



Thai experience of using TRIPS flexibilities: need and impact

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Outline

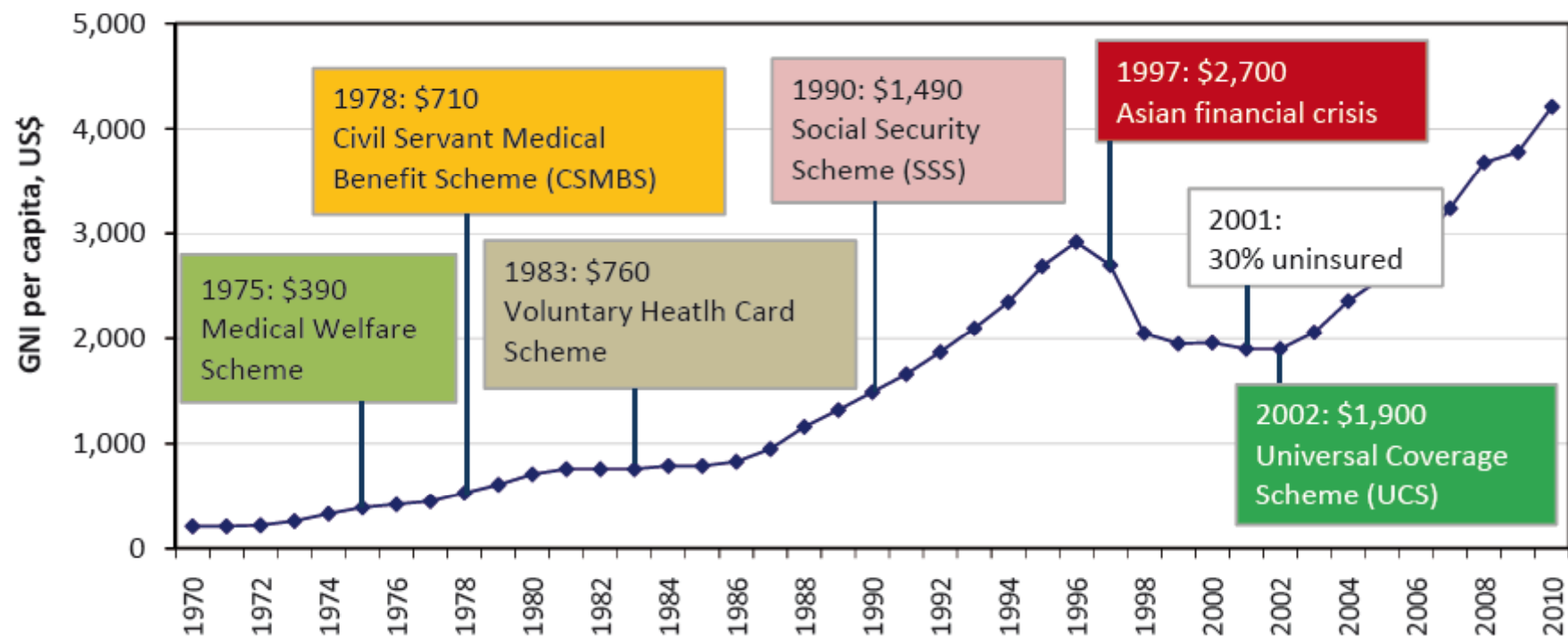
- Health system in Thailand
- Legal context related to TRIPS flexibilities
- Issuing the GUL
- Impact of GUL

Thailand at glance



- Population 65.7 million
- GDP (2014) US\$ 5,519.4
- Gini index 39.4 (2013)
- 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% of THE
- HRH density: doctor/nurse/midwife 24.7/10,000pop.
- 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)³

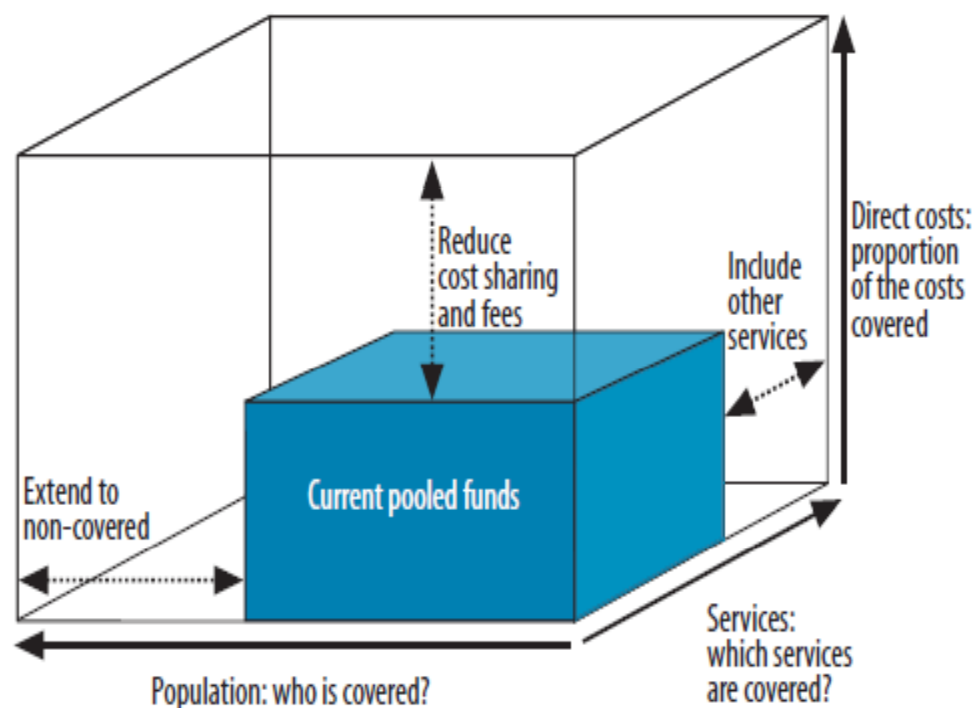
Thailand's path to universal health coverage against GNI per capita, 1970-2010



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.

