Summary of the 6th Asian Network Meeting

1. **Overview**
   - The 6th Asian Network Meeting (ANM) was held in Tokyo, Japan on 24 April 2024, which was attended by 44 participants from 10 countries.
   - The meeting was co-hosted by China, India, Japan and Singapore.

2. **Regulatory updates by each country**
   - Common area of works related to innovative technologies stood out such as technologies for coding system, coping with new modality, risk-based inspection, promotion of e-labeling, Risk management plan, and Reliance approach.
   - Follow-ups on information of interest to participating countries will be updated through the focal point list.

3. **Presentation and Discussion**
   In session 5 and 6, several countries made presentations, which were followed by panel discussion. Major points highlighted in each Session were the followings:

   Session 5: R&D for innovative pharmaceuticals in Asia from regulatory perspective

   - For timely introduction of innovative pharmaceuticals in Asian countries, it is necessary to respond to demands of patients and the lack of experience with new modality products at the same time.
   - It is needed to address the issues such as strengthening regulatory capability of Asian regulators, accumulating knowledge/experience with new modalities, and ensuring transparency in approval processes and approval decisions.
   - Not so many clinical trials have been conducted in Asian region, accumulation of experience on innovative products is limited for both regulators and healthcare professionals.
   - ANM will cope with this challenge by supporting to conduct MRCT including in Asian countries, ensuring communication and enhancing regulatory capacity for Asian regulators and healthcare professionals in response to the evolving Regulatory Science. And this will lead to enhancement of the use of reliance and early sharing of review reports of innovative products subject to reliance.
   - The PMDA Asia Office, which will be established in the summer of 2024, is expected to play a role in advancing regional collaboration with Asian regulatory authorities to resolve these issues.

Session 6: Digitalisation and fast patient access

- Each regulatory authority is addressing and planning to promote digitalization, depending on the needs and situation of its own country.
- The scope and context of digitalization vary in each country, but the common points raised were progress in compatibility and confidentiality, incentives for digitalization among stakeholders, cost-related issues (e.g. development and maintenance costs), and transparency in development process.
- The needs for sharing of best practices and training for regulators were identified as challenges. The need for partnerships and the establishment of a single platform in the Asian region was also raised.
- Participants shared understanding for the need of continued discussions on this issue in order to promote regulatory convergences among Asian countries.
- PMDA's Asia Training Center is expected to continue supporting capacity building of Asian regulators in this area.

4. Others

- A follow-up survey will be conducted after the meeting.
- The meeting summary will be shared to all the participants and will be published on PMDA webpage for keeping transparency of the meeting.
- The 7th ANM will be held in Tokyo, Japan, around the 4th week of April 2025, back-to-back with APAC, in terms of obtaining synergy effect as this year.
- Co-hosting countries will continue preparations for the next meeting as well.

5. Outcome

Based on the presentations and discussion held during the meeting, the outcome of the 6th ANM was summarized as below.

- In Asian countries, regulations on innovative technologies are being updated. As innovative technologies involve multiple stakeholders, participating countries agreed to promote mutual understanding through ANM and work together to address challenges.
- To this end, the need to establish a post-meeting follow-up framework was raised. It was agreed that all participating countries would continue to collaborate in activities aimed at resolving issues.