Migration and HIV vulnerabilities in the GMS: Promoting access to HIV prevention, treatment, care and support

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Consultation on MOU to Reduce HIV Vulnerability associated with Population Movement
Bangkok
11-13 July 2012

Outline

- Migration & HIV vulnerabilities
  - Challenges to migrants' access to HIV programmes
- Policy and legal frameworks
  - International rights and obligations
  - National policies and health systems
  - Relevance of IPR and TRIPS Agreement
- Joint actions to reinforce an enabling environment for access
  - National measures
  - Case example: Thailand
  - Regional and cross-border strategies

Challenges to migrants' access to HIV treatment and services

- Lack of national and regional legal frameworks guaranteeing rights of migrants
  - Discrimination and stigmatization
  - Lack of access to health and HIV services in host countries
- Migrants not defined or targeted as a HIV-vulnerable group
  - Lack of epidemiological and health needs data
  - Absent/inadequate coverage for migrants under national health and HIV programmes
- Policy and implementation inconsistencies
- Need for cross-border policy coordination on migration and HIV responses

International rights and obligations

- Right to health and right to work
  - Universal Declaration of Human Rights
  - ILO Conventions
  - International Covenant on Economic, Social and Cultural Rights
  - Political Declaration on HIV/AIDS, 2006
- Access to HIV treatment and services
  - World Health Assembly Resolution on the Health of Migrants, 2008
  - UNGASS Declaration of Commitment on HIV/AIDS, 2001
  - UN General Assembly High Level Meeting on AIDS, 2011
  - Global Commission on HIV and the Law, 2012

➔ **Countries should offer the same standards of protection to migrants, visitors and residents who are not citizens, as those offered to its citizens**

International rights and obligations

- A core minimum of health services for migrants without discrimination
  - Elimination of barriers to health service access - regulatory reform to allow legal registration of migrants with national health services
  - Access to the same quality of HIV prevention, treatment and care services and commodities that are available to citizens – coverage under national HIV programmes
  - Cross-border policy coordination between home and host countries and mechanisms for continuity of care
  - **Funding and human resources?**
- Recognition of economic contributions of migrants – by home and host countries
  - Financial investments and allocation of human resources targeted towards protection of migrant rights and provision of health and HIV services

Challenges to provision of healthcare and HIV services at national level

- Political will and public awareness
- Capacity and human resources
- Implementation challenges
- Costs and sustainability concerns
  - Costs of HIV treatment and continuing care
  - Drug resistance and need for new treatments (2nd and 3rd line treatments)
  - ARVs as prophylaxis and prevention (HPTN 052 trial: 96% reduced risk of transmission; Partners PrEP study: 62-73% reduced risk)
  - Continued access to donor funding?
  - Continued access to generic ARVs?

Intellectual property rights, patents and access to drugs

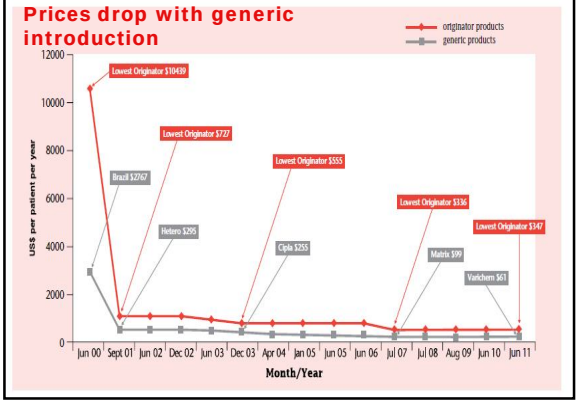
- Global ARV scale up effort – introduction of generic ARVs has been key contributing factor to increased access coverage
- Generic ARVs are the mainstay of many national HIV treatment programmes
- Massive reduction in costs for first-generation, first-line treatments – >99% reduction in prices
- **Generic ARVs from India account for 87% of volume in donor funded ARV purchases**

Trade, TRIPS & access to medicines

- **Patents affect access to medicines because patent monopoly allows patent holders to control production, supply and pricing of medicines**
- **Market competition and generic introduction are key factors in driving, and keeping, drug prices down**
- **All WTO Members required by the TRIPS Agreement to provide patent protection for pharmaceutical products for a minimum 20-year period**
- **What are the implications for pharmaceutical production, prices and access to medicines?**

The competition effect :

Prices drop with generic introduction



Doha Declaration on TRIPS Agreement and Public Health, 2001

- **Debate over impact of patents on medicines and access to ARVs from 1990s**
- **Arose out of developing countries' proposal to examine impact of TRIPS Agreement on access to medicines**
- **Clarification that TRIPS Agreement does not prevent WTO Members from taking measures to protect public health**
  - Interpretative guide to TRIPS Agreement provisions
  - Affirmation of right to use "flexibilities" in TRIPS
  - August 30 Decision – an "expeditious" solution for countries with insufficient or no manufacturing capacities
  - Extension of transition period for least-developed countries to 2016

Types of flexibilities in TRIPS

Time-based provisions

- Transition periods for developing countries and LDCs
- Deadlines: ~~2000~~, ~~2005~~, ~~2006~~, 2013, 2016

