3. Current focus or interests

- Leading NPRA's digital transformation via QUEST 5 to enhance pharmaceutical regulatory services.

Presentation Title:

Malaysia's Journey in Structuring Legacy PDF Data for the Global ePI Standard 7

Miao-Ju Chien

Associate Researcher,
Medicinal Products/ Taiwan Food and Drug Administration (TFDA)



Education

Master of Science in Toxicology, National Taiwan University, Taiwan (2015)
Bachelor of Pharmacy, Kaohsiung Medical University, Taiwan (2010)

Experience

Associate Researcher, Division of Medicinal Products, TFDA (2025-Present)
Specialist, Division of Medicinal Products, TFDA (2025)
Associate Technical Specialist, Division of Medicinal Products, TFDA (2018-2025)

Miao-Ju Chien is a pharmacist specializing in pharmaceutical regulation and drug policy. She has over seven years of experience at the Taiwan Food and Drug Administration (TFDA). She has been actively involved in the development and implementation of e-labeling, including system establishment and regulatory promotion. Currently, she oversees and coordinates e-labeling initiatives to support the digital transformation of drug information in Taiwan.

Presentation Title:

E-Labeling in Taiwan: Implementation Status and Future Directions

Miki Ota



Director, Office of Informatics and Management for Safety
Pharmaceuticals and Medical Devices Agency (PMDA)

Ms. Ota joined the Ministry of Health, Labour and Welfare (MHLW) in 2000. After joining the ministry, she has been involved in wide range of experience in public health field especially pharmaceutical administration, including pharmacovigilance.

She worked in several organizations including the Ministry of the Environment, PMDA, and National Personnel Authority.

This is her second assignment to PMDA. During her previous assignment, she gained experience in the review of pharmaceuticals and medical devices. Since April 2024, she has been working as the current position.

Presentation Title:

Presentation Title

Panelists



Su Lin Dorothy Toh

Assistant Group Director,
Health Sciences Authority

Dr Dorothy Toh is the Assistant Group Director of the Medicinal Products Pre-market Cluster at the Health Products Regulation Group, Health Sciences Authority. Her responsibilities include providing leadership and directing the operations to ensure that clinical trials are approved and conducted in accordance with regulatory requirements and health products are regulated to meet appropriate standards of safety, quality and efficacy.

Dorothy has won several awards for her achievements in both public service and scientific arenas. During the COVID-19 pandemic, she co-led the development of Biologics Testing capability and won the Dare to Do Public Service Transformation Awards. Her team was awarded the Inaugural Mrs Tan Shook Fong – Pharmaceutical Society of Singapore Innovative and Scientific Research Award, for successfully implementing new testing protocols that reduced serious adverse events to certain medicines.



Nguyen Van Loi

Head of the Drug Registration Division
Drug Administration of Vietnam (DAV), Ministry of Health

Dr. Nguyen Van Loi is currently the Head of the Drug Registration Division at the Drug Administration of Vietnam (DAV), Ministry of Health. With over 30 years of experience in the pharmaceutical sector, he possesses extensive expertise in laboratory testing, quality management, and drug registration. Prior to his current appointment, he held key leadership positions as Head of the Drug Quality Control Division and Head of the Cosmetics Management Division. In addition to his regulatory career, Dr. Loi previously served as a Lecturer in the Department of Biochemistry at the Hanoi University of Pharmacy. He earned his Bachelor of Pharmacy in 1990 and his PhD in Pharmaceutical Sciences in 2002, both from the Hanoi University of Pharmacy.

Panelists



Nada Kim

Assistant Director
Ministry of Food and Drug Safety

Nada Kim is a pharmacist by training and a pharmaceutical regulator at the Ministry of Food and Drug Safety (MFDS), Republic of Korea. She works on the development and implementation of regulatory policies related to pharmaceutical labeling, with a focus on improving patient-centered information and advancing digital approaches to product information.

She has been involved in advancing e-labeling initiatives in Korea, including the development of guidelines to enhance accessibility, readability, and integration with digital health systems. She is also actively engaged in international regulatory collaboration through organizations such as WHO and PIC/S, contributing to global harmonization efforts in various regulatory areas.



Kharlo De Guzman

Food-Drug Regulation Officer III
Food and Drug Administration Philippines

Kharlo de Guzman is a Food-Drug Regulatory Officer at the Product Research and Standards Development Division of the Center for Drug Regulation and Research, FDA Philippines. He is actively involved in policy development, with a primary focus on strengthening drug product regulation. In his current role, he contributes to enhancing pharmaceutical regulatory frameworks through the development of new policies and the review and refinement of existing FDA issuances. Prior to this, he served in the Vaccine and Biological Unit of the FDA Philippines' Common Services Laboratory, where he played a key role in the technical evaluation and procedural development for the National Lot Release of vaccines and biological products. He also demonstrated expertise in laboratory analysis for pharmaceuticals and medical devices, supporting quality and safety assurance.