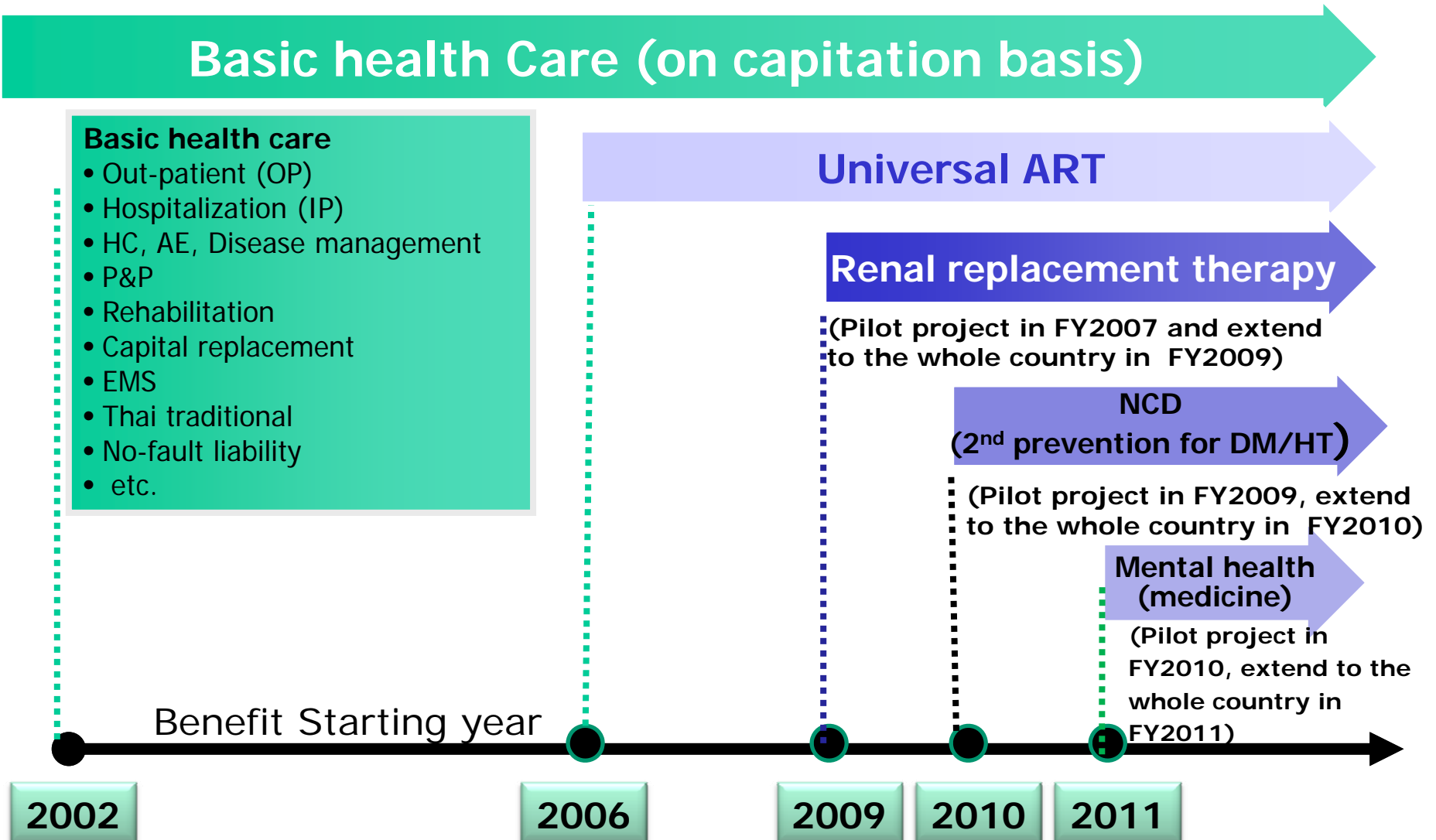
Ref: McManus J, et al (2012). Thailand's universal coverage scheme: achievements and challenges: an independent assessment of the first 10 years (2001-2010), synthesis report.

