Migration and HIV vulnerabilities in the GMS: Using TRIPS Flexibilities to increase access to ART

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Outline

- **Thailand case study**
  - **Compulsory licensing to increase access**
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- **TRIPS implementation in GMS countries**
  - **National laws and TRIPS flexibilities**
  - **Options for GMS countries**
- **Addressing migration and HIV vulnerabilities**
  - **Increasing migrants' access to ART**
  - **Joint action by GMS?**
  - **Broader relevance beyond GMS**

Thailand

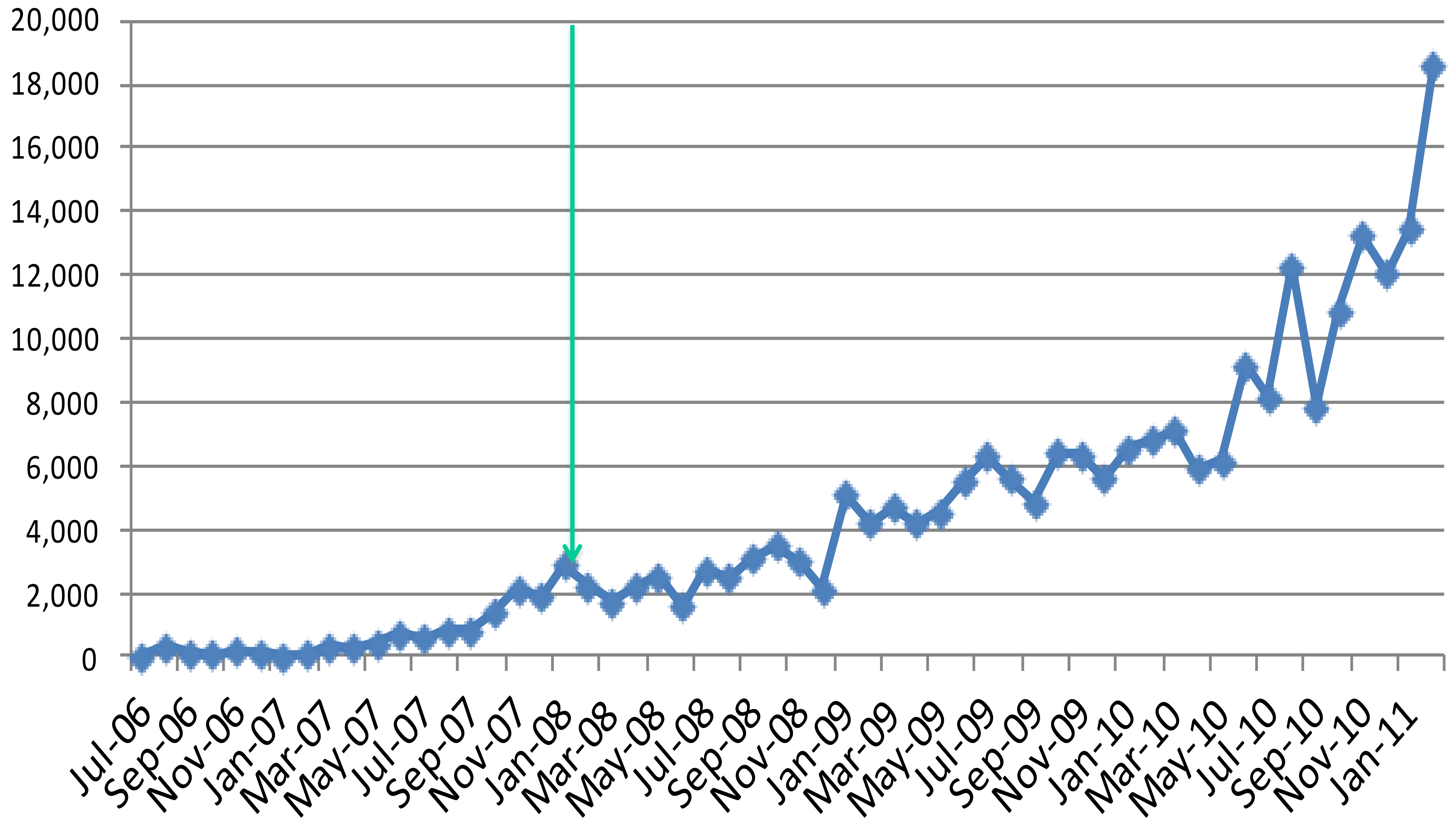
- **2001-2003:** Universal health coverage under UCS. Start of discussions with pharmaceutical companies for price reductions, in order to provide universal ARV access
- **2006-08:** Failure of price negotiations. Decision to grant govt use licences permit the Government Pharmaceutical Organization to import and/or locally produce 7 drugs
- **2007-2008:** Import of generic drugs
  - EFV (Jan 07)
  - LPV/r (Jan 08) and clopidogrel (Aug 08)
  - Docetaxel (2008-2010)
  - No import of imatinib, agreement by Novartis to provide free drugs under access programme

