Reliance Pathway in Thailand (1)

- Presenter: Usanee Harnpramukkul, 5 minutes
- **Abbreviation Registration (Abridged Evaluation)**: refer to full (un-redacted) assessment report of reference authority (US FDA, EMA, MHRA, Swiss Medic, TGA, Health Canada and PMDA)
  - NCE timelines
    - Normal review: 200 wd (80 wd earlier than non-Abridged evaluation)
    - Priority review (e.g. HIVs, Oncology, Tuberculosis, Malaria): 150 wd (70 wd earlier than non-Abridged evaluation)
  - New Biological product timelines
    - Normal review timeline: 220 wd (100 wd earlier than non-Abridged evaluation)
    - Priority review timeline (e.g. HIVs, Oncology, Tuberculosis, Malaria): 180 wd (40 wd earlier than non-Abridged evaluation)
  - Conditions: The manufacturer, packager and release site, the dossiers of Manufacturing and Quality part and Indication, Dose & Administration and Patient group must be the same as those approved by reference authority. The products must be registered & marketed in reference country before submission.
  - The numbers of products submitted (and approved) via this route are not high.
- **WHO Prequalification Program**: refer to the products already approved via Pre-Qualified Program, the reviewing process & timeline can be shortened. This is more beneficial to old products.

Reliance Pathway in Thailand (2)

- **ASEAN Joint Assessment:**
  - Same MA application is submitted simultaneously to all participating authorities (at least 3 authorities). Assessment is carried out together and joint assessment report is prepared. The final decision on the approval of application is taken by each individual authority.
  - Product in scope: Treatment of priority diseases (Malaria, etc), already approved by reference authority and manufactured in PIC/s-GMP compliance site.
  - Pilot product has been done.

- **ASEAN Mutual Recognition**: ASEAN BE MRA, ASEAN GMP MRA
- **Other:** GMP Clearance for Overseas Manufacturers (Compliance Verification)

CHALLENGES

1) Maximizing Reliance Pathway opportunity to further accelerate approval of innovative medicines

- Expand product scope
- Nearly simultaneous submission with US/EU
- Expand Joint Assessment for "innovative product" with the reference authorities (TGA, Health Canada, etc) outside ASEAN region. It can be bilateral/trilateral/quadrilateral.
- Optimize the condition/limitation
- Work Sharing with other authorities

2) Infrastructure of the authority to further support Reliance Pathway

"Move towards to Regulatory Convergence and Patient focused"

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