Wrap-up for all program and session

APAC steering committee & JPMA APAC management committee

Nobuo Murakami

RA session

Regulations and Approvals

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Initiatives to Facilitate Reliance Examinations ~From the Perspective of Predictability and Transparency~

◆ Summary of Session

- Predictability and transparency of review are important when applicants are establishing NDA/BLA strategy
- In Asian countries, systems to promote efficient drug review using Reliance Scheme are being established, and it is expected that applicants will actively utilize these systems
- To promote the Reliance Scheme, it should be discussed between applicants and reviewers on which points of predictability and transparency to facilitate the Reliance Scheme are expected from each other

◆ Conclusion of Session

- Under the WHO-driven Reliance, applicants' expectations for predictability and transparency, and best practices implemented by Asian regulators, were shared
- Applicants and reviewers exchanged views and deepened common understanding regarding their expectations and requests for predictability and transparency of the review process based on the Reliance Scheme.
- The importance of the Reliance Scheme was also recognized in terms of predictability and transparency of the review process.

DA session

Drug Alliances

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Progress on Microbiome Therapeutics Drug Developments in Asian countries

Background:

The microbiome is gaining attention as a new modality in drug discovery research, and active research is being conducted in Asia. Recently, new drugs have been approved, and in Japan, the creation of quality guidelines for FMT approval has begun.

Summary of Session:

At first, two leading experts in microbiome research in Japan will present on the following topics:

1. Accelerating microbiome research through industry-academia collaboration.
2. Challenges and possibilities of microbiome research in Japan.

Finally, a representative from PMDA will present the perspective for creating microbiome therapeutics regulatory guidelines.

Conclusion of Session:

- Confirm the current status of microbiome research as a new modality in drug discovery and consider its potential applications.
- Gain insights into the collaboration between industry, academia, and government when utilizing microbiome research in drug discovery.
- Consider approaches to regulatory formulation and guideline creation from a different perspective through the new modality of microbiome drug discovery.

e-labeling Session

Asia Partnership Conference of Pharmaceutical Associations

Accelerate e-labelling initiatives, interoperability across digital health platforms, as part of health data ecosystem for patients

Summary of Session

- 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 focused on achieving interoperability across digital health platforms and the use of FHIR as a common e-labeling standard. They are shifting towards implementation. When introducing structured contents of e-labeling in APAC region, we have discussed the benefits/risks of implementing FHIR, as the international electronic common standard, which is interoperable with national healthcare systems and will be used to support digital health services for patients.
- 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.

Conclusion of Session

- Accelerate implementation of e-labeling in APAC region for more products and more markets.
- Consider implementing FHIR e-labeling and utilizing interoperability across 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.

MQS session

Manufacturing, Quality Control and Supply

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GMP Inspection Reliance

◆ **Summary of Session**

- In MQS session, the vision and benefits of GMP Inspection Reliance, which is applicable for lifecycle management of pharmaceutical products, were shared, and deepen our understanding through real-world examples, including the processes of building and maintaining such frameworks. Furthermore, the future benefits of GMP Inspection Reliance discussed by identifying the key points and challenges for its promotion, referring to specific mechanism.

◆ **Conclusion of Session**

- GMP Inspection Reliance avoids duplicate inspections and optimize resource allocation based on risk. For low-risk sites, GMP certificates may be accepted instead of having to perform duplicate inspections. GMP inspection reliance support innovation by generating resources for both regulatory authorities and companies.
- Promoting GMP Inspection Reliance requires mutual understanding and trust among authorities through communication, training, assessment. It will lead to maintain a high level of GMP standards in each economy.
- The realization of GMP inspection reliance will contribute to early approval by conducting GMP assessments with minimal resources and time, enabling patients to access high-quality medicines earlier.

aUHC session

Universal Health Coverage in Asia

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Realize True UHC in Asia

◆ Summary of Session

Main Theme:

- The status of UHC in Asian countries (especially access to innovative medicines) and the challenges and solutions to ensure its sustainability.

Topics Covered:

- **Utilization of HTA:** Comparison of HTA implementation status in each country, and concrete methods to ensure transparency, fairness, and efficiency.
- **Role of Private Health Insurance:** Collaboration with public health insurance, and possible measure to address rising medical costs due to aging and advances in medical technology.
- **Establishment of Funds:** Mechanisms for financial support to improve access to innovative medicines. Examine the feasibility of implementation in Asian countries, referencing the Taiwan case.

◆ Conclusion of Session

- **Utilization of HTA:** Recognition of the differences and common challenges in HTA implementation in Asian countries, and awareness of the importance of being mindful of fair drug pricing, efficient allocation of medical resources, and improved access to new drugs.
- **Role of Private Health Insurance:** Potential for utilization as a countermeasure to rising medical costs associated with aging, new drugs, and advances in medical technology. However, it is important to clarify the role and responsibility of private health insurance in ensuring equitable access to medical care.
- **Establishment of Funds:** Clarify the purpose and significance of establishing funds to overcome financial barriers to access to innovative medicines. Discuss the fund's management system, fundraising methods, and selection criteria for target drugs and medical technologies, referencing the Taiwan case to discuss the possibilities and challenges of establishing funds in other Asian countries.

Thank you for participating in the 14th APAC

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