Comparison of originator vs. generic drug prices

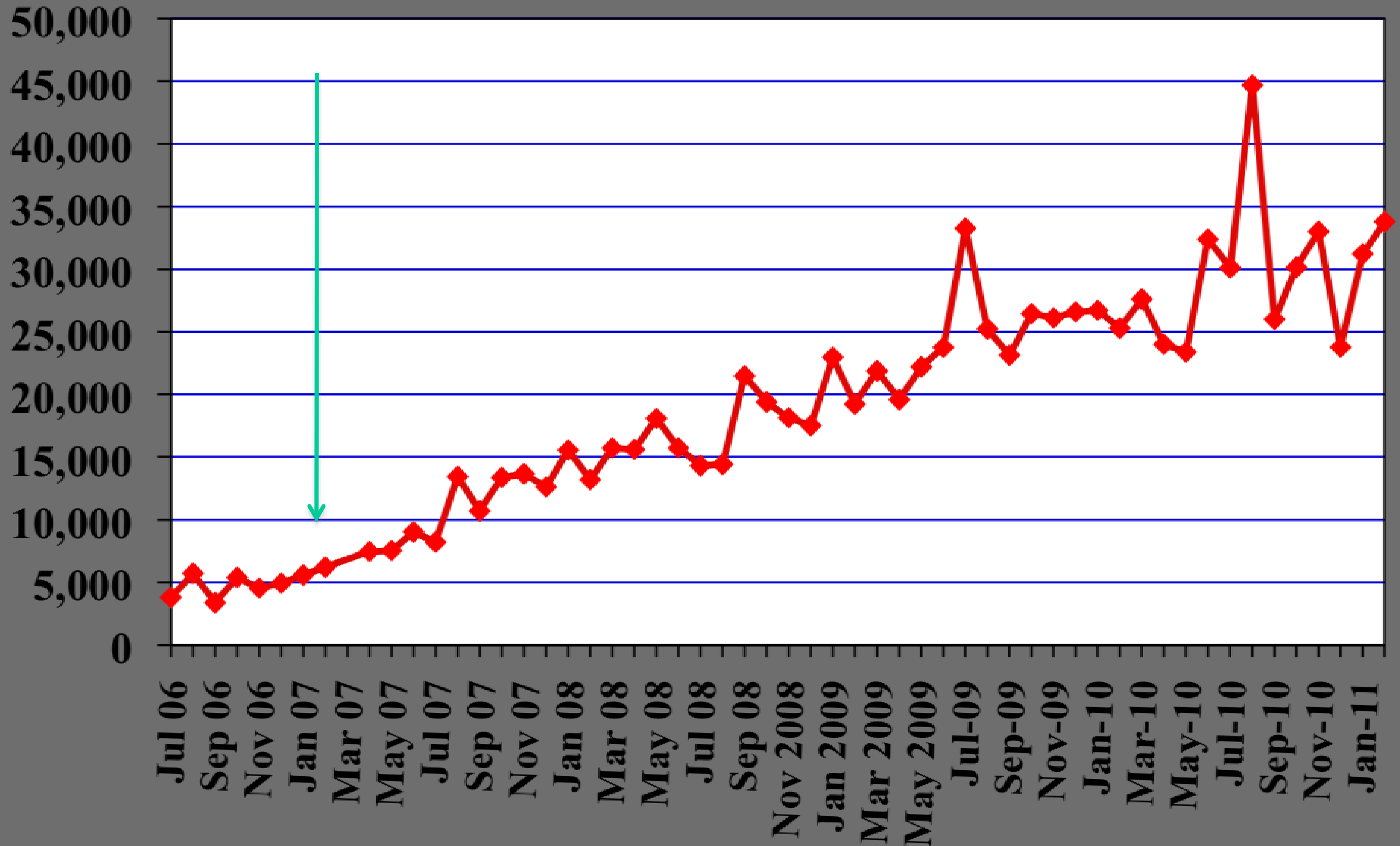
Drug specification	Price (USD)		% of price reduction
	Original	Generic	
1. EFV 600mg	2.0	0.7	66%
2. LPV/r 133mg/33mg	2.1	-	70%
LPV/r 200mg/50mg	-	0.6	
3. Clopidogrel 75mg	2.3	0.1	98%
4. Letrozole 2.5mg	7.0	0.2	97%
5. Docetaxel 80mg	863	37.9	96%
Docetaxel 20mg	237.71	9.1	96%
6. Erlotinib 150mg	83.7	22.4	73%
7. Imatinib 400mg	111.6	-	-

