Co-chairs

Co-Chair

Junko Sato

Dr. Junko Sato is an Office Director of Office of International Program at Pharmaceuticals and Medical Devices Agency (PMDA). She joined Regulatory Agency in 1998. She became a review director of Office of New Drug in 2004 and moved to Office of Safety in 2009 to develop a new risk management system through life cycle of drugs. During the period, she visited U.S.FDA as a guest reviewer from September 2002 to March 2003. From May 2012 to April 2014, she was dispatched to EMA as MHLW/PMDA Liaison. She enhanced collaboration between EMA and MHLW/PMDA and brought a huge success as the liaison.

She contributed to some global harmonization activities, for example, ICH, CIOMS etc. She also contributes many DIA activities. She received DIA Outstanding Service Award 2010. She led the activities of PMDA Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) including planning/conduct of all the trainings, and contributes to building stronger bilateral relationship with ASEAN countries by playing the role as the contact point. She also works for AMR project like EMA-FDA-PMDA tripartite meeting to discuss convergence on approaches for the evaluation of antibacterial drugs.
She is an Infection Control Doctor certificated by The Japanese Association of Infectious Disease.

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Rie Matsui

Ms. Rie Matsui is Senior Director, Regional Labeling Head for APAC of International Labeling Group (ILG), Global Regulatory Affairs at Pfizer Japan. She is also the Head of External Engagements for ILG. She is the founder of Asia Labeling Hub at Pfizer. The Asia Labeling Hub has created various local label updates for more than 25 countries in Asia ever since its launch and she works with 15 affiliates in Asia. She served as a member of the Advisory Council of DIA Japan until June 2020 and she won the DIA Japan regional award in 2015.

She has been actively involved in a number of conferences in Japan, China, Singapore, and the U.S., both as a session chair and speaker. Her papers were published in several medical/scientific journals including “Therapeutic Innovation & Regulatory Science”. She has more than 25 years experiences in labeling, regulatory, and pharmacovigilance areas.

E-labeling Session

APAC
Asia Partnership Conference of Pharmaceutical Associations

***Goal*: Raise an awareness for benefits of e-labeling in Asia**

Time	Presentation	Speakers
13:15-13:20	Opening with sharing the circumstances for e-labeling initiatives across regions	Rie Matsui, JPMA
13:20-13:30	Current and planned e-labeling initiatives in Japan	Sayaka Kurihara, PMDA
13:30-13:40	Current and planned e-labeling initiatives in Taiwan	Po-Wen Yang, Taiwan FDA
13:40-13:50	Current and planned e-labeling initiatives in Singapore	Mark Wong, HSA
13:50-14:10	Panel discussion	All speakers and Thanh Lam Nguyen,DAV
14:10-14:15	Conclusion	Dr. Junko Sato, PMDA

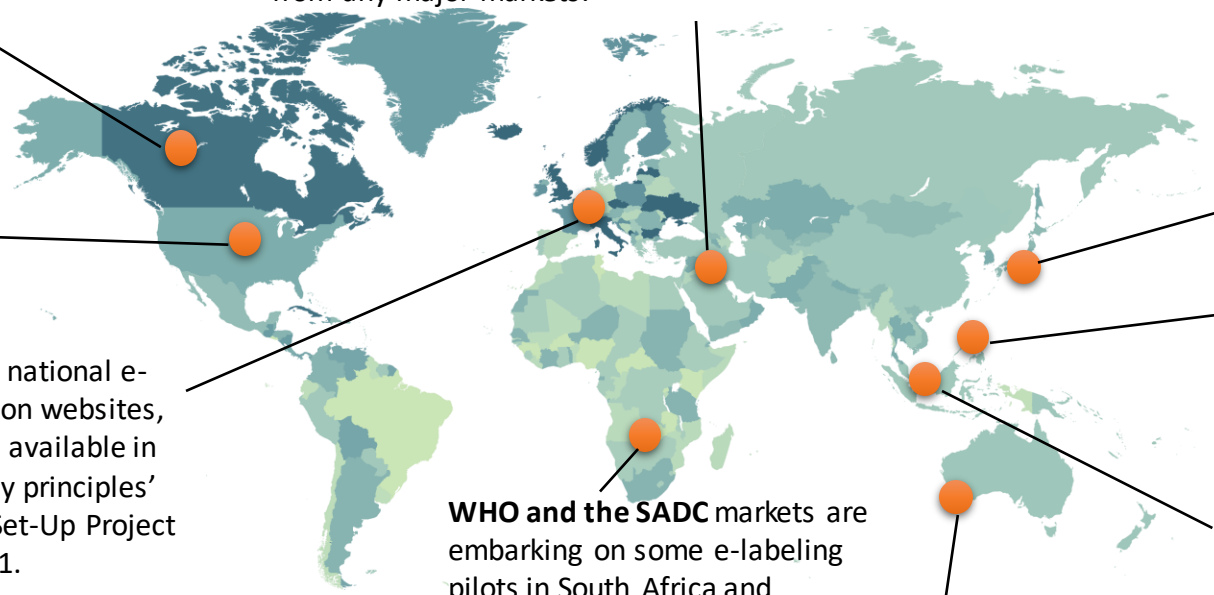
E-labeling is Hot Topic Across Regions

In Canada, a Notice of Intent was issued in Apr 2019 advising of a transition from Product Monographs to an XML Structured Format; whereby they communicated the structured information would increase the level of detail available to the public for search. And together with the machine-readable nature, it will be easier to index and search.

