Vaccine Procurement Practitioners Exchange Forum (VPPEF)

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PRAMOTE AKARAPANON, MR

BUREAU OF DRUG CONTROL

FOOD AND DRUG ADMINISTRATION, THAILAND

Sourcing vaccines of assured quality: Regulatory perspective

- Manufacturer
  - GMP
    - PIC/S GMP
    - Thailand FDA Notification: GMP Clearance of Oversea Pharmaceutical Manufacturer
      - New applications
      - Licensed products
- Product
  - Quality
  - Safety
  - Efficacy
  - Post marketing Surveillance: RMP

Sourcing vaccines of assured quality: Regulatory perspective

REGULATORY RELIANCE

- Thailand FDA Notification: New Drugs, New Biological Products and Vaccines Registration
  - Good Reliance Practice
    - Stringent Regulatory Authorities
      - USFDA, EMA (Centralized System), MHRA, Swiss Medic, TGA, Health Canada, PMDA)
    - WHO PQ Lists

Changes & Challenges

Changes

- **Licensing Facilitating Act:** Thai FDA has to prepare the licensing manual for the public comprising the rules, procedures, workflows published timeline as well as documents to be submitted with applications.
- **The National Council for Peace and Order (NCPO) Order Number 77/59(2016).**

The purpose of the Order is to increase the efficiency of the approval processes. It allows Thai FDA to collect application and evaluation fees.

Changes & Challenges

Challenges

- Because NCPO order number 77/59(2016) allows Thai FDA to collect application fees and evaluation fees, In this regards, Thai FDA has to commit to reduce the approval timeline by 20 % compared with the original timeline.
- Licensing Facilitating Acts: Thai FDA has to commit to the published timeline of each procedure.
- Thai FDA is in a transition period, some obstacles await to be solved.

  - Human resources are limited
    - Number of staff
    - Internal/External reviewers
  - Technical problems
    - E-submission

THANK YOU VERY MUCH