

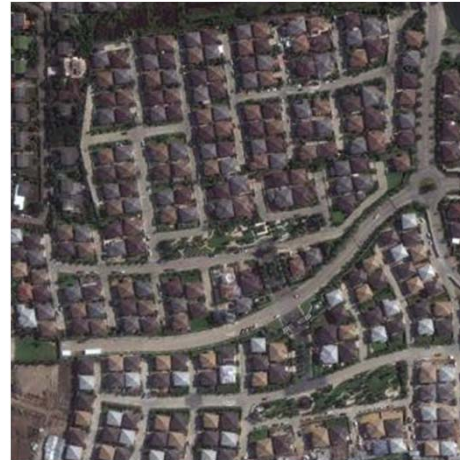
# *The Case Study of Siam Bioscience Co., Ltd.*

## *Addressing Medical Needs through Research and Innovation*

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## *Thailand can achieve self-reliance on 3 of the 4 Basic needs*

**Food:** Thailand is among the world leading exporters



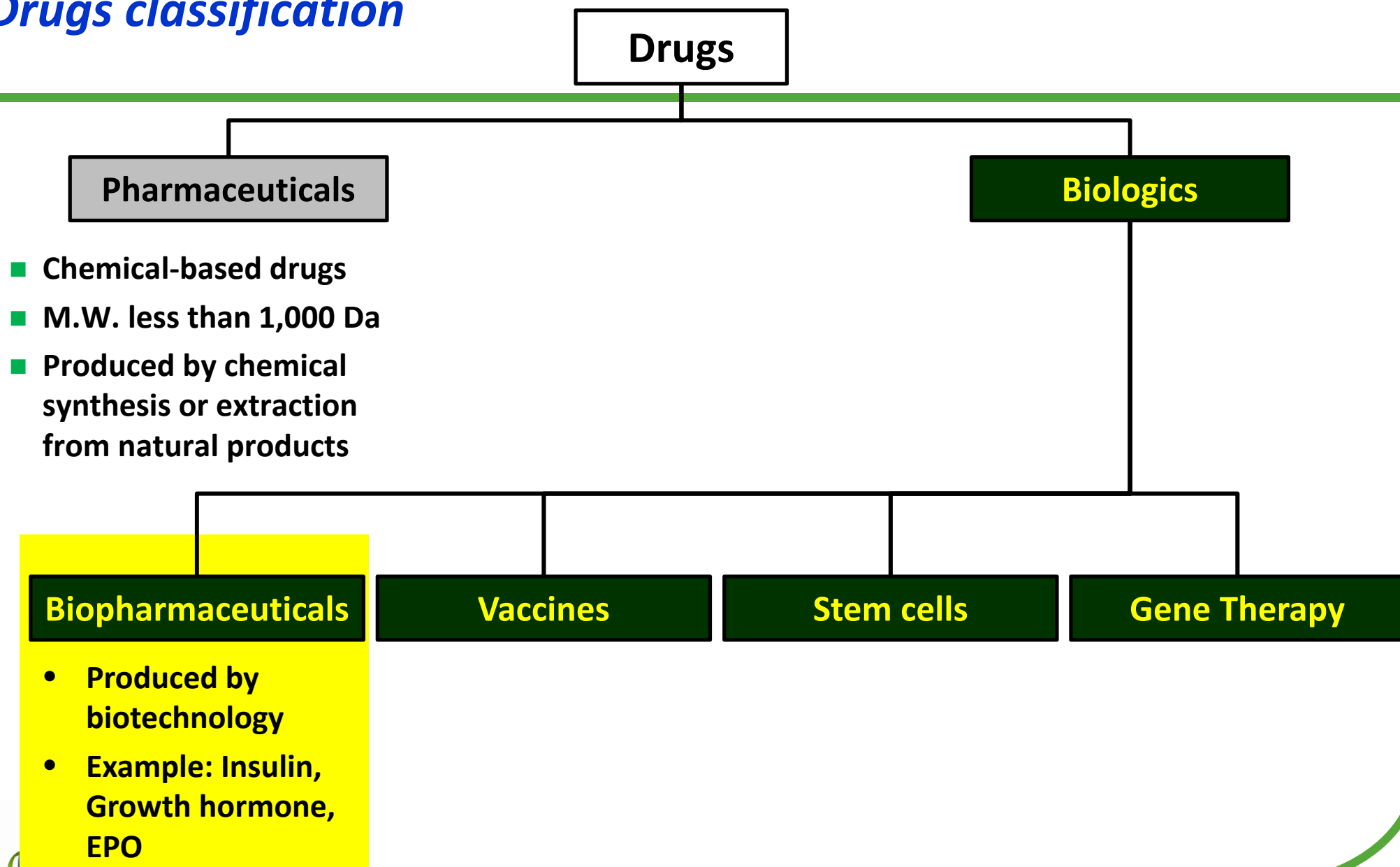
**Housing:** The main industrial sector in Thailand

