Conditional Early Approval

Indonesia's Perspectives

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Questions to Indonesia

1. Does your economy plan to introduce conditional early approval system (CEA)?
   Otherwise, do you plan to introduce any other expedited/accelerated approval system. If yes what are they?

2. What is your opinion on the new drug submission without confirmatory clinical data?
   In case of the product approved through Conditional Early Approval Pathways?
   In case of medicinal products for rare/orphan disease?
   By any chance, will you (or your economy) request confirmatory clinical data in the submission dataset? If no, in what kind of situations?

3. What is your opinion using the foreign data in the post marketing evaluation of Conditional Early Approval Systems?
   Will it be possible to gather the post marketing evaluation data through multi-regional collaboration?

Plan to introduce conditional early approval system (CEA) in Indonesia

- According to the current regulation for drug registration, conditional early approval system has not yet been introduced in Indonesia.
- Current regulation for drug registration: Regulation of the Head of NADFC No.24/2017
  - Required full dataset (quality, nonclinical and clinical data) for new drug registration.
  - Accelerated approval system (100 WD) for:
    - Medicines used for the National Healthcare Program
    - Medicines used for life threatening/saving disease with no therapy
    - Medicines developed in Indonesia using the IND systems
    - Medicines used for rare/orphan diseases according to Indonesia condition.
- Plan to develop specific regulation for orphan drug registration

New Drug Submission without Confirmatory Clinical Data

- **Limited and inadequate data to assure the safety and efficacy of new drug**
  - Limited subject involved in study
  - Open design clinical trial (without comparison to placebo or standard treatment)

- **In the case of rare/orphan diseases**
  - In case the medicinal product has been approved in countries using the conditional early approval systems: confirmatory clinical data in the submission data set will be requested.
  - Phase 2 clinical trial with placebo controlled may be considered for approval in condition no other choice of medicines for the particular disease/proposed indication.

Using the Foreign Data in The Post Marketing Evaluation of Conditional Early Approval Systems

- According to the current regulation for drug registration in Indonesia, using foreign clinical trials data from foreign countries is acceptable.

- Gathering post marketing evaluation data through multi regional collaboration is possible as supporting data, where possible to include Indonesia in the multi-regional collaboration.


BADAN POM
Thank You
Terima Kasih