Summary of the 8th Asian Network Meeting

1. Overview

- The 8th Asian Network Meeting (ANM) was held in Tokyo, Japan on 22nd April 2026, attended by approximately 40 participants from Asian regulatory authorities.
- The meeting was co-hosted by China, India, Japan and Singapore.
- China and India participated virtually, while the other authorities attended in person.

2. Regulatory updates by each country

- Each regulator made presentations on regulatory reforms, policy developments and recent activities since the previous meeting.
- Common topics observed among participating regulators included:
  -Digitalization of regulatory procedures, including eCTD, e-labeling and IDMP
  -Utilization of AI and digital tools in regulatory activities
  -Measures to ensure stable supply of essential medicines
  -Strengthening lifecycle management of safety and quality
  -Introduction and expansion of reliance and work-sharing approaches
  -Strengthening pharmacovigilance and post-marketing safety measures
- Other recurring themes included:
  -Strengthening regulatory frameworks for new modalities such as ATMPs
  -Quality risk management for nitrosamine impurities and related issues
  -Participation in international harmonization activities such as WHO, ICH, PIC/S and ASEAN
  -Capacity building and international cooperation among regulatory authorities

3. Presentation and Discussion

In Sessions 5 and 6, several regulatory authorities made presentations followed by panel discussions on common challenges among regulators. Major points highlighted in each session were as follows:

Session 5: Reliance – Regulators' Role in Ensuring Safety and Implementation

- Participating regulators discussed challenges associated with ensuring safety when utilizing reliance approaches. Major issues identified included:
  - Difference in accumulated safety information between approval by reference authorities and relying authorities
  -Access to and availability of post-marketing safety information
  -Consideration of local population characteristics, including ethnic factors and pharmacogenomics
  -Management of post-approval changes and lifecycle management
- Several practices/actions shared by regulators included:

-Utilization of RMPs, PSURs/PBRERs and post-marketing surveillance systems
-Additional data requests and supplementary assessment where necessary
-Safety assessment taking into account pharmacogenomics information and local data
-Conditional approval and enhanced post-marketing monitoring
-Strengthening information sharing and collaboration among regulatory authorities

- Participating regulators also emphasized:
  -The importance of maintaining independent regulatory judgment while utilizing reliance approaches
  -The need for timely access to updated safety information from reference authorities
  -The importance of trust-building and international cooperation among regulatory authorities

Session 6: Risk Mitigation Measures for Impurities

- Participating regulators made presentations on approaches to quality risk management for medicinal products, using nitrosamine impurities as an example. Common challenges identified included:
  -Detection of impurities at extremely low concentration levels
  -Limited testing and analytical capacity
  -High testing costs
  -Variability in API quality and supply chains
  -Balancing patient safety and stable supply of medicines
- Several practices/actions shared by regulators included:
  -Risk-based evaluation and testing approaches
  -Lifecycle-based impurity management
  -Development and sharing of analytical methods
  -Strengthening collaboration between regulatory authorities and testing laboratories
  -Utilization of international guidelines such as ICH Q3, M7 and Q9
- Participating regulators also discussed:
  -Information sharing on recalls and impurity-related risks
  -Cooperation on analytical methods and enhancement of testing capability
  -Strengthening GMP inspection cooperation and regional collaboration

4. Shared Understanding on AI

- The co-hosting regulators shared a draft document entitled “Shared Understanding on AI”. The document included:
  -Foundational understanding of AI
  -Shared terminology and core principles
  -Future directions for cooperation
- The document was introduced as a non-binding and principle-based document.

- Participating regulators agreed to review the document internally after the meeting and provide comments.

5. Others

- The co-hosting regulators confirmed that discussions and cooperation through ANM would continue.
- Participating regulators also recognized the importance of maintaining agile information-sharing and communication networks within Asia.
- Furthermore, participating regulators shared the recognition that continued capacity building and regulatory cooperation would contribute to strengthening regulatory functions in the region.

6. Outcome

- Based on the presentations and discussions held during the meeting, the following points were shared:

  -Participating regulators shared recent developments regarding digitalization and utilization of AI, lifecycle management, measures to ensure stable supply of essential medicines, reliance approaches and impurity risk management.

  -Participating regulators also recognized the importance of:

  • Strengthening post-marketing safety measures in reliance pathways
  • Timely information sharing and collaboration among regulatory authorities
  • Balancing patient safety and stable supply of medicines
  • Strengthening trust-building and regional cooperation among Asian regulatory authorities

  -In addition, participating regulators shared the recognition that continued exchange of experiences, information sharing and cooperation through ANM would contribute to strengthening regulatory functions across the region.