EFTA-Thailand FTA: Access to medicines and TRIPS

Dr. Jiraporn Limpanananont

- Social Pharmacy Research Unit (SPRU)
  Faculty of Pharm. Sciences,
  CHULALONGKORN UNIVERSITY
- FTA Watch
  Coalition of Thai NGO working on FTA
Overview Presentation

- HIV Situation & ARVs Demand
- IPRs Protection in Thailand
- IPRs Protection & Access to Medicines
- EFTA-Thailand FTA & Access to Medicines
- FTA & Right to Health
HIV Situation & ARVs Demand

- Untill 2005, HIV infected 1,070,000 adults
- 510,000 died
- 560,000 HIV+ and AIDS

- in 2006 new infections 17,000
- 37,000 HIV+ and AIDS

- The government policy is to provide the ARVs for the fiscal year 2005 is 80,000 cases
- GPO-vir as the first line ARVs
Estimated number of HIV+ people on ARVs treatment upto 2025
Estimated number of people need first and second line ARVs

- **First line**
- **Second line**

![Chart showing estimated number of people needing ARVs](chart.png)
IPRs Protection in Thailand

- Drug Patent Situation in Thailand
- Impact in Access to Medicines in Thailand
RESULTS:

- 98% PATENTEES WERE FOREIGNERS
- Patent Granting Process Took 7-8 years
  - Filing date to Publishing date: 1-1.5 Yrs
  - Publishing date to Exam date: 4-5 Yrs
  - Exam date to Patent issued date: 1.5-2 Yrs
- The number of new drugs still on-patent up to July 2003 was 215 drugs out of 966 drugs (22.4%) and the remaining patent life were 7.5 to 18.2 years.
### DAILY COST of ARVS THERAPY

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<th>REGIMEN</th>
<th>2001</th>
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<th>2003</th>
<th>2004 B(฿)</th>
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TRIPs Plus of EFTA-Thailand FTAs

- Extension of Patent Term
- Data Exclusivity
**Patent Granting Process**

- Filing date to Publishing date: 1-1.5 Yrs
- Publishing date to Exam date: 4-5 Yrs
- Exam date to Patent issued date: 1.5-2 Yrs

Total: 7-8 Yrs
**Extension of patent term**

- Unreasonable request:
  - to compensate for up-front administrative or regulatory delays in granting the original patent

![Diagram showing patent term, filing date, and expired date]

- Filing date: 0
- Expired date: 20 years
## 2. Data Exclusivity

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In this period no any flexibility in TRIPs can be applied.
DATA EXCLUSIVITY & PATENT

YEAR
0
APPLY for PATENT

1
DRUG REGISTRATION

2
DRUG APPROVED to be in MARKET

18
DRUG REGISTRATION

19
DRUG APPROVED to be in MARKET

20
PATENT LIFE 20 Yrs.

YEAR
NO PATENT

DATA EXCLUSIVITY 5-10 Yrs.

DATA EXCLUSIVITY 5-10 Yrs.
Art. 15: As a condition in law requiring of the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, to the government agency, the origination of which involves a considerable effort and they are declared to be protected, the government agency must protect such data from disclosure and against unfair commercial use.
TRIPS Article 39.3

- As a condition of approving the marketing of
  - pharmaceutical or agri. chemical products
  - new chemical entities
  - undisclosed test or other data

- protect such data against
  - disclosure
  - unfair commercial use
GENERIC DRUG REGISTRATION IS USED/RELIED ON UNDISCLOSED DATA OF ORIGINAL DRUG?

NO

POST-MARKET SURVEILLANCE

ORIGINALS
- SUBMIT UNDISCLOSED (SAFETY & EFFICACY DATA)

GENERICS
- SUBMIT BIOEQUIVALENT STUDY
Conclusion

- Strengthen IPRs to TRIPs Plus
  - High drug price > Inaccessibility to drug
  - Obstacle to Thai Drug Industry to develop
- Data Protection
  - Thai drug registration process comply to TRIPs
- Extension of Patent Term
  - Propose for the Technological Co-operation System instead of extension of patent term
THANKS

ขอบคุณค่ะ