11th APAC “e-labeling session”
Where are we Now and What are the Next Steps in APAC?

05-April-2022

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

Co-chair

Junko Sato

PMDA

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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Co-chair and panelist

Rie Matsui

JPMA

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.

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E-labeling has started to discuss by IPRP & ICDRA

IPRP
International Pharmaceutical Regulators Programme

Geneva, 6 December 2021

Public Statement
8th Meeting of the IPRP Management Committee
19th & 22th November 2021

The eighth meeting of the Management Committee (MC) of the International Pharmaceutical Regulators Programme (IPRP) was held on the 19th and 22th of November 2021. 24 IPRP Members and Observers were represented in the meeting, which was organised in a virtual setting in view of the COVID-19 pandemic.

As usual in IPRP MC meetings, the 8 IPRP Working Groups (WGs) provided a report to the MC on, respectively, Nanomedicines, Cell Therapy, Gene Therapy, Identification of Medicinal Products (IDMP), Quality, Biosimilars, Bioequivalence for Generics, and Pharmacovigilance, presenting their achievements over the past months and their future activities. The MC endorsed the publication drafted by the Quality WG on *Survey on Administrative Procedures and Terminologies for Quality Variations/Post-approval Changes*. This paper will assist in clarifying differences in Regulators' terminologies and procedural aspects and aims to increase an understanding of the procedures used for changes to APIs and drug products (e.g., categories/levels) for both regulators and the pharmaceutical industry, and will be available shortly on the IPRP website. Additionally, the *Frequently Asked Questions (FAQ)* document of the IDMP WG was updated and will be published on the IPRP website to promote the understanding of IDMP standards in order to support the implementation.

The main focus topics of MC discussion at the meeting were Reliance and e-labelling. The MC is continuing further discussion on technical aspects of Reliance and on identifying steps for concrete action within IPRP, taking into account roles to be played by other fora such as ICMRA (International Coalition of Medicines Regulatory Authorities). The MC reviewed progress on the development of an article informed by the results of the survey conducted among IPRP parties on e-labelling of pharmaceuticals, when the product information is distributed via electronic means. The article is expected to include an overview of e-labelling status amongst IPRP Regulatory Members as well as considerations on the importance of e-labelling and reflections on its future. Publication is expected in 2022.

Additionally, the IPRP Members shared their experiences on challenges encountered within the course of implementation of ICH Guidelines, in particular on ICH Q12 on Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management. The MC will keep this topic as an agenda item for the next meetings with the aim of facilitating the implementation of ICH Guidelines.

Finally, the MC noted the results of the survey conducted among IPRP parties on their practices in Environmental Risk Assessment (ERA) and confirmed to discuss more at the next meeting.

The next IPRP MC meeting is planned for the 25th and 26th of May 2022 and is foreseen to be held in person in Athens, Greece, situation permitting.

https://admin.iprp.global/sites/default/files/2021-12/IPRP8_PublicStatement_Final_2021_1206.pdf

WHO Extraordinary International Conference of Drug Regulatory Authorities (ICDRA) 20 to 24 September 2021

Plenary 4: Facilitated Registration of Medical Products

Member States:

- Maintain and adopt the best practices introduced during a pandemic in a post-pandemic setting, in the "new normal", to ensure faster regulatory procedures on medicines and vaccines. New possible regulatory tools include emergency approval, rolling application submissions, remote inspections, digital submission, risk-based approaches, e-signatures, e-CPPs, e-labelling, and lot release reliance on other trusted laboratories;
- Information exchange and data sharing are the bases for reliance-based regulatory activities and decision-making. Member states should seek to promote transparency and to conclude confidentiality agreements or equivalent to efficiently exchange actionable information, documents, and data on which regulation through reliance decisions can be informed. The development and implementation of IMS, including the capacity to conduct virtual meetings, at the country, regional and continental level, aligned with international standards, is encouraged.

World Health Organization
Extraordinary Virtual International Conference of Drug Regulatory Authorities (ICDRA)
20-24 September 2021
4

WHO efforts to promote reliance

e-labeling session:
Where are we Now and What are the Next Steps in APAC?