Source: HITAP (2009) Assessing the Implications of Thailand's Government Use Licences issued in 2006-2008
http://www.hitap.net/backoffice/news/news_display2_en.php?id=3750

Rate of use of Lopinavir/Ritonavir, 200/50mg (bottles) under Universal Health Coverage scheme



Rate of use of Efavirenz, 600 mg. (bottles) under Universal Health Coverage Scheme



Lessons from Thailand use of CLs

1. **No restrictions on type of diseases or drugs**
   - Use of TRIPS flexibilities not limited to HIV drugs, no restrictions placed by TRIPS or Doha Declaration
2. **No need for emergency or pandemic situation**
   - Governments are free to determine what constitutes a public health problem
3. **CLs were for import and/or local production**
   - GPO was mandated to import generic drugs, while conducting R&D for domestic generic production
4. **Legal validity of CL maintained**
   - Absence of challenges in Thai courts or dispute in WTO
5. **Established transparency processes**
   - The "White papers" and WHO-led expert Mission

Lessons from Thailand

- **Similar/related concerns in all GMS countries:**
  - Increased migratory flows within GMS and risks of HIV transmission
  - Concerns about continued access to donor funding for treatment costs
  - Rising treatment costs and drug resistance
  - Long-term access to affordable generic ARVs and other medicines – TRIPS-compliance around the world
  - Affordability of medicines is an important component in ensuring long-term sustainability of HIV treatment programme and general access to medicines
  - **What are the best means of promoting affordability in GMS countries?**

Medicines cost containment strategies

1. **Price regulations**
   - Existence of pharmaceutical price controls in GMS countries?
2. **Competition law**
   - Existence of competition law and policy to address abuse of patent rights and market dominance?
3. **Improved medicine procurement practices**
   - More efficient medicines procurement, including introduction of pooled or joint medicines procurement within GMS region?
4. **Medicine price negotiations**
   - Success and sustainability of price discounts on medicines in GMS countries
5. **Use of TRIPS flexibilities**
   - CL and government use licences can be granted for import/domestic production of generics; parallel imports can enable the import of *patented* medicines sold at cheaper prices