The Three Dimensions of Achieving Universal Health Coverage



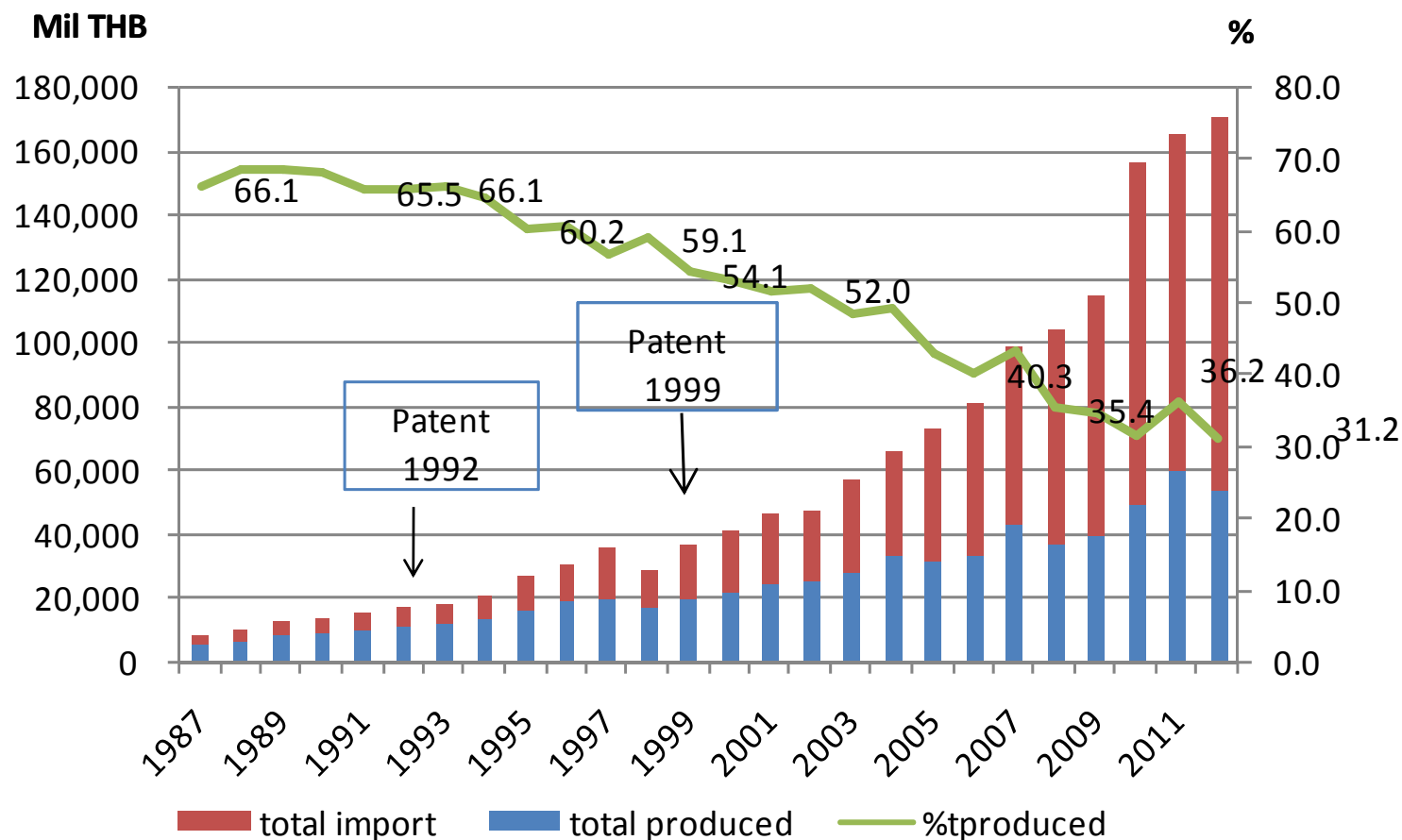
- **X axis:**
 - 99% population coverage by 3 schemes [UCS 75%, SHI 20%, CSMBS 5%]
- **Y axis:**
 - Free at point of services, very minimum OOP,
 - Low incidence of catastrophic health expenditure and medical impoverishment
- **Z axis:**
 - Extensive and comprehensive benefit package, very small exclusion list,
 - Most high cost interventions were covered: dialysis, chemotherapy

Health care interventions and medical treatments included in the UCS benefit package



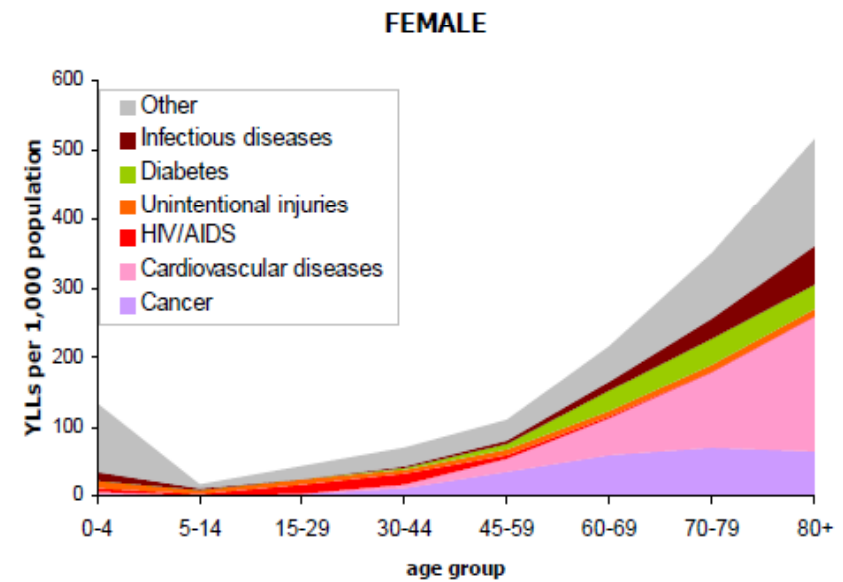
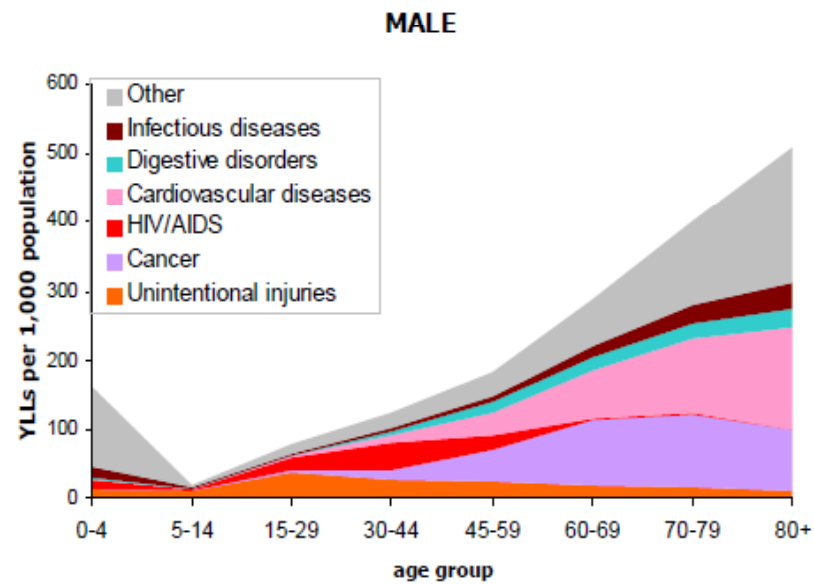
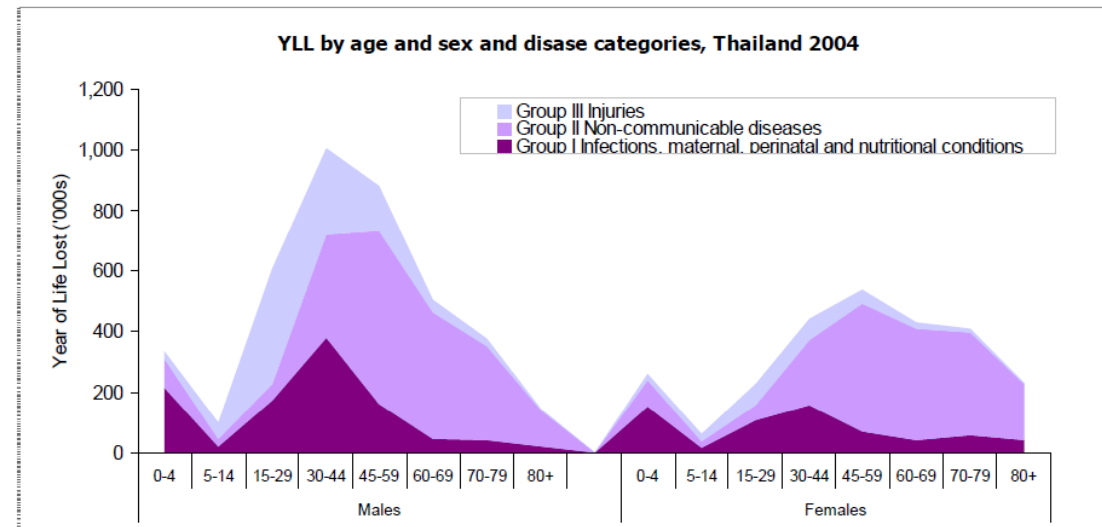
However...