Goals

- Share the activities for the APAC e-labeling EWG including the e-labeling survey result
- Agree with the proposed roadmap
- Raise some key discussion points for the position paper from the panel discussion

Time	Presentation	Speaker
15:00-15:12	Opening with sharing the updates from e-labeling EWG (Survey result, blueprint and road map)	Rie Matsui, JPMA
15:12-15:25	Current utilization of e-labeling at NCC Hospital and expectation on e-labeling from the HCP's point of view in Japan	Yoshihiro Aoyagi, National Cancer Center Hospital East, Japan
15:25-15:32	Current and future of e-labeling in Japan	Kaori Ogawa, PMDA
15:32-15:39	Current and planned e-labeling initiatives in Taiwan	Po-Wen Yang, Taiwan FDA
15:40-16:25	**APAC e-labeling summit** All speakers, Mark Wong, HSA, Jesusa Joyce Cirunay, Philippines FDA, Rosilawati Ahmad, NPRA, Dr. Rubina Bose, CDSCO, Industry rep Rie Matsui, APAC e-labeling EWG	
16:25-16:30	Closing	Dr. Junko Sato, PMDA

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Charter for APAC e-labeling EWG

Initiative Overview

Initiative Description

Under the COVID-19 pandemic, various electronic labeling (e-labeling) initiatives have begun worldwide. E-labeling will improve the accessibility and understanding of approved labeling, thereby enhancing adherence to medicines and patient outcomes. The adoption of e-labeling will enhance the user's ability to navigate the labeling on how to use, handle, and to better understand safety and efficacy information. Eventual transformation from paper labeling in the pack to e-labeling will shorten the lead time to launch the new products, reduce operational steps for inserting paper labeling in packs, and support environment-friendly practice. In the future, e-labeling will be integrated with the wider digita
opportun
importan
common
e-labeling

- HCP a
- All ma
- Techn
  web-
- Assoc
  applic
- Standard
- All prescription medicines including combinations

Strategic Milestones

Key Milestone

- Establish the EWG
- Prepare a survey questionnaire, conduct a survey and publish the result
- Prepare a blueprint and roadmap
- Prepare a position paper (Tool kit type)
- Develop platform (including a proof of concept and a pilot (TBD)
- Provide a training (TBD)

Metrics

Measurement of Success	Frequency
Check the progress of key milestones	Quarterly

Meetings

Meeting Title & Objectives	Frequency
EWG meeting ✓ Share the updates on e-labeling initiatives and pilot studies monthly ✓ Discuss and prepare the deliverables	Monthly

Expected Benefits

Near & Mid -Term Benefits	Long-Term Benefits
• Deliver a common platform for publishing the latest and trusted labeling information • Improve the accessibility and understanding of approved labeling information, thereby enhancing adherence to medicines and patient outcomes • Improve better readability and searchability	• Shorten the lead time to launch the new products, reduce 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 ities across e sector

APAC e-labeling EWG has been established since 27-July-2021
36 colleagues from 13 member associations are participating!

Byung-Jo Jin, Jeong-Min Seo	KPBMA (Korea)
Ina Park	KRPIA (Korea)
Nitika Garg, Anagha Padhye	OPPI (India)
Voon Yuen Cheah, Alice (Seat Mee) Chee	PhAMA (Malaysia)
Richard Simon Binos, Paul Marvin Quizon, Rose Anne Evangelista	PHAP (Philippines)
	PhIRDA (China)
Usanee Harnpramukkul, Pichapon Noonbhakdi	PReMA (Thailand)
Amy Zhao, Mo Runyi	RDPAC (China)
Aik Han Tey, Ellen Sem	SAPI (Singapore)
Thuy Thi Thanh Nguyen, An Thi Thuy Pham, Giang Nguyen	Pharma Group Vietnam (Vietnam)

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* Includes the commonly used 'standard terminologies', 'technical standards', 'formatting requirements'

What is “e-labeling”?