In US, US SPL (an XML format) is available post FDA approval and is posted to DailyMed to enable advanced searching.

In EU, Regional (EMA) and national e-labels commonly published on websites, with enhanced information available in some markets. EMA ePI 'key principles' published Jan 2020 and ePI Set-Up Project initiated Jan 2021.

In Saudi Arabia, a Saudi Drug Information (SDI) website has been developed which will hold all PILs and SmPCs for registered products. MAHs requested to upload labels.
There is also a requirement to have standardisation of format aligned to the EU format despite reference market labels being from any major markets.



In **Japan**, PMDA has required SGML versions of the JPI (HCP labeling) for many years and has started to switch to XML in 2019. The pharmaceutical law was amended to introduce e-labeling officially in Dec 2019 and will be implemented in Aug 2021. Paper labeling (HCP labeling) will be eliminated from commercial pack.

In **Taiwan,** an app has been released which can be used to scan barcodes on the commercial pack to access the e-label

In **Singapore**, the HSA issued guidance for e-labeling on 19-Aug-2019 with no required paper in their packs and some companies have started a e-labeling pilot study using QR and GS1 codes linking the pack to the PI

WHO and the SADC markets are embarking on some e-labeling pilots in South Africa and Zimbabwe linking the packs to PI

In **Australia**, a third party website (the Pharmacy Guild) hosts e-labeling for many years now, with just-in-time printing available at the Pharmacy.

Due to the **COVID-19 pandemic**, digitalization should be enhanced in pharmaceutical area. e-labeling initiative should be one of them.

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Speaker

Sayaka Kurihara

Coordinator, Office of International Programs,
Division of Regulatory Cooperation, Division of Asia I,
Pharmaceuticals and Medical Devices Agency
(PMDA), Japan

Ms. Sayaka Kurihara entered PMDA in 2015 and has worked as an inspector in Office of Non-clinical and Clinical Compliance. Since 2018, she belongs to Office of International Programs, PMDA.

She is currently in charge of:
・The contact point of Taiwan FDA
・Coordinating bilateral events between Japan and Taiwan
She is also in charge of ICH and administration of ICH Expert Working Group's activity and also ICH Management Committee member's support.

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Speaker

Po-Wen Yang

Mr. Po-Wen Yang graduated with a Bachelor of Pharmacy and a Master of Pharmacology. He served at the Taiwan Food and Drug Administration for 12 years. He is currently the section chief at the Division of Medicinal Product.

His experience includes pharmacovigilance, drug analysis, and pharmaceutical services.

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Speaker

Mark Wong

Mr. Mark Wong is a Regulatory Consultant in the Therapeutic Products Branch and has been with the Health Sciences Authority, Singapore for the last 12 years. Trained as a pharmacist, his main work in HSA includes the clinical review of new drug and variation applications. He currently leads a team in the management of post-approval variations, including the reclassification of medicines to facilitate public access to safe and effective treatments. He has worked in collaboration with both local industry stakeholders and international regulators to provide digital solutions to streamline business and review processes.

Since 2019, he has been driving the e-labelling initiative for prescription medicines supplied in Singapore in consultation with industry representatives.

Panelist

Thanh Lam Nguyen

Deputy Director General
Vietnam Drug Administration (DAV)
Ministry of Health

Mr. Thanh Lam Nguyen currently serves as the Deputy Director General of the Vietnam Drug Administration ("DAV"), Ministry of Health; directly overseeing all medicine, vaccines registration and circulation aspects in Vietnam. He has been working at the DAV since 1997 after graduating from the Hanoi University of Pharmacy.

Introduction of Co-chairs/Panelists

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Panel Discussion

(1) What are the future/planned benefits of e-labeling in your countries? What challenges do you anticipate you need to overcome to introduce e-labeling from your point of view? Do you have any insight in how these may be overcome?

(2) How can we collaborate in terms of e-labeling in Asian region?

- Knowledge sharing
- Establish a platform (website) for e-labeling in Asian region
- Prepare a position paper for Asian region

Benefits of e-labeling in Asia

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- Deliver the latest labeling information immediately in efficient and friendly way
- Improve the accessibility and understanding of approved medical product information, thereby enhancing adherence to medicines and patient outcomes
- Shorten the lead time to launch the new products, improve efficiencies on reducing operational steps for inserting paper labeling in packs, and support environment-friendly practice
- Enable integration of e-labeling with the wider digital healthcare system such as electronic medical record, resulting to greater efficiencies, and opportunities across a wide spectrum within the healthcare sector

Panel Discussion

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Conclusions and Next Steps

- We have confirmed that there are various benefits of e-labeling in Asia.
- We have agreed that collaboration between agencies and industry associations are important to move the e-labeling initiative forward in Asia.
- As next steps, a survey to confirm the needs for member associations will be conducted and e-labeling blueprint as well as a roadmap will be prepared at APAC.