1987 – 2012 trend and value of imported and locally produced western medicines



Source: FDA database

Burden of diseases in 2004



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

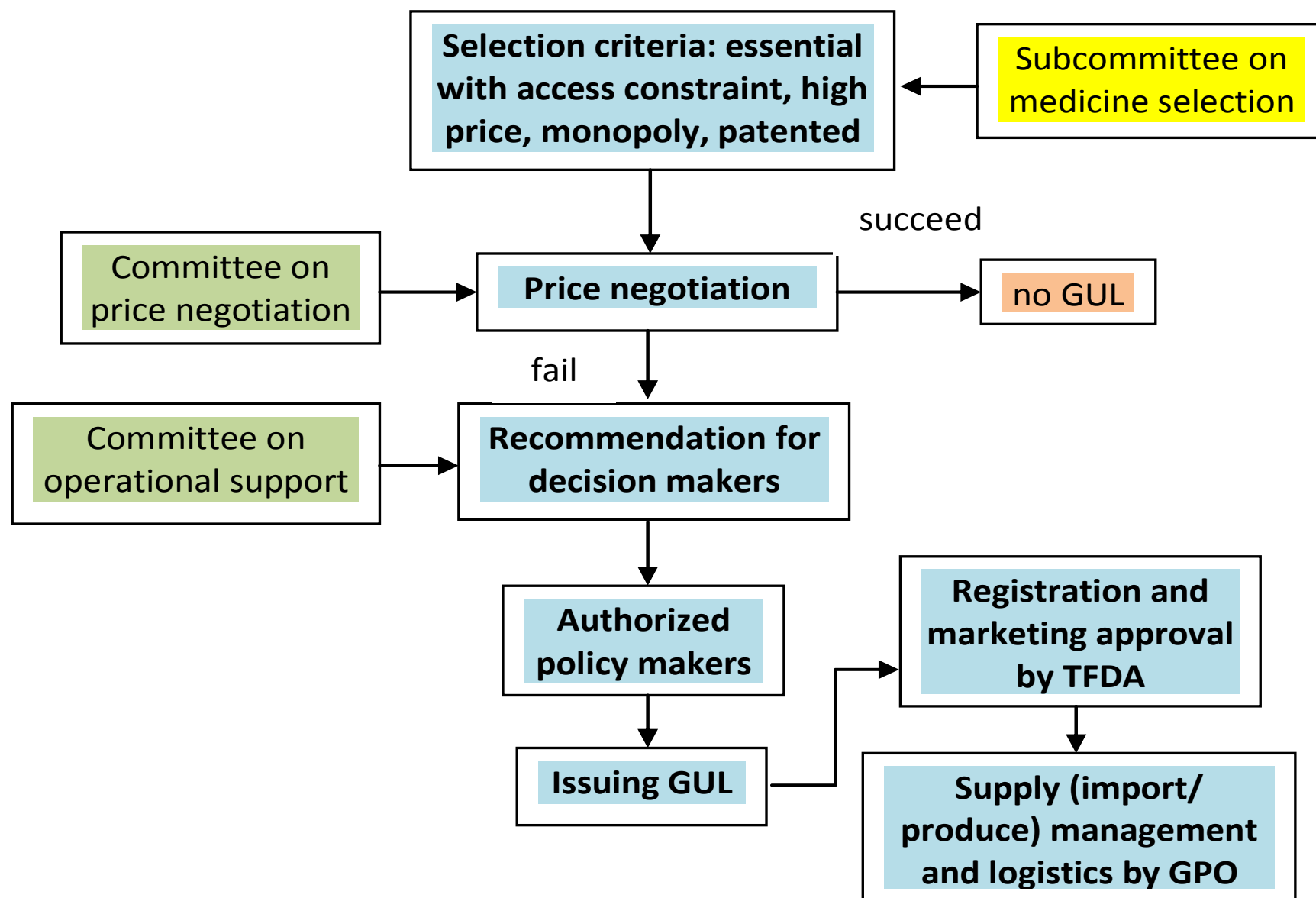
Legal context on patent

- 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



Issuing GUL on 7 medicines

Anti-retroviral	Efavirenz (EFV)	29 Nov 2006
	Lopinavir/Ritronavir (LTV/RTV)	24 Jan 2007
Cardiovascular	Clopidogrel	25 Jan 2007
Antineoplastic	Docetaxel	4 Jan 2008
	Letrozole	4 Jan 2008
	Erlotinib	4 Jan 2008
	Imatinib (conditional GUL)	4 Jan 2008

Reactions...

