Thai experience of using TRIPS flexibilities: need and impact

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Outline

• Health system in Thailand
• Legal context related to TRIPS flexibilities
• Issuing the GUL
• Impact of GUL
Thailand at a glance

- Population: 65.7 million
- GDP (2014): US$ 5,519.4
- Fiscal space:
  - Tax: 17.6% GDP (2011),
  - Revenue: 21.3% GDP (2011),
  - GGHE: 15.3% GGE (2011)
- Total Health Expenditure (2012 NHA):
  - US$215 per capita, 3.9% GDP,
  - Public: 68%, SHI: 8%, Private: 24%, OOP: 14%
- HRH density: doctor/nurse/midwife
  - 24.7/10,000 pop.
- Health status:
  - Life expectancy at birth: 74.1
  - Total fertility rate: 1.5 (2011)
  - U5MR: 14
  - MMR (per 100,000 live birth): 26 (2014)
  - ANC & hospital delivery: 99% (2014)
Thailand’s path to universal health coverage against GNI per capita, 1970-2010

Sources: GNI per capita from World Bank at http://data.worldbank.org/data-catalog/GNI-per-capita-Atlas-and-PPP-table; chronological events were summarized by the authors.

The Three Dimensions of Achieving Universal Health Coverage

- **X axis:**
  - 99% population coverage by 3 schemes [UCS 75%, SHI 20%, CSMBS 5%]

- **Y axis:**
  - Free at point of services, very minimum OOP,
  - Low incidence of catastrophic health expenditure and medical impoverishment

- **Z axis:**
  - Extensive and comprehensive benefit package, very small exclusion list,
  - Most high cost interventions were covered: dialysis, chemotherapy
Health care interventions and medical treatments included in the UCS benefit package

**Basic health Care (on capitation basis)**

**Basic health care**
- Out-patient (OP)
- Hospitalization (IP)
- HC, AE, Disease management
- P&P
- Rehabilitation
- Capital replacement
- EMS
- Thai traditional
- No-fault liability
- etc.

**Universal ART**

- Renal replacement therapy
  - (Pilot project in FY2007 and extend to the whole country in FY2009)
- NCD
  - (2nd prevention for DM/HT)
  - (Pilot project in FY2009, extend to the whole country in FY2010)
- Mental health (medicine)
  - (Pilot project in FY2010, extend to the whole country in FY2011)

**Benefit Starting year**
- 2002
- 2006
- 2009
- 2010
- 2011
However...
1987 – 2012 trend and value of imported and locally produced western medicines

Source: FDA database
Burden of diseases in 2004

Ref: Burden of Diseases and Injuries of the Thai Population 2547
UHC and health system

In summary:
- All health insurance schemes (UCS, SHI and CSMBS) are tax financed, benefit package is extensive and comprehensive.
- Fiscal burden to the country, though great achievement, hence needs for technical efficiency.
- Medicines and medical technologies are major cost drivers and high cost hinders access to health care.
- Demographic and epidemiologic transition results in people live longer and more NCD for which NCD medicines are expensive, e.g. NCD and cancer treatment are out of reach by people.
ISSUING Government Use of License on Medicines
Legal context on patent

- Thailand has amended its Patent Act to conform with the main points of TRIPS since 1992, eight years before the 2000 deadline in WTO agreement.

- Currently, the Thai Patent Act is 2nd amended (1999).

- Thai Patent Act and Trade Secret Act conform with all TRIPS’ requirements. However, the Patent Act still does not cover exporting CL as agreed in the Doha Declaration on the TRIPS Agreement and public health.
Legal context: GUL (Section 51)

- Government Use of License for
  - public utility; or national defense; or natural resource and environment reservation; or relieve severe shortage of food, drug or other consumption products; or for public benefits
- Any ministry, bureau or department of government can issue GUL
- Paying royalty and submitting to the DG of IP Office, Ministry of Commerce
- Notification to the patent holders without delay
In 2006..., Process of GUL

Selection criteria: essential with access constraint, high price, monopoly, patented

Committee on price negotiation

Committee on operational support

Price negotiation

Recommendation for decision makers

Authorized policy makers

Issuing GUL

Subcommittee on medicine selection

succeed

no GUL

Registration and marketing approval by TFDA

Supply (import/produce) management and logistics by GPO

Adapted from Dr. Siriwat’s presentation
# Issuing GUL on 7 medicines

<table>
<thead>
<tr>
<th>Category</th>
<th>Medicine</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anti-retroviral</strong></td>
<td>Efavirenz (EFV)</td>
<td>29 Nov 2006</td>
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<tr>
<td></td>
<td>Lopinavir/Ritronavir (LTV/RTV)</td>
<td>24 Jan 2007</td>
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<tr>
<td><strong>Cardiovascular</strong></td>
<td>Clopidogrel</td>
<td>25 Jan 2007</td>
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<tr>
<td><strong>Antineoplastic</strong></td>
<td>Docetaxel</td>
<td>4 Jan 2008</td>
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<tr>
<td></td>
<td>Letrozole</td>
<td>4 Jan 2008</td>
</tr>
<tr>
<td></td>
<td>Erlotinib</td>
<td>4 Jan 2008</td>
</tr>
<tr>
<td></td>
<td>Imatinib (conditional GUL)</td>
<td>4 Jan 2008</td>
</tr>
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</table>
Reactions...

