"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

Co-Chairs

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.

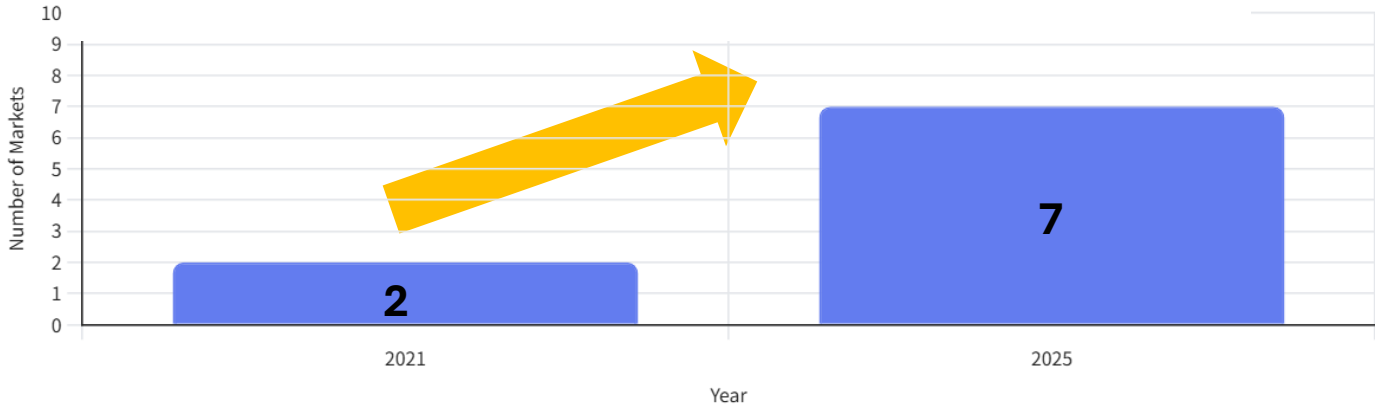
Empowering Patients Through e-labeling: Bridging Digital Health and Accessible Information

APAC Asia Partnership Conference of Pharmaceutical Associations

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 Gravitate 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 Regulators-Industry e-labeling Workshop(Closed)

Participants	**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**)
Program	**1. Opening Remarks** (5 min) **2. FHIR e-Labeling** (95 min) (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 Gravitate Health Project in Europe (20 min + 5 min Q&A) – Shimon Yoshida, International Advisory Board member for IMI Gravitate Health **3. Break** (15 min) **4. Patient-Centric Product Information** (30 min) (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) **Exercise: Creating a Roadmap for FHIR ePI** (45 min) ・ 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? **Sharing of Group Discussion Results** (15 min: 3 min × 4 or 5 groups) **6. Closing Remarks** (5 min)

Speaker

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

Speaker

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-Labelling, 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

Speaker

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

Speaker

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 Gravitate 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 Gravitate 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 Gravitate Health, Pfizer

Panel Topics 1

- 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)	✓

Panel Topics 2

- 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).

Panel Topics 3

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

Panel Topics 4

- 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