EXECUTIVE OFFICE OF THE PRESIDENT
THE UNITED STATES TRADE REPRESENTATIVE
WASHINGTON, D.C. 20508

MAR 06 2007

His Excellency
Krikk-krai Jirapaet
Minister of Commerce
of the Kingdom of Thailand
Bangkok

Dear Mr. Minister:

I am writing on a matter of great interest to the United States that concerns both access to medicines and the broader trade and investment climate in Thailand. In recent months, Thailand has announced decisions regarding the compulsory licensing of several patented medicines. These decisions have attracted considerable attention in the United States and internationally. This attention has increased as a result of indications that Thailand may consider using compulsory licensing with respect to drugs for treating a broad range of medical conditions.

APINAKULLEE IREKRU I RUANKUL

Thailand is pushing ahead with its plan to give the public better access to more medicines under the patents of pharmaceutical giants.

Public Health Minister Mongkol na Songkhla yesterday said experts from the ministry and the National Health Security Office were studying the pros and cons of adopting compulsory licensing for use with the five groups of medicine still under patent in Thailand.

"As a matter of fact, we don't want to use the compulsory licensing policy because we don't want to upset the pharmaceutical industry. However, we have to think about the many Thais who need the medicines badly but cannot have them," Dr Mongkol said.

The five groups comprising 11 regimens cover Aids, antibiotics, cancer, heart and cardiovascular and neuropathic drugs, including atazanavir and second-line antiretroviral treatments and insulin, a cancer drug marketed as Gleevec/Glivec, according to a study by a sub-panel on compulsory licensing.

Patent holder Novartis last month filed a lawsuit against the government of India following its refusal to grant a patent for the cancer drug. Dr Mongkol said the panel had submitted the drug list many years ago, but it had never been considered by any government in the past.

Cancer and heart disease rank as the top causes of death in Thailand.

Although the plan has not yet been

finalised and the drug list may be subject to change, the minister said he was confident that any state move to gain access to inexpensive drugs would not discourage medical companies from investing in the development of new drugs in Thailand.

He also hoped that the policy or compulsory licensing would lead to a dialogue between health authorities and the pharmaceutical industry over public access to inexpensive and quality medical treatments over the long run.

A report released by the Drug Control Division showed that more than 200 new medicines registered with the Ministry of Health and Drug Administration in 2005 by Thai pharmaceutical manufacturers in Thailand, while the total cost of imported drugs in the same year came to 10 billion baht.

Meanwhile, Teera Chakajarn, president of the Pharmaceutical Manufacturers Association of Thailand, said he was disappointed with the ministry's latest move on compulsory licensing for the import and production of generic versions of the anti-Aids drugs Zidovudine and Kaletra, and Plavix, a blood thinner.

Peter Piot, executive director of UNAIDS, commended Thailand for stressing the need to provide affordable access to drugs for people living with HIV/AIDS.

Vichai Chokewiwat, chairman of the Government Pharmaceutical Administration's board, said the "white paper" on compulsory licensing would be completed within the week.

the supreme decision-making body of the World Health Organisation (WHO).

"We will discuss the issue with friendly states," Mongkol said yesterday. The minister said seven or eight countries had already contacted him for talks on the sidelines of the assembly - officials mainly from Asia, Latin America and Africa.

The World Health Assembly meets in Geneva each year, and this year the meeting will run from May 14 to 23. Delegates from 193 member states attend the event, the main function of which is to determine the WHO's policies.

Mongkol said he had received more than 200 emails and letters from foreigners in support of the Thai move to enforce compulsory licensing on medicines to treat HIV/AIDS and heart disease.

"We have done it transparently and in good faith. We hope that Thai patients with Aids or heart diseases will have access to quality medicines at an affordable price," Mongkol said.

He spoke after the US Trade Representative (USTR) announced this week it was downgrading Thailand's trade status to its "Priority Watch List" over intellectual-property violations.

The move is widely seen as a retaliation against the Ministry's move to enforce compulsory licensing on certain drugs - including an Aids drug sold by a big US-based firm.

In Geneva, he would fly to meet with USTR US ambassador Robert L. Zoellick. Ralph Boyce, has already been asked to help in the licensing process for the drug efavirenz, sold by pharmaceutical giant GlaxoSmithKline.

Compulsory licensing under WTO rules allows countries to enforce the patent rights of pharmaceutical companies in emergency or public health cases. Patent holders receive some royalties.

The Public Health Ministry already enforced the licensing process for the drug efavirenz, sold by pharmaceutical giant GlaxoSmithKline.

It also plans to break the patent on HIV drug Kaletra made by Abbott Laboratories, and the anti-clotting agent Plavix, made by Sanofi-Aventis and its local subsidiary.

Prime Minister Surayud Chulanont yesterday stood by the Public Health Ministry's move.

"We have reasons to explain to the world. We are confident that relevant parties will understand our needs," Surayud said.

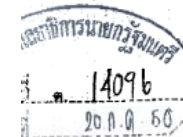
In regard to the downgrade of Thailand's trade status by the USTR, Surayud said the Commerce Ministry would work things out in a bid to remove Thailand from the US Priority Watch List.

"Our officials will work with US officials in addressing existing concerns... It's best to proceed by applying

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First Page
to lowering cost of Aids drug Kaletra

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EMBASSY OF THE
UNITED STATES OF AMERICA
BANGKOK



THE AMBASSADOR

July 20, 2007

ency:

we spoke in late March, before my trip to the United States, I gave our assurance that no new compulsory licenses on pharmaceuticals would be issued. I reported this news to my Government and industry on my subsequent travels back to Washington, which eased the tension. I now fear that the compulsory licensing issue will become a problem.

A number of U.S. pharmaceutical manufacturers are closely following the actions of the Ministry of Public Health and ad hoc committee formed to address pharmaceutical compulsory licenses. The Ministry of Public Health confirmed that it is actively considering a list of additional drugs for compulsory licensing. My staff has consulted with officials from the Ministry of Foreign Affairs and Ministry of Commerce, who have not been able to reassure us that no additional compulsory licenses are forthcoming.