**Clothes:** Thailand is among the world leading exporters



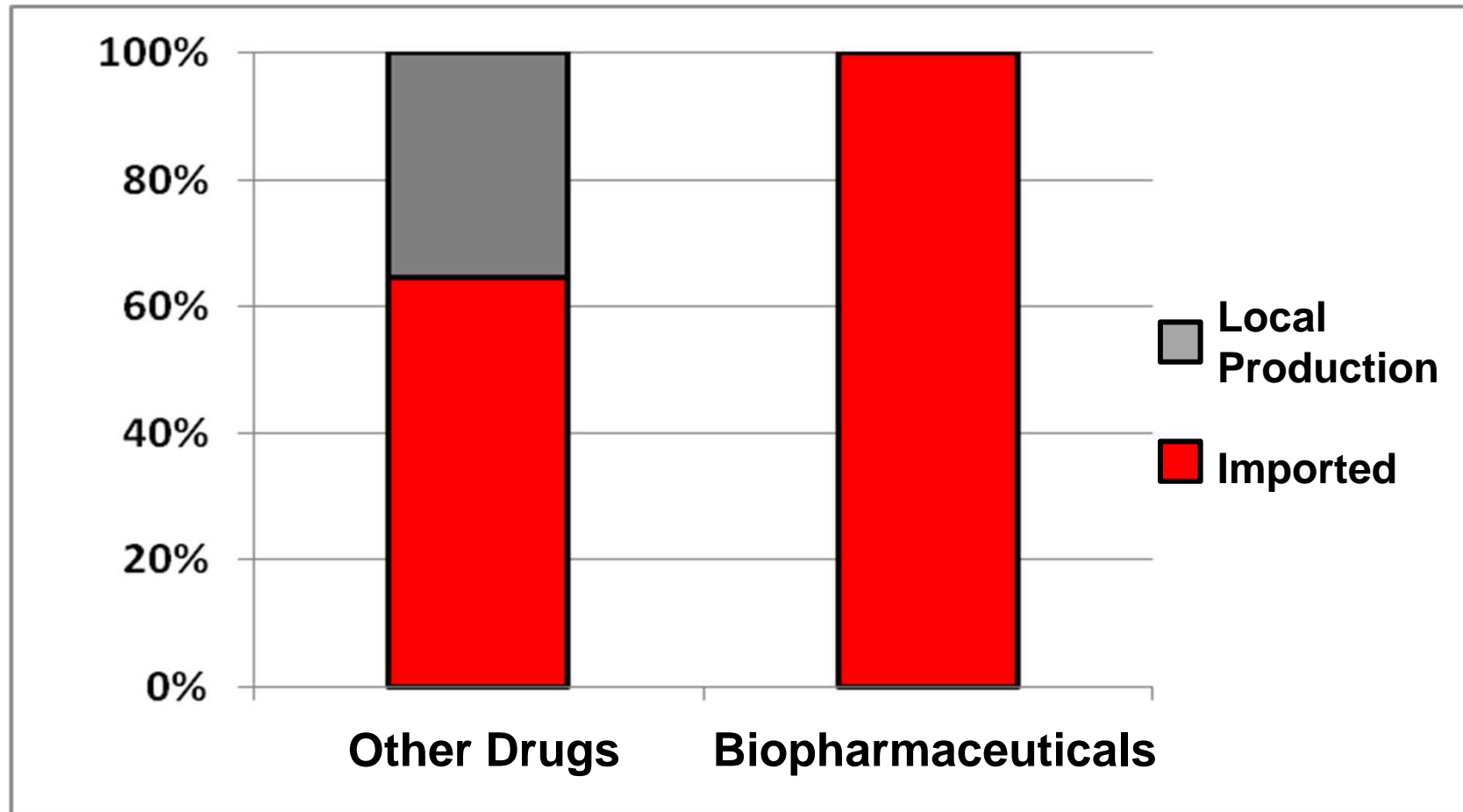
**Drugs:** Nearly 100% import

## Drugs classification



## *All biopharmaceuticals in Thailand are imported*

### *In 2012, import value will exceed 20 Billion THB*



กองควบคุมยา สำนักงานคณะกรรมการอาหารและยา, IMS Health database

# ***Siam Bioscience's Vision and Mission***

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## **Vision:**

- To be a pioneer company in Thailand for biopharmaceuticals focusing on life sciences and healthcare
- To enable Thailand in a long term to become self-sufficient in research, development, manufacturing, and commercialization of biopharmaceuticals
- To provide Thai citizens with high quality biopharmaceuticals at affordable price

## **Mission:**

- Focus on biopharmaceuticals R&D, manufacturing, and commercialization through alliance with research organizations in Thailand and licensing from renown licensors
- Set reasonable price for own products to allow patient access and to have margin to reinvest in development of products in the pipeline

## Definitions of Biosimilars

### Wikipedia:

*“...are terms used to describe officially approved subsequent versions of innovator biopharmaceutical products made by a different sponsor following patent and exclusivity expiry on the innovator product.”*

### EMA (European Medicine Evaluation Agency):

A biosimilar medicine is a medicine which is similar to a biological medicine that has already been authorised (the ‘biological reference medicine’). The active substance of a biosimilar medicine is similar to the one of the biological reference medicine. Biosimilar and biological reference medicines are used in general at the same dose to treat the same disease. Since biosimilar and biological reference medicines are similar but not identical, the decision to treat a patient with a reference or a biosimilar medicine should be taken following the opinion of a qualified healthcare professional.

### WHO (World Health Organization):

*“A biotherapeutic product which is similar in terms of **QUALITY, SAFETY and EFFICACY** to an already licensed reference biotherapeutic product”*



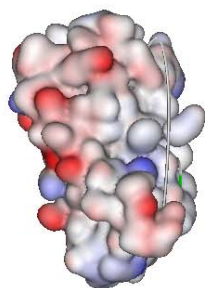
## *Biosimilars are more complicated than Generics*