Product information available on-line
- Online access to up-to-date labeling as pdf

Accessible, reader friendly format
- Easy access to trusted labeling via code on pack
- Searchability, font size, clickable links, videos, audit support

Eliminating paper labeling from a commercial pack
- Environmental friendly

Common electronic standard
- Simplification of labeling management

e.g. Structured content, platforms and tools

Efficient information flow
Integrating additional information, education material
e.g. interoperability between information systems

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APAC e-labeling Survey Results

- The HCP labeling information is available on the HA website in 9/12 economies. Most economies publish them as PDF. Only 2 economies publish them as structured labeling.
- The paper package Insert (labeling) in commercial pack is required by regulations or laws in 9/12 economies.
- Paper leaflet can be removed from the commercial pack in 2/12 economies as a part of e-labeling initiatives.
- HCP label is inserted as paper leaflet in the commercial pack in 10/12 economies. Both HCP and PIL are inserted as paper leaflet in the commercial pack in 2/12 economies.
- 6/12 economies do not have a mandatory national single template for HCP labeling that is implemented.
- 2/12 economies do have e-labeling related guidance documents.
- All APAC member associations have raised e-labeling topics or started e-labeling discussion.
- None of economies have started an interoperable e-labeling.

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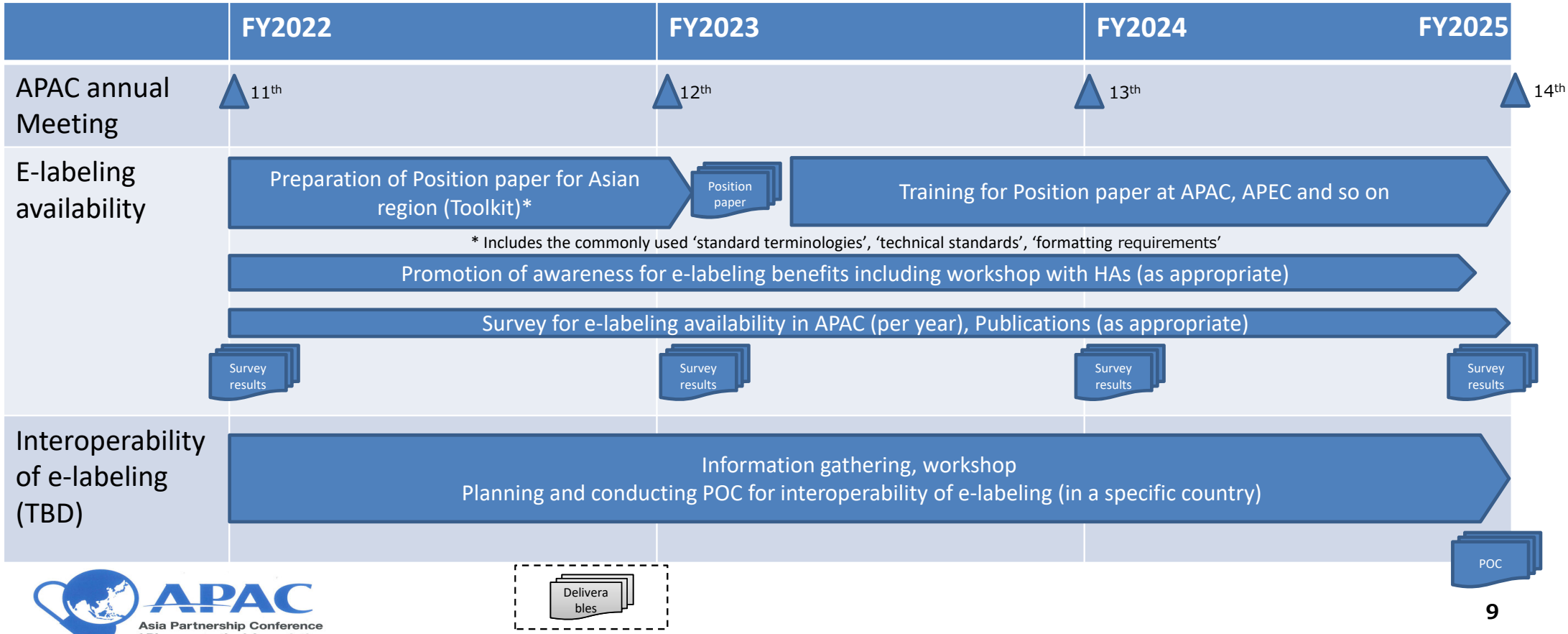
APAC e-labeling Roadmap (2022-25)