Lessons from Thailand

- **Can the generic ARVs imported/produced under CL in Thailand be provided to migrant populations?**
  - Compulsory licences granted in 2006 for efavirenz and lopinavir+ritonavir combination
  - "*… exercise of the right limited to annual provision of drug … to not exceeding 200,000 patients who are entitled persons under the National Health Security Act …, insured persons under the Social Security Act and persons entitled to medical benefits for civil servants and government employees scheme …*"
  - Self-imposed restrictions in the terms of CL limit the ability to provide access to migrants

BUT …

Use of TRIPS flexibilities in GMS

- **Can GMS countries provide the generic ARVs imported under compulsory licences to migrant populations?**

  YES - there is nothing to prevent the use of TRIPS flexibilities to provide access to medicines for both citizens as well as Migrant populations

- **Can generic ARVs produced in Thailand under CL be exported to other GMS countries?**

  YES – under TRIPS Agreement, this is possible but it will depend on a number of factors:

  (1) whether medicine is patented in country of import – if yes, need a compulsory licence from importing country

  (2) the national law provisions in the countries of import and export – national laws have to allow for such CLs

Doha Declaration & TRIPS Flexibilities

- **Doha Declaration**
  - Clarification and common understanding that TRIPS Agreement does not prevent WTO Members from taking measures to protect public health, through use of different types of flexibilities available under TRIPS
- **Time-based flexibilities**
  - Transition periods for developing countries and LDCs
  - Deadlines: ~~2000~~, ~~2005~~, ~~2006~~, 2013, 2016
  - LDC request at WTO TRIPS Council for further extension (November 2012)
- **Substantive flexibilities**
  - Flexibilities specifically recognised in Doha Declaration. E.g., compulsory licences, exhaustion of rights
  - Public health interpretation of other TRIPS provisions. E.g., exceptions, patentability criteria, test data protection

Implementation of TRIPS flexibilities in national laws

	China	Cambodia	Laos PDR	Myanmar	Thailand	Vietnam
Govt use licence	✔	✔	✗		✔	✗
Compulsory licence	✔ SIPO Order 64 of (May 2012)	✔ Draft Compulsory Licensing law (2012)	✔		✔	✔
Parallel import	?	✔	?		✔	✔
Bolar exception	✔	✗	?		✔	✗
2016 LDC deadline		✔	✔	✔		

Using TRIPS flexibilities to improve access to medicines:

- **Option 1: Import generics from abroad**
  - E.g., import of generics from India
  - Government can grant compulsory licence to third party to import, or government itself imports under government use licence for public, non-commercial purposes
  - Examples: Malaysia, Indonesia and Thailand

- **Option 2: Locally produce generics**
  - Countries with pharmaceutical manufacturing capacity can issue compulsory licence for local manufacturer to produce generics
  - E.g., Thailand, Indonesia

Using TRIPS flexibilities to improve access to medicines:

- **Option 3: Import generics made under CL**
  - Import generics made under compulsory licence, under the WTO 30 August Decision
  - E.g., Country A produces under CL, exports to Country B, which also grants a CL for the import
  - Example: Rwanda

- **Option 4: Parallel import**
  - Import patented medicines from another market where it is sold cheaper
  - E.g., Drug X is sold in Country A for $10, but is sold in Country B for $25. A manufacturer or distributor in Country B can parallel import Drug X from Country A at $10 to be sold in Country B for $15; which translates into a savings of $10.

Table 1. CL episodes by year and country.