### Pharmaceuticals (Generics)

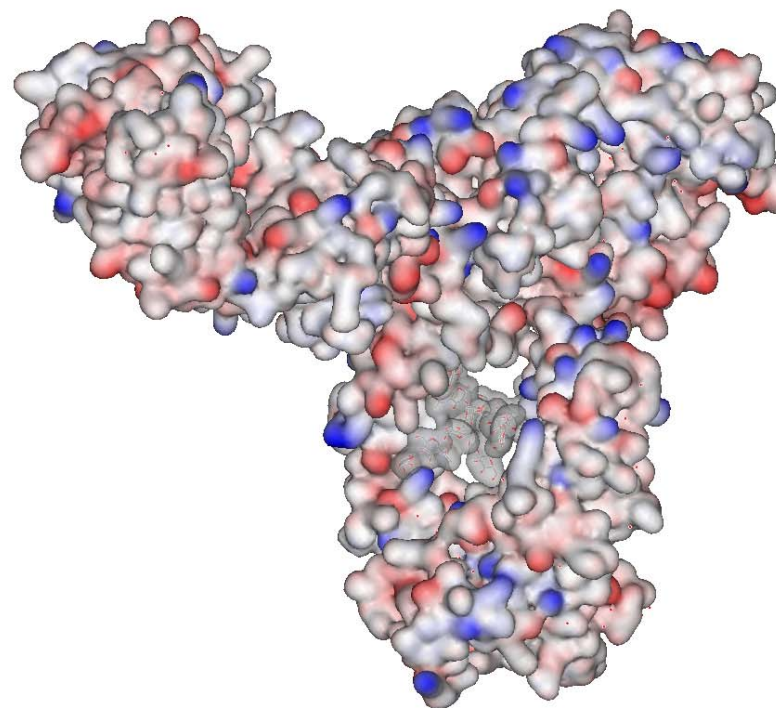


**Paclitaxel**  
M.W. ~850 Da

### Biopharmaceuticals (Biosimilars)

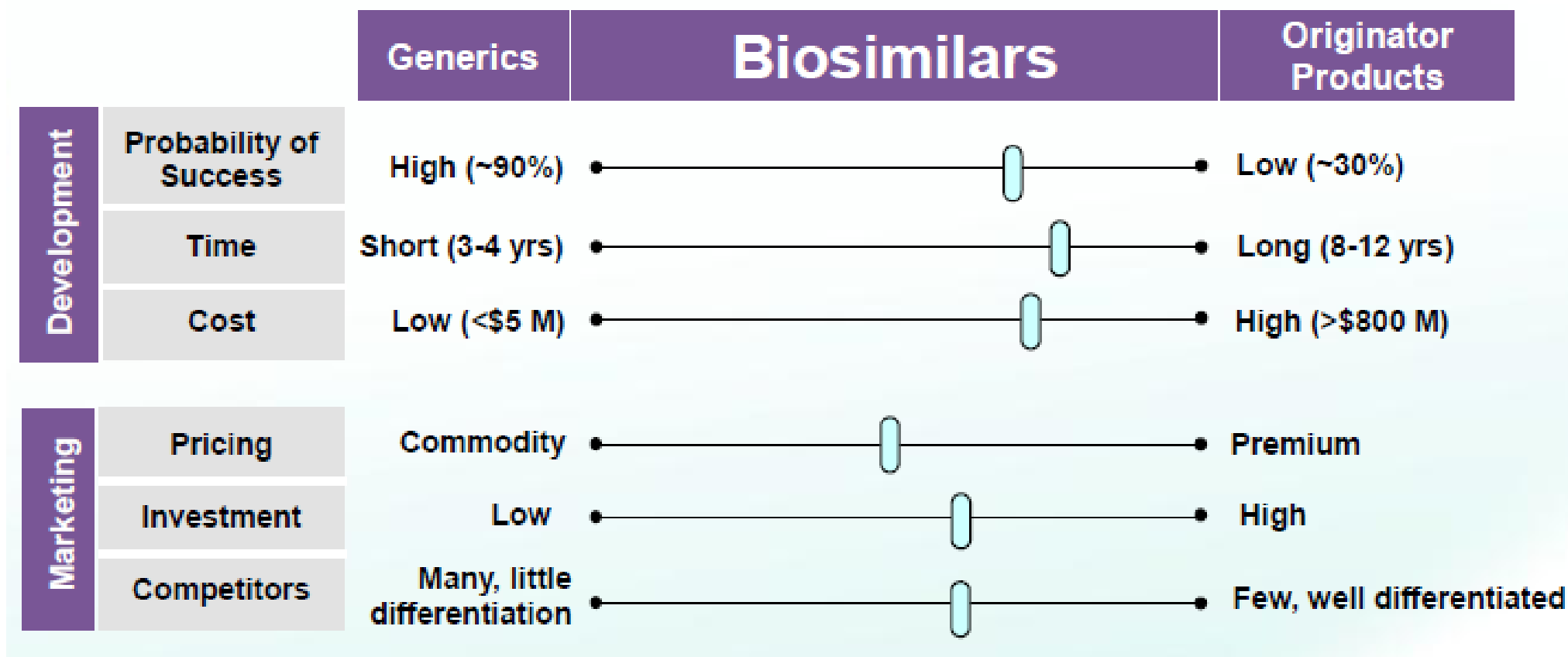


**Epoetin Alfa (EPO)**  
M.W. ~30,000 Da



**Monoclonal antibodies (e.g. Mabthera®)**  
M.W. ~150,000 Da

# Complexity Leads to Intense Development Effort

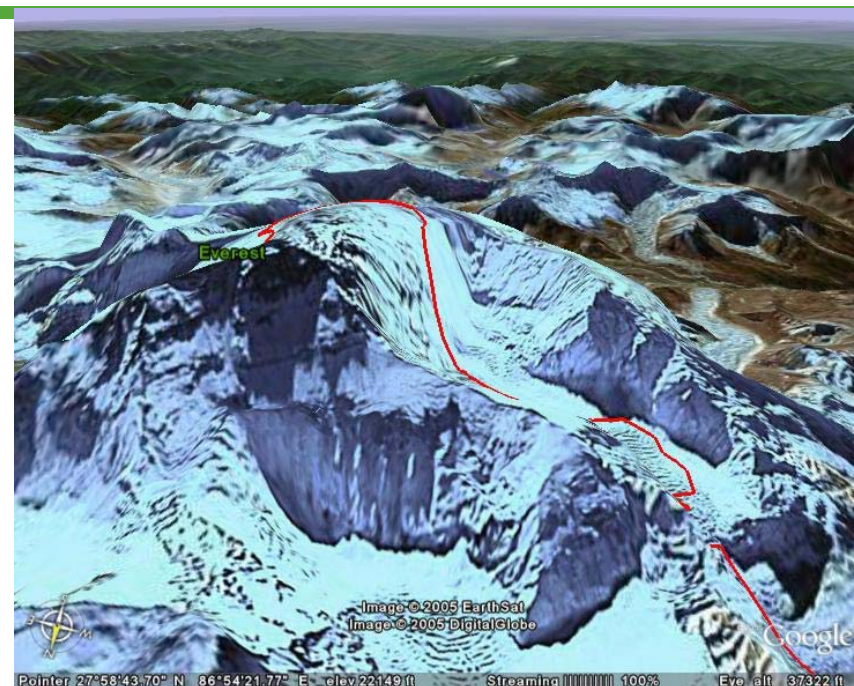




# *Sharing Ideas on Promoting Private Sector Investment in R&D: Biopharmaceutical Industry Perspective*

## ■ Facts:

- ▶ Require significant investment (billions of baht)
- ▶ Taking a long time to realize revenue (not to mention Profit)
- ▶ Heavily regulated industry
- ▶ Fierce competition, both from regional and global players
- ▶ As a high technology industry and dealing with life-and-death, need to convince users that Thailand is capable of producing high quality products
- ▶ Need consistent R&D investment to keep up



**To promote private sector investment in R&D**

**= To create environment where private sector want to enter to this business**

# *Sharing Ideas on Promoting Private Sector Investment in R&D: Biopharmaceutical Industry Perspective*

## ■ Enabling factors

- ▶ Fast-pace human resource development
- ▶ Infrastructure along the value chain
  - Pilot plant
  - Specialized research tools
  - Animal testing facilities
  - Clinical trial centers
- ▶ Encourage information exchange/licensing/co-development on research needs (Private) and research capabilities (Public)
- ▶ Clear and up-to-date regulatory guidelines and action plans
- ▶ Tax incentive



**Make it easier to climb!**

# ***Together, Thailand Can Achieve Self-Reliance on All Basic Needs... Including Medical Drugs***



<http://upload.wikimedia.org/wikipedia/commons/f/fe/Balinghe.jpg>

<http://www.highestbridges.hk/wiki/images/thumb/b/b9/1BalingheIntro.jpg/500px-1BalingheIntro.jpg>

*Privileged and confidential*