Goal:
- Enhance, harmonize and accelerate e-labeling initiatives in APAC economic areas
- Obtain POC for interoperability of e-labeling (TBD)



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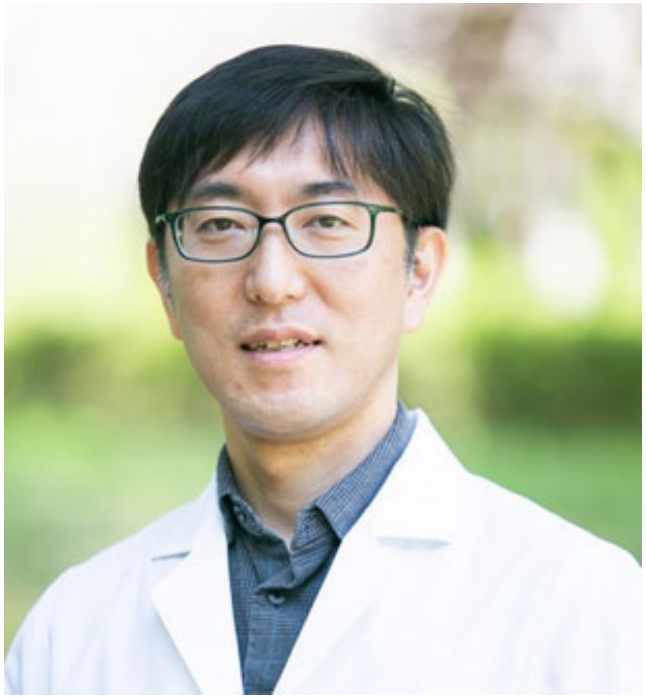
Speaker



Yoshihiro Aoyagi

National Cancer Center Hospital East, Japan

Mr. Yoshihiro Aoyagi is the section head in Information Technology Management Section at National Cancer Hospital East in Japan. His main areas of expertise are Integrating healthcare and research environments, data management, and digital transformation for clinical trials. He developed various information systems such as open-source EDC or Remote SDV environments to improve the utilization of information resources in the hospital. Yoshihiro has also belonged to the division of medical information and researched the usage of hospital information system data to improve its reliability and transparency. Previously, he had worked for a clinical pharmacist as a drug information specialist.

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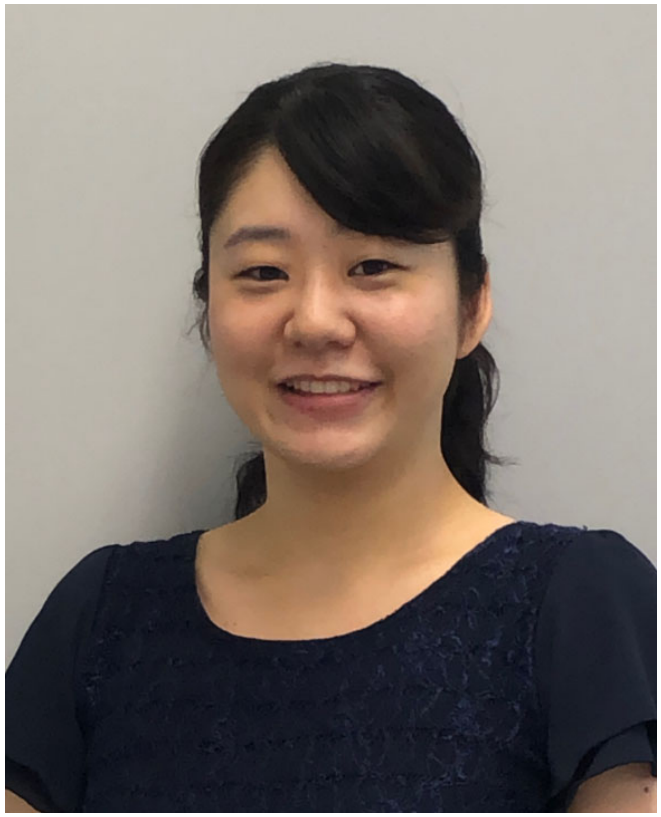
Speaker



Kaori Ogawa

Pharmaceuticals and Medical Device Agency, Japan

Ms. OGAWA Kaori is currently a Regulatory Cooperation Officer, in the Office of International Programs in Pharmaceuticals and Medical Devices Agency (PMDA), Japan. She started her work there in July 2019. She is tasked with projects related to bilateral cooperation.
She was formerly an Inspector of the Office of Manufacturing Quality and Vigilance for Medical Devices of PMDA (2016-2019). She has experience in the post marketing safety measures of medical devices.

