Case Study in Thailand

Presented by:

Chaiporn Pumkam, Ph.D.

Medicines Regulation Division

Thai Food and Drug Administration

Outlines

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02 Roles of drug regulatory authority during pandemic

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Disclaimer

This case study presentation will focus on measures for expediting regulatory procedures to ensure timely availability of medicines during an emergency situation for COVID-19. This covers measures for registration and variation, including the addition or change of manufacturing sites for finished products and raw materials.

The insights that I will present are gathered from colleagues who are responsible for reviewing applications for COVID-19 medicines.

Challenges during COVID-19 pandemic

Increased Demand and Production Pressure

An increased demand for certain medicinal products, such as vaccines, antivirals, antibiotics, and respiratory medicines, put pressure on manufacturers to increase production quickly to meet the needs of healthcare systems worldwide.

Access and Equity

Ensuring equitable access to medicinal products, especially vaccines, across different populations and regions.

Supply Chain Disruptions

Disruptions in transportation networks led to challenges in the procurement and distribution of raw materials and finished products, affecting the supply chain for medicinal products.

Regulatory Challenges

Regulatory agencies faced challenges in expediting the approval process for medicines and vaccines while ensuring that safety and efficacy standards were met. Adapting regulatory processes and some regulatory flexibilities are applied.

Research and Development

R&D for medicines & vaccines with limited knowledge on the disease and new manufacturing technologies.

Roles of Drug Regulatory Authority during pandemic

Ensure Access to Medicinal Products

Rapid increase in demand for medicinal products

Consumer Protection

Ensure Quality, Safety, and Efficacy
Risk benefit assessment

Promote Technology and Innovation

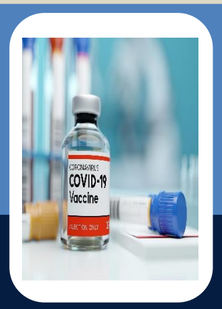
New Technologies

Benefit–Risk balance between innovation promotion and consumer protection in order to ensure that regulatory decisions are based on sound scientific evidence to mitigate risks to public health

During COVID-19 pandemic from 2020-2022

7 Vaccines
8 Medicines

COVID-19 vaccines & medicines



Risk-Benefit Assessment

- **Benefit**
  - efficacy
- **Risk**
  - Safety concerns or adverse effects
- **Quality**
  - Manufacturing Process & Control

Hospitals

Regulatory Decision

- Conditional Approval
- Risk Management Plan

13th

2020

- July — Remdesivir
- October — Favipiravir

2021

- January — AstraZeneca
- February — Sinovac
- March — Johnson & Johnson
- May — Moderna
- May — Sinopharm
- June — Pfizer Cominarty
- July — Casirivimab& Imdevimab
- September — Sotrovimab
- July — Moderna for Children >12 yr.
- December — Pfizer Cominarty for children 5-11 yr.
- December — Baricitinib

2022

- January — Molnupiravir
- January — Nirmatrelvir & Ritonavir (Paxlovid)
- March — Covovax
- June — Tixagevimab & Cilgavimab (Evusheld)

Measures to Accelerate Availability of Medicines (including adding suppliers for APIs and FPs) during COVID-19 Pandemic

- **Government Negotiation**
  - High-level discussions to facilitate the import of finished products (donation, exchange, purchasing) and certain restricted APIs (e.g. hydroxychloroquine).
- **Priority Review**
  - Accelerated assessment
  - Fast-track import permits to expedite the distribution of medicines and raw materials.
- **Pre-submission Consultation**
  - Regulatory advice, scientific advice and guidance throughout the drug registration process and variation process.
  - Regular communication with companies to enhance understanding of regulatory perspectives.

Measures to Accelerate Availability of Medicines (including adding suppliers for APIs and FPs) during COVID-19 Pandemic

- **Scientific Advice**
  - Expert subcommittees and working teams dedicated to expedite the review process for quality, safety, and efficacy of vaccines, as well as any subsequent changes.
- **Regulations & Guidelines**
  - Established regulations on conditional registration approval for emergency use of medicinal products and set up the procedures.
  - Compliance with ICH, WHO, ASEAN guidelines, ICMRA. Justification required to obtain certain flexibilities.
- **Rolling Submission & Review**
  - Allowed the submission of each complete section, study, or module of the drug application for evaluation based on justification of drug companies. However, the information provided for evaluation should be comprehensive and not fragmented.

Measures to Accelerate Availability of Medicines (including adding suppliers for APIs and FPs) during COVID-19 Pandemic

- **Reliance Pathway**
  - Reliance on the assessment and decisions by SRAs (e.g. WHO, EMA, USFDA, PMDA, TGA) to reduce duplicate work and expedite access to medicines.
  - Collaboration with international organizations and SRAs e.g. WHO, TGA, PMDA (Favipiravir imported from Japan) to support Emergency Use Approval and information sharing.
- **IT System**
  - E-submission to reduce document preparation time and paper work.
  - Implementation of e-labeling (labels and leaflets) to facilitate quick distribution of vaccines and enhance access to updated information (e.g. indications, administration guidelines, potential side effects, shelf-life) of the medicines.

Measures to Accelerate Availability of Medicines (including adding suppliers for APIs and FPs) during COVID-19 pandemic

- **Conditional Approval**
  - Allowed data submission after approval e.g. quality studies (stability study report, PV report), nonclinical and clinical studies. Justification should be made.
  - Risk management plan for addressing potential risks.
  - Limited use and distribution channels e.g. hospitals rather than pharmacies.
  - Conditional marketing authorization is valid for one year and can be renewed annually or can be converted to a standard marketing authorization .
  - Post-marketing surveillance and ADR monitoring.
- **GMP Clearance and GMP Certificate**
  - Desktop and remote inspections for oversea manufacturers of finished products rather than on-site inspection.
  - Reliance on inspections of PIC/S members and WHO PQ team
  - Extend the validity of GMP clearance certificates to accommodate delays in GMP inspection. The validity of GMP clearance certificates has currently been extended to the end of 2024

Lessons Learned for the Future

Timely Response to Emergency Use

Risk-benefit assessment with multiple approaches:

- Reliance pathway
- Pre-submission consultation
- Procedures in place for emergency use

etc.

Cooperation within the country and international organizations & agencies

- Data and work sharing
- Guidelines, standards, best practices
- Training and continuous learning

Effective Resource Allocation

- Allocation of capital, infrastructure, and human resources

Support for local manufacturing and research

- Ensure medicine sustainability during emergency situations

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