My Government thinks it is important for all countries, including Thailand, to play a role in, and benefit fully from, the development of new and more advanced medical treatments. Strong protection of intellectual property rights, including through patents, remains a vital part of that process. While all WTO members have the ability to make appropriate use of flexibilities to address urgent situations, these decisions should not be made lightly and only as a last resort.

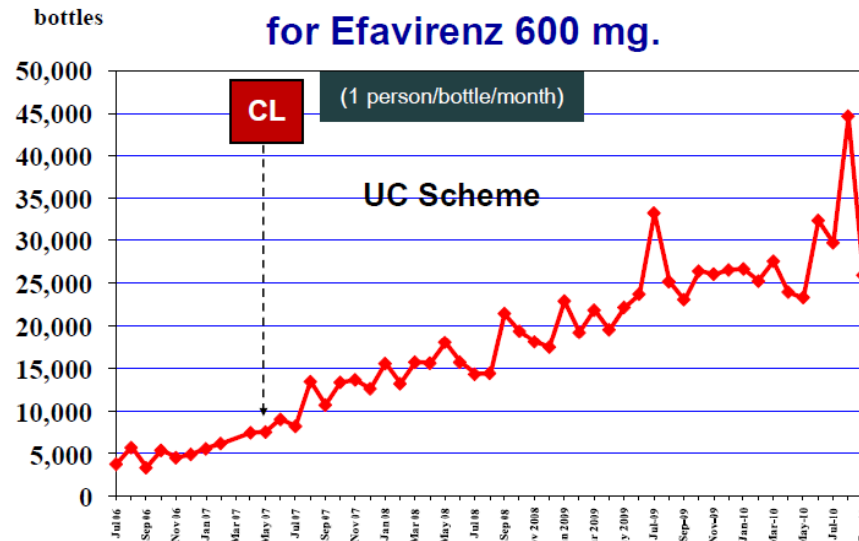
Compulsory licensing for essential medicines. The US and major drug companies must respect the laws of the WTO in the interests of public health.

Thai Network of People Living with HIV/AIDS chairman, Wirat Purahong, urged the Commerce and Foreign Affairs ministries to throw their support behind the Public Health Ministry.

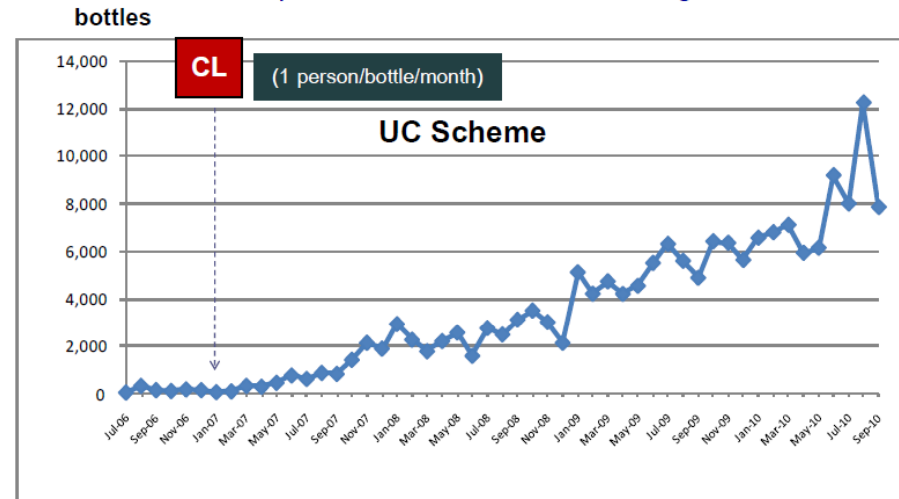
The USTR has said it was concerned by "an overall deterioration" in the protection and enforcement of intellectual property rights in Thailand.

Impact on access to medicines

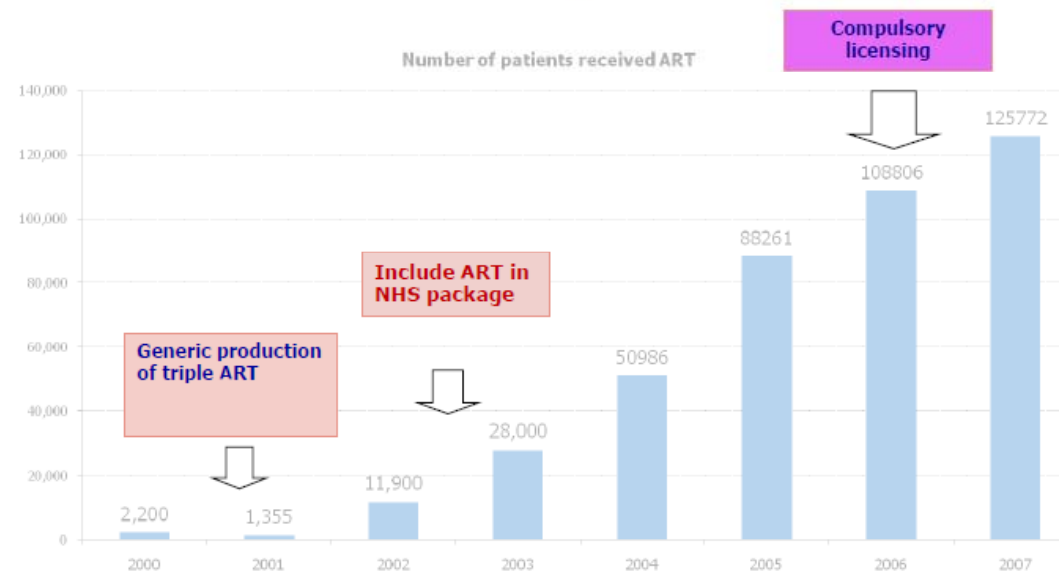
Increasing utilization rate
for Efavirenz 600 mg.