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Speaker

Po-Wen Yang

Taiwan FDA

Mr. Yang, Po-Wen 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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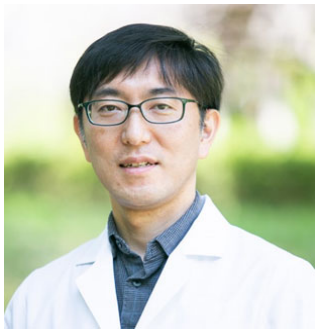
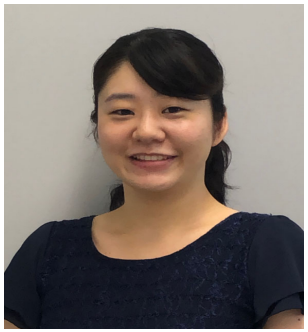
Speakers and panelists

Junko Sato
PMDA

Rie Matsui
JPMA



Yoshihiro Aoyagi
National Cancer Center Hospital East, Japan



Kaori Ogawa
PMDA

Po-Wen Yang
Taiwan FDA

Mark Wong
HSA

Jesusa Joyce Cirunay
Philippines FDA

Rosilawati Ahmad
NPRA

Rubina Bose, PhD
CDSCO

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Panelist

Mark Wong

HSA

Mark 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.

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Panelist

Jesusa Joyce Cirunay

Philippines FDA

JESUSA JOYCE N. CIRUNAY is currently the Director IV of the Center for Drug Regulation and Research at the Food and Drug Administration Philippines. She is a Registered Pharmacist (cum laude) with graduate studies on Pharmaceutical Science at the Vrije Universiteit van Brussel in Belgium. Her government service began at the Product Services Division (PSD) covering Marketing Authorizations as Pharmaceutical Researcher then as Senior Drug Evaluator including New Drug Applications and Vaccines. Before her current post, she was assigned to head several key offices of the Agency at various timelines, i.e., Field Cluster Director in various parts of the Philippines, as Head of the GMP Inspectorate; as Head of the Distribution Inspectorate and as Head of the Marketing Authorization. Her repertoire also covers experiences in international collaboration as former OIC–FDA International Affairs Office; media relations as former FDA Spokesperson; Quality Management System as former Quality Manager for the FDA Quality Management System on ISO 9001 initially for 2008 version and then 2015 version; on ASEAN Harmonization in the Healthcare Sector representing FDA PH as Head of Delegation or Delegate; on APEC as Delegate. Her publications include, among others, as lead author in several scientific articles published in peer-reviewed international journals (few accepted without correction) covering pharmaceutical science, chemometrics in drug formulation development (i.e. factorial designs, central composite designs) and liquid chromatography.

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Panelist

Rosilawati Ahmad

NPRA

Madam Rosilawati Binti Ahmad holds a Bachelor of Pharmacy from University of Science Malaysia and a Master of Pharmaceutical Analysis from the University of Malaya, Malaysia. She has 30 years of vast experiences within the Ministry of Health Malaysia.

Since 2018, she serves as the Deputy Director of Product and Cosmetic Evaluation of National Pharmaceutical Regulatory Agency (NPRA) and appointed as the Secretary of Drug Control Authority (DCA) by Minister of Health Malaysia which is responsible to ensure the registered pharmaceutical, traditional and health supplements products are safe, efficacious and of quality.

Committed to her duty, she has been involved in the collaborations of harmonization initiatives within ASEAN countries, specifically on Joint Assessment Coordinating Group (JACG) serves as the Chair. Besides, she actively participate as a member of Malaysia Medicine Advertisements Board, Malaysian Adverse Drug Reactions Advisory Committee (MADRAC), Malaysia Pesticide Board and Panel Member of JAKIM Halal Certification Malaysia. In addition, she is actively involved in initiating new policies related to pharmaceutical regulatory.