Year(s)	Nation	National Income Group	Disease	Disease Group	Total Products	Outcome
2001 (2007)	Brazil	UMIC	HIV/AIDS	HIV/AIDS	2	CL/discount
2001	Brazil	UMIC	HIV/AIDS	HIV/AIDS	1	Discount
2001	Canada	HIC	Anthrax	CD	1	Discount
2001–2003	South Africa	UMIC	HIV/AIDS	HIV/AIDS	8	VL/discount/none
2001	United States	HIC	Anthrax	CD	1	Discount
2002	Egypt	LIC	Erectile dysfunction	NCD	1	CL
2003–2004	Malaysia	UMIC	HIV/AIDS	HIV/AIDS	3	CL
2003, 2007	Brazil	UMIC	HIV/AIDS	HIV/AIDS	1	Discount
2003	Zimbabwe	LIC	HIV/AIDS	HIV/AIDS	All	CL
2004	Mozambique	LDC	HIV/AIDS	HIV/AIDS	3	CL
2004	Zambia	LDC	HIV/AIDS	HIV/AIDS	3	CL
2005–2006	Argentina	UMIC	Pandemic flu	CD	1	VL
2005–2007	Brazil	UMIC	HIV/AIDS	HIV/AIDS	1	Discount
2005–2009	Brazil	UMIC	HIV/AIDS	HIV/AIDS	1	Discount
2005	Ghana	LIC	HIV/AIDS	HIV/AIDS	All	CL
2005	Indonesia	LIC	HIV/AIDS	HIV/AIDS	2	CL
2005	Taiwan	HIC	Pandemic flu	CD	1	VL
2006–2007	India	LIC	Cancer	NCD	1	None
2006 (2010)	Thailand	UMIC	HIV/AIDS	HIV/AIDS	1	CL
2007	Rwanda	LDC	HIV/AIDS	HIV/AIDS	1	CL
2007 (2010)	Thailand	UMIC	HIV/AIDS, CVD	HIV/AIDS, NCD	2	CL
2007–2008	Thailand	UMIC	Cancer	NCD	1	Discount
2007–2008	Thailand	UMIC	Cancer	NCD	3	CL
2010	Ecuador	UMIC	HIV/AIDS	HIV/AIDS	1	CL

Totals: 24 Episodes, 17 Nations, 40 Unique Drug-Nation Combinations +2 Categorical CLs. Years in parentheses indicate CL renewals.
CVD, cardiovascular disease.
doi:10.1371/journal.pmed.1001154.t001

Beall R, Kuhn R (2012) Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis. PLoS Med 9(1): e1001154. doi:10.1371/journal.pmed.1001154
http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.1001154
PLoS MEDICINE

Joint action by GMS?

- **A component of joint action on migration and HIV –**
- **Implementing measures for improved coordination and coherence on IPR, TRIPS and medicines procurement**
  - Assess IPR legislation in GMS countries and status of TRIPS implementation
  - Promote incorporation of all TRIPS flexibilities in national legislation
  - Promote use of 2016 deadlines by LDCs – no patent protection for pharmaceuticals until at least 2016,
  - Determine patent status of key ARVs in use in GMS countries – training on use of UNDP patent search tool

Joint action by GMS?

- **Sub-regional coordination on procurement, IPR and TRIPS issues:**
  - Joint or pooled procurement for GMS countries to improve treatment access by vulnerable groups, including migrant populations
  - Where procurement of affordable medicines is hampered by patents, there should be consideration of use of TRIPS flexibilities as a sub-regional group:
    - **Scenario 1:**

      Grant of joint CL by GMS countries for import of generics from India or other countries able to manufacture generics
    - **Scenario 2:**

      Grant of CL by Thailand, Vietnam and China for production and export of generics. Grant of CL by other GMS countries to import, where the medicine is under patent in country of import. LDCs without patent protection need not grant CL.

Beyond GMS

- **Use of flexibilities – as above – is applicable and relevant to other developing countries**
  - Countries may act on individual basis
  - Countries may act jointly
  - E.g., GMS countries can act together, ASEAN countries can also consider similar regional approaches
  - Benefits of acting jointly
    - Nature of migratory flows – a regional issue requiring joint approaches
    - Pooling of resources – ability to share information and technical expertise
    - Strength in numbers – greater confidence to withstand undue political pressures