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



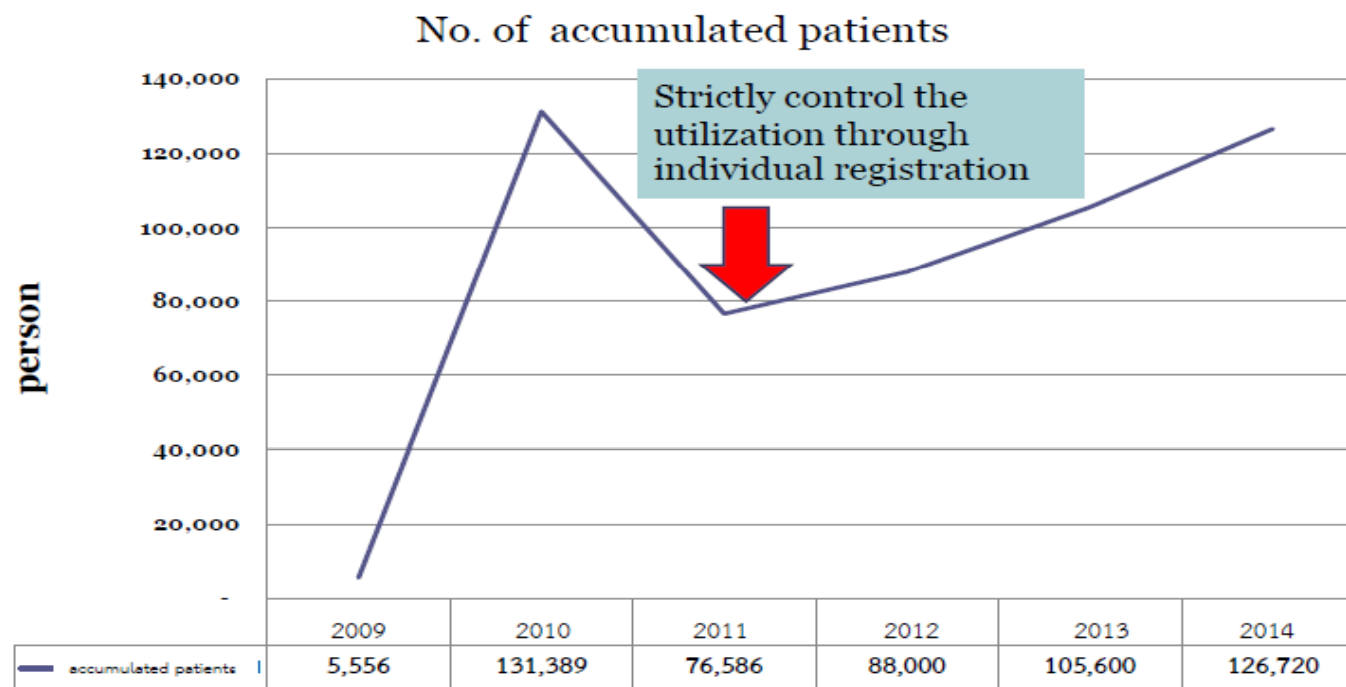
Health service delivery: Better coverage of ARV



Ref: NHSO

Impact on access to medicines (cont.)

Increasing of accessing patients to clopidogrel



Drugs	No. of new patients							total
	2009	2010	2011	2012	2013	2014	2015 Q2	
Letrozole	0	1,558	2,629	1,330	1,382	2,282	1,114	10,295
Docetaxel	321	527	879	1,439	1,447	2,892	725	8,230

Impact on government budget

Cost saving comparing with originated product price		
Antiretroviral drug (GUL)		
Year	Cost saving	
	Mil THB	Mil USD
2010	866.3	27.3
2011	1,732.8	56.8
2012	2,319.0	74.6
2013	2,377.1	77.3
2014	2,870.0	88.4
Total saving	10,165.2	338.8