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Panelist

Rubina Bose, PhD

CDSCO

Rubina Bose has regulatory experience of more than 21 years, working in Central Drugs Standard Control Organisation (CDSCO), the National Regulatory Authority of India in various capacities as head of zones, head of division of import registration, new drug, quality assurance of vaccines. She started her career in CDSCO as Drugs inspectors conducting GMP, GCP, GLP inspections. She has five years experience of working in production of Injectable drugs prior to joining CDSCO.

She is presently working in CDSCO (HQ), New Delhi as the head of the division of International Co-operation. She has worked in WHO Prequalification vaccine assessment team as Technical officer at WHO (HQ), Geneva and was involved in vaccine dossier assessment, and inspection of vaccine manufacturer as a member of prequalification team. She is working as WHO temporary advisor and has worked (i) in various national and international Advanced Good Manufacturing Practices (GMP) Training of inspectors (ii) for developing GMP guidelines of biological, Good Regulatory Practices guideline, QMS guidelines National Regulatory Authorities (NRA) assessment tools etc. and nominated to represent Govt of India in various WHO meetings/training abroad. She is presently involved as CDSCO representative (Topic leader) in ICH guidelines preparation working groups and working as WHO temporary advisor and Govt. of India's representative in various WHO meetings on guidelines preparation.

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Panel Discussion

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1. During the COVID-19 pandemic, the importance of risk communication has been heightened and e-labeling has been used for the COVID-19 vaccines and so on. Could you please share the situation on the delivery of product information in electronic way in each market.
2. (Non-COVID 19 related products) Let me ask a couple of economies about the challenges regarding implementations, e-labeling pilots, and how were you able to overcome them?
3. Before the conference, a quick survey was completed by all speakers and panelist.
   Please choose from the following 5 factors, which areas would you like to move forward in the next couple of years and the reasons.
   - availability of the latest labeling on a publicly accessible website (e.g. product information available online);
   - accessible, reader friendly format (e.g. scanning a machine-readable code);
   - eliminating paper labeling from commercial pack;
   - common electronic standard (e.g. structured contents);
   - efficient information flow (e.g. interoperability between systems
4. What do you expect from APAC e-labeling EWG? For example, regarding the e-labeling workshop planning, could I ask the panelists how they would like to contribute to the workshop and what they would like to discuss at the workshop in order to facilitate cooperation among the regulators?

Quick Survey Results

	IND	JPN PMDA	JPN NCCHE	MYS	PHL	SGP	TWN
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)		✔	✔				✔
5) Efficient information flow (e.g. interoperability between systems)		✔	✔				

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Conclusions and Next Steps

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We shared APAC e-labeling EWG activities including the e-labeling survey result.

- APAC e-labeling EWG was established in July 2021 and 13 Asian industry associations participated it.
- APAC e-labeling survey was conducted at the end of November 2021.
  - ✓ Labeling information is available on the HA website in 9 economies. Most economies publish them as PDF. Only 2 economies publish them as structured labeling.
  - ✓ A paper labeling in commercial pack in Asia is mostly written for the HCPs. 2 economies do not need to insert paper labeling in a commercial pack as a part of e-labeling initiatives.
  - ✓ All member associations have started to discuss e-labeling initiatives.
  - ✓ No economies have started an interoperable e-labeling.
- We agreed to the proposed roadmap. Agreements are follows:
  - ✓ Create a position paper as a next step. The position paper will consist of 5 factors, 1) Product information available on-line, 2) Accessible, reader friendly format, 3) Eliminate paper labeling from a commercial pack, 4) Common electronic standards, 5) Efficient information flow.
  - ✓ Plan an e-labeling workshop to facilitate cooperation among the regulators.
  - ✓ Start the pilot study for FHIR version of J-PI.
  - ✓ Conduct the e-labeling survey to monitor the progress of e-labeling initiatives in the Asian region.

e-Labeling is still evolving in most economies in Asia, but with close collaboration between the regulators and the industry, a lot of things can be done!

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