Thai FDA's regulatory update:
Evolving regulatory paradigm for the quality management of medicinal products throughout product life-cycle

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Outlines

• Thailand government consideration on healthcare industry and strategic plans
• Thai FDA perspective - moving forward to the new regulatory paradigm
• Regulatory actions from Thai FDA
• Conclusion
Thailand Public Health Strategic Plan
TOWARDS BECOMING NO.1 MEDICAL HUB OF ASIA

10 Targeted Industries for the National Policy “Thailand 4.0”

**5 New S-Curve**
- Biofuels and Biochemical
- Digital Economy
- Medical Hub
- Automation and Robotics
- Aviation and Logistics

**5 First S-Curve**
- Agricultural and Biotechnology
- Smart Electronics
- Affluent Medical and Wellness Tourism
- Next-Generation Automotive
- Food for The Future

Source: Thailand Board of Investment
In order to achieve the goal, all involved partners have to develop and improve their functions.
Government policy has set to promotes technology and innovation development to help support Thailand sustainability

Ministry of Public Health has implemented the policy by promoting research and development on health products from both private and government sectors
Thai FDA Perspective
Old Paradigm:
Consumer protection

New Paradigm:
Consumer protection and
Science and technology promotion and support
What are strategies from Thai FDA?

- Regulatory framework development
- Collaboration
What are strategies from Thai FDA?

- Regulatory framework development
Drug Development and Market Authorization

Drug development phase
- Basic research
- Pre-clinical studies
- Clinical studies
- Market Authorization
- Commercialization

Drug discovery phase
- Good Manufacturing Practice (GMP)
- Good Clinical Practice (GCP)
- Good Laboratory Practice (GLP)

Risk-Benefit Assessment
(Assessment core results before a product go to patients)

Pharmacovigilance Activities

GXP
Regulatory Approach for Medicinal Products with Advancing Regulatory Science

Consultation system
(Understanding the innovation earlier and better prepare appropriate regulations or actions)

Risk Management Plan
(Strengthened post-marketing activities)

Consultation panel

National Regulatory Agency

Quality part
Non-clinical part
Clinical part

Industries and R&D Units

Potential Research

Public Health

Market Authorization

GXP

Good Manufacturing Practice (GMP)
Good Clinical Practice (GCP)
Good Laboratory Practice (GLP)

Risk-Benefit Assessment
(Assessment core results before a product go to patients)

Announcing a list for medicinal products impacting public health
(Encouraging industries and R&D units to develop the innovative medicinal products to use in the country)

Appropriate regulatory pathways
(To modernize the regulatory system in order to accelerate access of innovation to patients, while not compromise consumer or patient protection)
The 6th Amendment of the Drug Act (B.E. 2562)

- Regulatory function improvement
- Research and development
  - Clinical trials
  - Pharmaceutical industries
    - Good Clinical Practice (GCP)
    - Intellectual property
      - Recognized international guideline/pharmacopoeias
    - Drug re-evaluation (7 years from an approval date)
- Post marketing strategy strengthening
Regulatory system strengthening program

The list of targeted medicinal products impacting a public health

The list of medicinal products reducing drug registration application fee for domestic pharmaceutical industries
Consultation unit for promotion and support of technology and innovation research and development on medicinal products

- Guidance for animal studies
- Regulations involving in non clinical studies
- Medicinal product development plan
- Etc.

- Pre-Investigational new drug (Pre-IND) meeting
- Guidance for clinical studies
- Regulations involving in non clinical studies
- Updates on clinical study results
- Readiness of data for drug application submission

Regulatory and Administrative Consultation
Pre-Clinical Development
Clinical Development
New Drug Application Consultation

- Basic laws and regulations on medicinal products
- Requirement for manufacturer or importer licensures
- Basic requirements for medicinal product manufacturing plan and layout
- Etc.
What are strategies from Thai FDA?

Collaboration
Why collaboration is so important?
Public Health Network in Thailand

- National Regulatory Authority (Thai FDA)
- R&D Units and Industries
- National Control Laboratory
- Policy makers
- Supporting Agencies
- Users

Network
Medical Product Consortium of Thailand (MPCT)

Collaboration

Government Agencies
Domestic Industries
Funding Agencies
Domestic R&D Units

Regulation
Funding
Manpower
Facilities
Policy
Technology

Drug
Medical Devices
Memorandum of Understanding (MOU) Signing Ceremony on January 30th, 2019
Medical Product Consortium of Thailand

- Relevant Government Agencies
  - Funding
    - Financial Support
  - Mentor
    - Projects
- Academics and Industries
  - Expert panel
    - Experts
- MPCT
  - Regulatory Sandbox Development
  - Innovative Products
- Thailand Food and Drug Administration
  - Drugs
  - Medical Devices
Working Paradigm Shift Towards Regulatory Reliance

Reliance:
“...an act whereby a regulatory authority in one jurisdiction may take into account/give significant weight to work performed by another regulator or other trusted institution in reaching its own decision...”

Risk-based Approach:
“...focuses on those areas which present the greatest risk. Assist in prioritizing & determining the appropriate regulatory response...”

- Efficient use of available resources
- Reducing regulatory burden & duplication of works
Reliance mechanisms employed in Thailand

Mutual recognition
- ASEAN GMP MRA
- ASEAN BE MRA

Referencing decision using unredacted assessment report of other NRAs
- Abbreviated registration pathway
- WHO PQ collaborative registration procedure

Joint assessment program
- ASEAN Joint assessment coordination group (JACG)
- Assessment cooperation program with TGA on Antimalarial drug
Conclusion

• Thai FDA values science and technology development, while consumer protection is still priority.

• Regulatory strategies for medicinal products from Thai FDA including organization internal development and forming collaboration in order to overcome limitation.

• Our goal is “The Medical hub of Asia”.
Thank You for Your Attention