Expedited pathways for Pharmaceuticals

- Conditional Approval Systems in Korea-

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Disclaimer

The information in this presentation is based on my experience.

The following slides represent the presenter's views and not necessarily the views of the Korea MFDS.

Presentation Outline

1. Regulation

2. Current Status

Regulation

- **Purposes of expedited pathways are:**

  - to **facilitate** the development of pharmaceuticals for **unmet medical needs**, and

  - to improve the **accessibility of patients**

Regulation

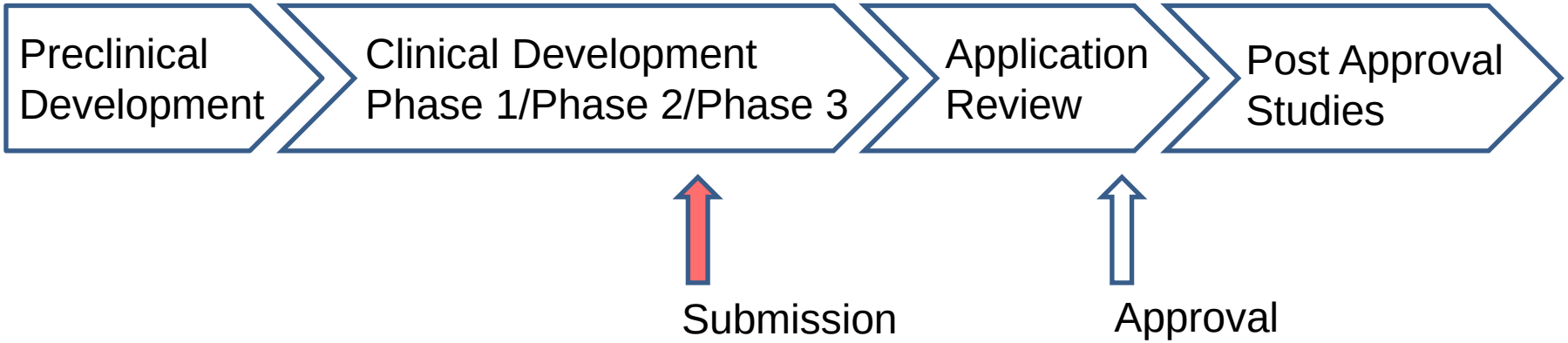
- **To be qualified**, drugs:

  - Intended to treat **life-threatening or serious condition**
  - Provide a **meaningful therapeutic benefit** over available therapies
  - **orphan drugs** for life-threatening or serious conditions

Regulation

- **A drug** reviewed through an **expedited pathway is:**
  - Eligible for **submission of some documents** required under formal regulation **after product approval** (**conditional approval**), or
  - **Reviewed** preferentially through **the fast track process** (priority review)

Summary



Life-threatening or Serious Conditions

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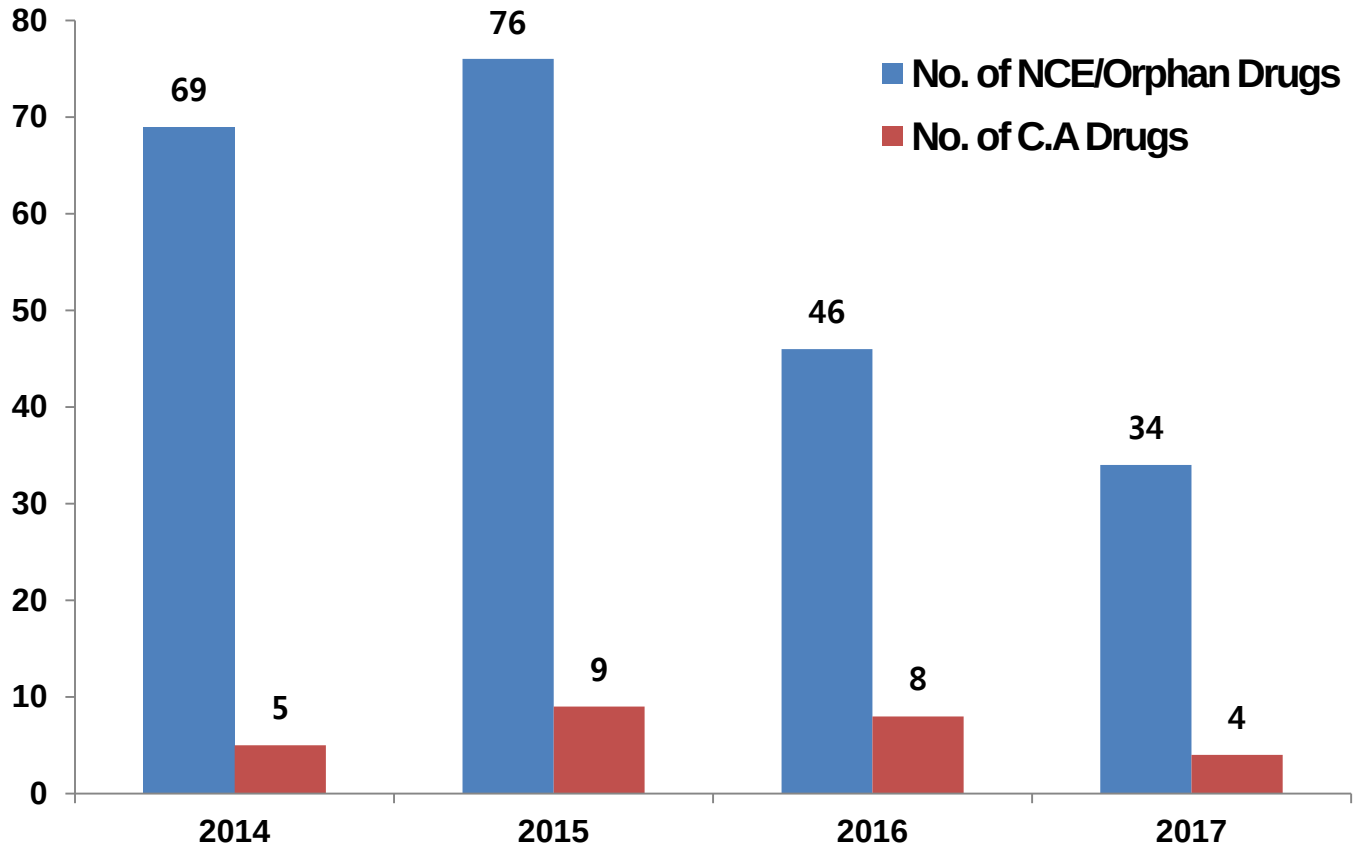
Unmet Medical Needs

- No Available Therapy
- Meaningful advantage over available therapies

Conditional Approval Status (2014-2017)



Short Presentation Questionnaire

Please include have your opinions on the following three questions in your short presentation during the panel.

1. Dose your economy plan to introduce a 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 the case of the products approved through Conditional Early Approval pathways?
   In the case of medical products for rare / orphan diseases?
   - 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?

Question 1:
Dose your economy plan to introduce a Conditional Early Approval System (CEA)?

Expedited pathway in Korea

- Conditional approval

  (to facilitate and expedite development of new drugs)

- Fast track process(reviewed preferentially)

Question 2:
What is your opinion on the new drug submission without confirmatory clinical data?

Drugs are intended

- To fill unmet medical needs
- To treat life-threatening or serious conditions

→ Conditional approval

Question 3:
What is your opinion using the foreign data in the post marketing evaluation of Conditional Early Approval systems?

When a drug is approved on condition of ph 3 CT, post marketing evaluation data(study) cannot replace ph 3 CT results.

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