Financial Feasibility Study of Incremental Modified Drugs Development by Domestic Pharmaceutical Industry

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INTRODUCTION

Thailand's pharmaceutical industry aims for **self-sufficiency** by focusing on the **research, development, and production of vaccines, drugs, and biologics** as per the National Strategic Master Plan.
However, the industry lacks research capabilities, and imported drugs have been more valuable than domestic ones since 2002.

Require more research on
Incremental Modified Drugs (IMDs)
to
enhance self-sufficiency
of the local pharmaceutical industry

OBJECTIVE

To assesses the financial feasibility of developing a dosage form for IMDs, aiding policy and investment decisions.

METHODOLOGY

The investigation of this study comprised 4 stages:

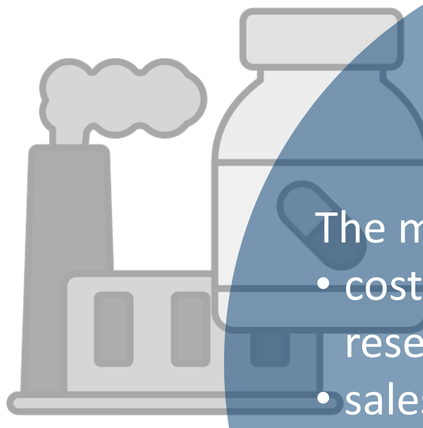
1 **Selection of IMD Types**
Through a feasibility study of domestically developed incrementally modified drugs, the research identified nasal spray as one of the most favorable IMD types

2 **Creation of Investment Models**
Appropriate investment models were formulated to align with the specific circumstances and capabilities of the local pharmaceutical sector

3 **Identification of Cost Structure and Cost Estimation**
The cost structure was established, and the expenses linked to investments in IMDs within the manufacturing industry were approximated.

4 **Financial Feasibility Analysis of IMDs**:
Assumptions were defined, and pertinent data regarding investment variables were gathered to evaluate the financial viability of IMDs. Following the collection of relevant variables, sensitivity analysis and scenario analysis were conducted.

MODEL AND ASSUMPTIONS



The model consist of **2 sections**
- cost model for drug dosage form research and development
- sales revenue model that computes the required revenue to achieve capital recovery

a unique model for evaluating financial feasibility
provides a customizable framework allowing investors to modify **the payback period and market growth rate**

RESULTS

Process	Cost scenario 1* (Million USD)	Cost scenario 2** (Million USD)
Sourcing		
R&D lab scale	0.66	0.66
Pilot scale		
Non-clinical study	0.16	0.21
Clinical study		
-Phase I	0.86	0.86
-Phase II	4.29	4.29
-Phase III	12.86	12.86
Registration	0.003	0.003
Process validation batch	0.99	0.99
Total	**19.82**	**19.87**
Duration (years)	**13**	**13**

1

*Scenario 1: Perform only non-clinical trials, covering the pharmacokinetics and pharmacotoxicity aspects, followed by clinical trials in phases I to III.
**Scenario 2: Carry out non-clinical trials as well as comprehensive clinical trials spanning phases I to III

2

The massive cost and extended timeline in developing nasal spray formulations can be attributed to

- **New formulations and analytical techniques**
- **Unavailable specific analytical methods in local laboratories**
- **Conducting non-clinical and clinical studies to validate the effectiveness, safety, and accuracy of drug delivery to the target site**

3

The income to recover invested capital of **5 years payback period** **3.13 to 28.18 million USD**

DISCUSSION

- The examination of investment in nasal spray shows **elevated expenses and extended timeframes** when compared to new generic drugs
- The primary allocation of this investment goes around **conducting non-clinical and clinical trials** for registration
- Methodology in this study proves to be suitable for examining the financial dimensions of **new drugs, even in scenarios of limited data availability**

CONCLUSION

Investment for IMDs is high and time-consuming and key findings from the financial and investment analysis of IMDs in the domestic pharmaceutical industry emphasize the impact of clinical studies on costs, the importance of research duration and registration processes, drug selection in investment decisions, and market feasibility assessment.

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