Substantive provisions

- 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

TRIPS Flexibilities

Type	Examples
Preventative: Ensure that patents do not hinder access. Easier, faster, less politically sensitive	• **Exclusion from Patentability**: new use of known substances, methods, processes (Articles 27.2 and 27.3) • **Patentability Criteria**: Mitigate frivolous patents and "evergreening" opportunities. (Articles 1 and 27.1). • **Patent Opposition**: Pre-grant and post-grant • **Waiver for LDCs**: until 1 January 2016
Remedial: Preventative flexibilities cannot always be used	• **Compulsory Licences and Government Use Orders** (Article 31 (a) – (j)) • **Compulsory Licences for Export** - WTO 30 August, 2003 Decision. • **Parallel Import** (Article 6) • **Exceptions:** Bolar, research and experiments, individual use (Article 30) • **National Competition Laws** to prevent IPR abuse and provide remedies (Articles 8.2, 31(k) and 40)
Enforcement: Part III TRIPS sets **minimum standards** for IPR enforcement.	• **No border measures** for suspected patent infringement (Article 51) • **No criminalization** of patent infringement (Part III, Section 5)

Using TRIPS flexibilities to improve access to medicines:

- **Compulsory licences (Article 31 of TRIPS)**
  - Permits pharmaceutical company/distributor to import and/or produce of generic versions of patented drugs
  - Permits government/public agency to import and/or produce generic versions of patented drugs, usually through "fast-track" procedures
- **Parallel importation (Article 6)**
  - Allows import of patented medicines that are sold cheaper in another country
- **Bolar or early-working exception (Article 30)**
  - Allows generic company to conduct R&D for production of generic and to make preparations for marketing approval prior to expiry of patent, to enable prompt marketing of generic drug

Price impact of compulsory licences

Source: Global Commission on HIV and the Law (2012), UNDP

Country	Type of License and medicine	Impact on prices
Malaysia (November 2003)	Government-use order for the production of combination of generic stavudine + didonasine + nevirapine	Resulted in price reduction of 83%
Indonesia (October 2004)	Government-use order to locally manufacture generic lamivudine, nevirapine	Resulted in price reduction of 53.3%
Thailand (January 2007)	Government-use order to import or locally produce generic lopinavir/ritonavir	Projected price reductions of 80.2%
Brazil (May 2007)	Compulsory licence issued by Government to import generic efavirenz	71.8% price reduction
Ecuador (April 2010)	Compulsory license to import and, if necessary, locally produce generic ritonavir	Patent holder reduced price of branded medicine by 70%
India (March 2012)	Compulsory license to locally produce sorafenib tosylate to treat kidney cancer and liver cancer	Price set by Patent Controller will result in 97% reduction

GMS joint action

- **Efforts to reduce HIV vulnerabilities of migrant populations require coordinated action by host and home countries**
  - Research and exchange of information on migration patterns, HIV trends, etc. to identify and determine health/HIV needs of migrant populations
  - Joint design, planning, funding and implementation of programmes
- **Host country measures**
  - Assessment of legal and policy environment to determine reforms needed
  - Financial investment and human resource allocation
  - Implementation of programme/measures in host country
- **Home country measures**
  - Resource and technical support to implementation efforts in host country
  - Assessment of reforms needed to ensure continuum of care in home countries

GMS joint action
Case of Thailand as host country

Legal and policy environment for health & HIV services

- Universal health coverage scheme in Thailand
- National HIV treatment programme and universal access to ARVs policy
- Assessment of standard of care for migrant populations vs. citizens – elimination of barriers to access
- Determination of contributions from home countries – financial, human resource and technical

GMS joint action:
Case of Thailand as host country

Key implementation issues for host country:

- Increased capacity needs for service delivery
- Treatment compatibility issues
- Increased costs for implementation and treatment provision
- Use of CL for import/production of generics
- Use of generic medicines imported/produced under CL for migrant populations
  - Can Thailand provide the generic ARVs imported under CL to migrants not covered under the UCS?
  - Are there restrictions to such use?
- Import/export of generics within GMS
  - Can generic ARVs produced in Thailand be exported to other GMS countries?
  - Could there be joint procurement of ARVs by GMS countries?

GMS joint action:
A case study of Thailand

- Use of generic ARVs imported/produced under CL for 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 ..."
- Import/export of generics within GMS
  - What is the patent status of medicine? Determination of patent status in both exporting and importing countries
  - What does the national law state? State of TRIPS implementation in national law

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		✔	✔	✔		

Source: Musungu & Oh (2006) "The use of TRIPS flexibilities by developing countries: Can they promote access to medicines? South Centre and WHO

Recommendations for joint action programme

1. Assessment of national health systems and HIV treatment programmes
   - Inclusive health and HIV services targeted at migrant populations
   - Which policy and legal reforms are required?
2. Evaluation of capacity and resource needs
   - Allocation human resources for service delivery
   - Increased funding for drug procurement, incorporation of migrant HIV needs in funding proposals

Recommendations for joint action programme

3. Coordination on IPR and TRIPS issues
   - Survey of IPR legislation in GMS countries and assessment of status of TRIPS implementation
   - Determine status of key ARVs in use in GMS countries
   - Promote use of 2016 deadlines by LDCs – no patent protection for pharmaceuticals until at least 2016
   - Promote incorporation of all TRIPS flexibilities in national legislation
   - Sub-regional coordination on IPR and TRIPS issues, including use of TRIPS flexibilities
   - Coordination on ARV procurement – option of joint procurement for GMS countries?