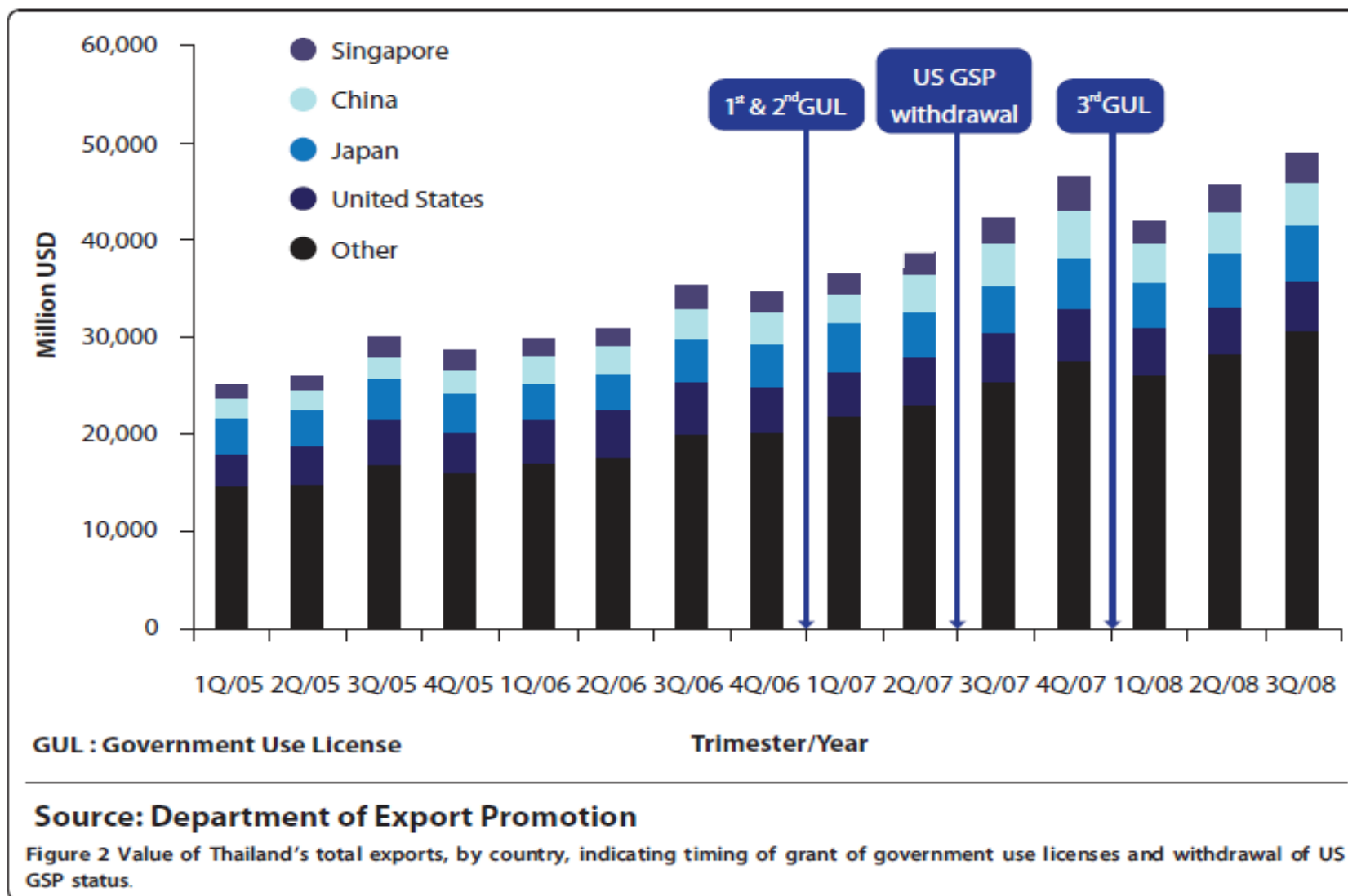
Ref: NHSO

Impact on government budget (cont.)

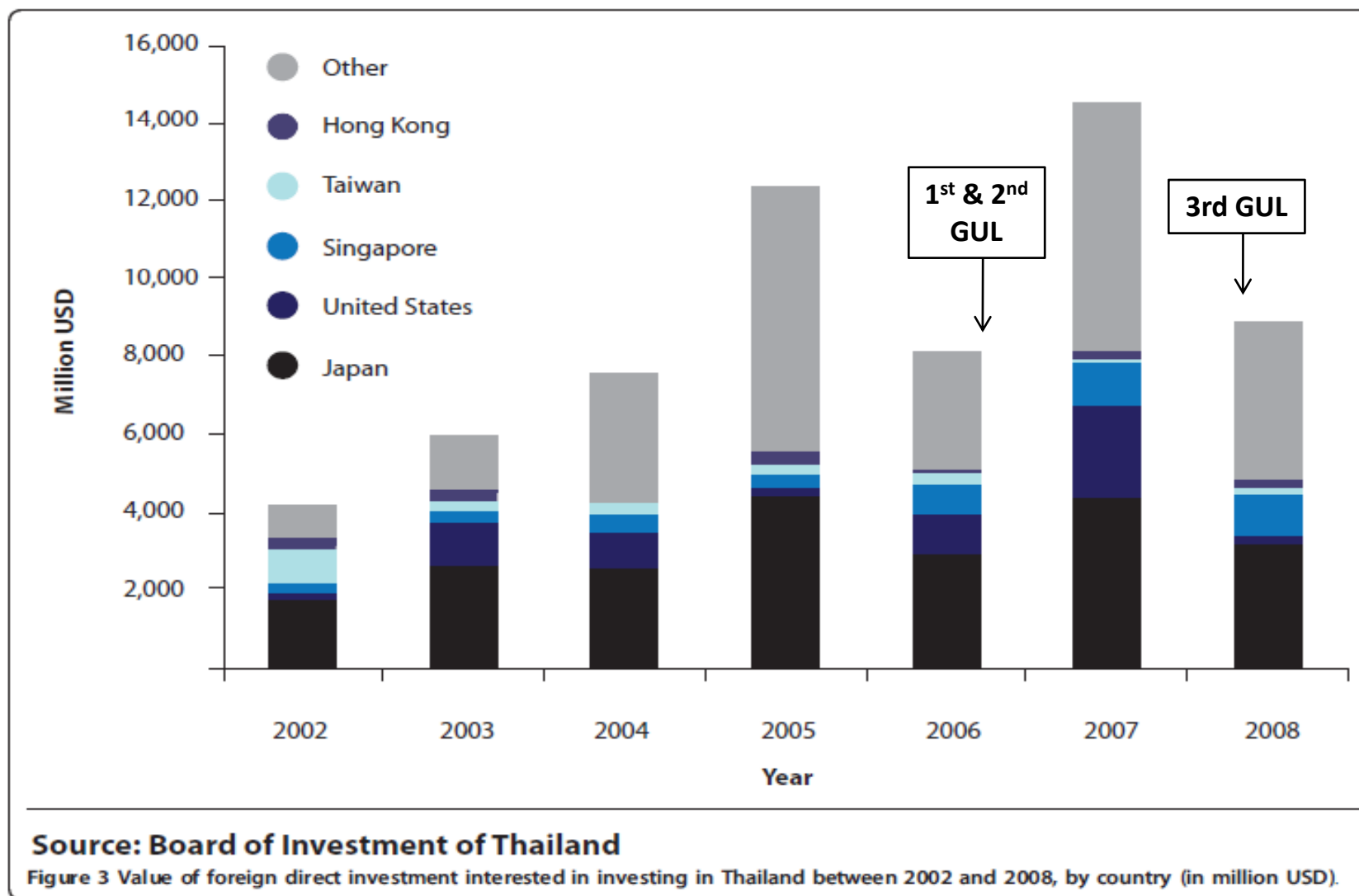
Cost saving comparing with originated product price		
Oncology drug and Clopidogrel (CL)		
Year	Cost saving	
	Mil THB	Mil USD
2010	108.0	3.4
2011	1,738.5	57.0
2012	1,172.6	37.7
2013	1,429.0	46.5
2014	2,382.3	73.3
Total saving	6,830.4	227.7

Ref: NHSO

Impact on economics: Export sector



Impact on economics: Foreign Direct Investment



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 Eksaengsri, et al](#)
- DIP (Department of Intellectual Property) [Ratchawan Jindawat](#)



International Health Policy Program -Thailand

THANK YOU