Panelists



Worasuda Yoongthong

Director of Medicines Regulation Division
Food and Drug Administration
Ministry of Public Health, Thailand

Ms. Worasuda Yoongthong is Director of the Medicines Regulation Division at the Thai Food and Drug Administration, with over 30 years of experience in health product regulatory control. She previously served as Director of the Food Control Division and played significant role in formulating Thailand's National List of Essential Medicines.

She has extensively participated in numerous international and regional activities, including the WHO Expert Committee on Essential Medicines, ASEAN Harmonization, APEC and ICH as an observer.

She currently serves as the Thai FDA Head of Delegation (HOD) in the Pharmaceutical Product Working Group (PPWG) and contributed to establishing Thailand's abbreviated drug licensing pathway in 2018.

Ms. Yoongthong holds a Bachelor's degree in Pharmaceutical Sciences from Prince of Songkla University, Thailand, and a Master of Science in Epidemiology from Harvard University, USA.



Shimon Yoshida

International Advisory Board member for IMI Gravitare Health
HEAD OF INTERNATIONAL LABELING & ARTWORK
PFIZER

Shimon Yoshida has worked in the pharmaceutical industry for over 25 years in a number of positions across pharmacovigilance, clinical development, medical writing and regulatory affairs. He is currently on the International Advisory Board for the IMI Gravitare Health project for electronic product information (ePI). Shimon heads the International Labeling and Artwork group in Pfizer, responsible for all local labeling documents for Pfizer's medicines around the world and the associated artwork change control processes.

Speakers and panelists



Chih-Kang Chiang
Taiwan FDA



Rie Matsui
JPMA



**Erlina Widianty
Pratiwi**
BPOM



**Kobu
Thiruvanackan**
NPRA



Miao-Ju Chien
Taiwan FDA



Mika Ota
PMDA



Dorothy Toh
HSA



Nguyen Van Loi
DAV



Nada Kim
MFDS



Kharlo De Guzman
FDA Philippines



**Worasuda
Yoongthong**
Thai FDA



Shimon Yoshida
IMI Gravitare Health,
Pfizer

- Please share your experiences with e-labeling initiatives to date and your perspectives on future developments.
- Based on the experiences from the GH project, please share the benefits of the FHIR e-labeling and challenges from the industry perspective.

2026 Quick Survey Results: Which areas would you like to move forward in the next 3-5 years?

	BPOM IDN	PMDA JPN	MFDS KOR	NPRA MYS	PFDA PHL	HSA SGP	TFDA TWN	Thai FDA THA	DAV VNM
1) Availability of the latest labeling on a publicly accessible website (e.g. product information available online)	Pilot started	Implemented	Implemented	Implemented	Implemented	Implemented	Implemented	Implemented	Implemented
2) Accessible, reader friendly format (e.g. scanning a machine readable code)	Implemented	Implemented	Implemented	Implemented (voluntary basis)	✓	Implemented	Implemented (not mandatory)	Implemented	✓
3) Eliminating paper labeling from commercial packs	✓ Pilot started	Implemented	Implemented	Implemented (voluntary basis)	✓ Pilot started	Implemented	Implemented (not mandatory)	Implemented	✓
4) Structured contents of e-labeling	✓	Implemented	✓	✓	✓	✓ (FHIR)	Implemented	✓ (Planning)	✓
5) Interoperability with international standard (FHIR)	✓	✓ MHLW research project started.		✓ To be implemented in QUEST 5 [Sep 2027]			✓ (Under evaluation)	✓ (Planning)	✓

- Based on the survey results, please share your target outcome for interoperable FHIR e-labeling, in relation to Topics 4) Structured contents of e-labeling and 5) Interoperability with international standard (FHIR).

- Please share the status and key challenges related to patient-centric product information in your region.

- Please share your view on what the e-labeling initiative should look like three years from now.

Empowering Patients Through e-labeling: Bridging Digital Health and Accessible Information:

■ Summary of Session

- Provide an update on the continued advancement of e-labeling initiatives across the APAC region
- Explore the development of e-labeling based on International electronic common standard (HL7FHIR), with a focus on ensuring interoperability with digital healthcare systems and enabling seamless integration into broader digital health ecosystems.
- Emphasize how e-labeling can support future healthcare systems and empower patients by improving access to information, enhancing usability, and promoting more effective use of e-labeling.
- By strengthening regional collaboration and alignment with global standards, explore how e-labeling can serve as a bridge between digital health innovation and accessible, patient centric product information

■ Agreed next steps

- Accelerate and continue driving the advancement of e-labeling initiatives across the APAC region.
- Continue discussing what will be achieved by digitalization of labeling using FHIR format in the future and what are the milestones and action items to implement FHIR and realize the envisioned future (i.e. empowering patients) in Asia
- Discuss and set the roadmap including use cases for FHIR e-labeling