EXECUTIVE OFFICE OF THE PRESIDENT
THE UNITED STATES TRADE REPRESENTATIVE
WASHINGTON, D.C. 20500

MARCH 6, 2007

Dear Mr. Minister:

I am writing in response to the recent visit by the U.S. Trade Representative and the U.S. National Security Advisor to Thailand. I understand that they discussed the issue of compulsory licensing and its impact on the Thai pharmaceutical industry.

As a member of the WTO, Thailand has the right to issue compulsory licenses for patented medicines. However, it is important to note that these licenses must be issued in accordance with the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

It is concerning to hear reports of the Thai government considering compulsory licenses for certain medicines. This could lead to a loss of confidence in the pharmaceutical industry and affect future investments in research and development.

I would like to reiterate the importance of maintaining a balance between access to medicines and the need for innovation. Compulsory licensing should not be used as a default option, but rather as a last resort in situations where access to medicines is critically needed.

I hope we can work together to find a solution that respects the interests of all stakeholders.

Thank you for your attention to this matter.

Sincerely,

[Signature]

[Name]

[Position]
Impact on access to medicines

Increasing utilization rate for Efavirenz 600 mg.

UC Scheme

Increasing utilization rate for Lopinavir/Ritonavir (200/50mg)

Health service delivery: Better coverage of ARV

Ref: NHSO
Impact on access to medicines (cont.)

Increasing of accessing patients to clopidogrel

No. of accumulated patients

<table>
<thead>
<tr>
<th>Year</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>2015 Q2</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Letrozole</td>
<td>0</td>
<td>1,558</td>
<td>2,629</td>
<td>1,330</td>
<td>1,382</td>
<td>2,282</td>
<td>1,114</td>
<td>10,295</td>
</tr>
<tr>
<td>Docetaxel</td>
<td>321</td>
<td>527</td>
<td>879</td>
<td>1,439</td>
<td>1,447</td>
<td>2,892</td>
<td>725</td>
<td>8,230</td>
</tr>
</tbody>
</table>

Ref: NHSO
## Impact on government budget

**Antiretroviral drug (GUL)**

<table>
<thead>
<tr>
<th>Year</th>
<th>Cost saving (Mil THB)</th>
<th>Cost saving (Mil USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>866.3</td>
<td>27.3</td>
</tr>
<tr>
<td>2011</td>
<td>1,732.8</td>
<td>56.8</td>
</tr>
<tr>
<td>2012</td>
<td>2,319.0</td>
<td>74.6</td>
</tr>
<tr>
<td>2013</td>
<td>2,377.1</td>
<td>77.3</td>
</tr>
<tr>
<td>2014</td>
<td>2,870.0</td>
<td>88.4</td>
</tr>
<tr>
<td><strong>Total saving</strong></td>
<td><strong>10,165.2</strong></td>
<td><strong>338.8</strong></td>
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</table>

Ref: NHSO
## Impact on government budget (cont.)

<table>
<thead>
<tr>
<th>Year</th>
<th>Cost saving</th>
<th>Mil THB</th>
<th>Mil USD</th>
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</thead>
<tbody>
<tr>
<td>2010</td>
<td>108.0</td>
<td>3.4</td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td>1,738.5</td>
<td>57.0</td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>1,172.6</td>
<td>37.7</td>
<td></td>
</tr>
<tr>
<td>2013</td>
<td>1,429.0</td>
<td>46.5</td>
<td></td>
</tr>
<tr>
<td>2014</td>
<td>2,382.3</td>
<td>73.3</td>
<td></td>
</tr>
<tr>
<td>Total saving</td>
<td>6,830.4</td>
<td>227.7</td>
<td></td>
</tr>
</tbody>
</table>

Ref: NHSO
Impact on economics: Export sector

Source: Department of Export Promotion

Figure 2 Value of Thailand’s total exports, by country, indicating timing of grant of government use licenses and withdrawal of US GSP status.

Impact on economics: Foreign Direct Investment

Source: Board of Investment of Thailand
Figure 3 Value of foreign direct investment interested in investing in Thailand between 2002 and 2008, by country (in million USD)

Ensuring quality of medicines

- Quality assurance on GUL medicines:
  - Determining medicinal specification for every item, referred to multisource knowledge and information
    - Pharmacopoeia
    - Expert s’ and stakeholders’ opinion
  - Pre-marketing surveillance by Department of Medical Science and international lab
  - Post-marketing surveillance for quality control
Access to affordable medicines

• Factors contributing to improving access to medicines in Thailand
  – GUL is a means for country to lower the price by acceleration generic substitution and negotiation with the original
  – Capacity of GPO/ generic manufacturers in locally produced generics or in import with technology transfer
  – Medicine registration and marketing approval
  – Central procurement to increase bargaining power, as appropriate
  – Nation-wide medicine delivery and healthcare service system
Acknowledgement

Information, data and presentations from

• Dr Siriwat Tiptaradol, Ex-advisor to the Health Minister, Ex-SG of TFDA, Ex-DPS of MOPH
• HITAP (Health Intervention and Technology Assessment Program) Inthira Yamabhai, et al
• NHSO (National Health Security Office), Netnapis Suchonwanich, et al
• GPO (Government Pharmaceutical Organization) Achara Ekasaengsri, et al
• DIP (Department of Intellectual Property) Ratchawan Jindawat
THANK YOU