EXPANDING ACCESS TO ARV DRUGS

Regional Consultation and Planning Workshop on ‘Use of TRIPS Flexibilities to Access Affordable ARVs in Asia’

29-31 May

Bangkok, Thailand

Introduction/Background

Access to affordable, generic Anti-Retroviral (ARV) medicines has been instrumental in the scale up of treatment and progress towards the three zeros in the Asia- Pacific region. As such, protecting and expanding access to generic ARV medicines is a vital priority for countries in the region.

In this period of rapid economic development in the Asia Pacific, the need to strike the right balance between securing intellectual property protection to foster genuine innovation to protect the public health of the 4.9 million people living with HIV in the region becomes more urgent.

On the 29-31th of May, 81 delegates including 20 international resource persons and 61 representatives from 9 countries in the region met in the Imperial Queen Park Hotel in Bangkok, Thailand. Delegates met to share their experiences, achievements and challenges in their collect objective in securing access to affordable medicines under the World Trade Organisation's Agreement on Trade-Related aspects of Intellectual Property Rights (TRIPS) and other trade-related agreements.

The three-day workshop was structured as follows:

Day 1 focused on the implications of the Doha Declaration on public health interests and the use of various flexibilities under the TRIPS Agreement to ensure access to affordable drugs.

Day 2 focused on the risks and challenges posed by the inclusion of TRIPS+ provisions in on-going free trade negotiations between countries in the region and high-income countries and on experiences in dealing with these risks and challenges.

Day 3 focused on opportunities for countries in the region to strengthen collaboration to ensure access to affordable ARVs across the region. This was followed by presentations of country action plans.

The following is a summary report of the proceedings.

Maximising TRIPS Flexibilities.

The opening remarks by Shiba Phurailatpam (Regional Coordinator, Asia Pacific Network of People Living with HIV) and Steve Kraus (Director, Regional Support Team for Asia and the Pacific, UNAIDS) highlighted the importance of maintaining access to generic medication for national HIV responses and the lives of PLHIV in the region.

Also highlighted, was the fact that mechanisms for increasing access to affordable ARVs can also be used to secure access to other essential medicines, creating the potential for further significant development gains in this area.

Speakers also remarked on the need to strike the right balance between fostering real pharmaceutical innovation through intellectual property protection and ensuring the right for all to access lifesaving medications.

In the opening day of the workshop, international experts briefed participants on the importance of the 1995 TRIPS Agreement and the 2001 Doha declaration on access

to medicines and on the use of public health related TRIPS flexibilities. Country delegations in turn, shared their experiences in utilising various TRIPS flexibilities such as compulsory licenses and stricter patentability criteria to improve access to generic drugs.

Over the past decade, the annual cost of a first line antiretroviral regimen for low-income countries has dropped significantly. Treatment costing more than US$10,000 per person in 2000 is now below US$100 per person per year in a number of low-income countries in the region by 2010.

During this period, the number of people on treatment in Asia-Pacific has more than tripled to reach nearly one million by the end of 2010. Yet currently more than 60 per cent of those in need of treatment in the region have no access.

Such scale ups in ARV coverage both in the past and into the future would only be possible due to the existence of competition among suppliers of generic drugs, principally from India where the drugs were not patented as the country used transitional period flexibilities allowed under TRIPS and maintained a strong public health friendly patent law after 2006.

The TRIPS Agreement is one of three primary agreements of the WTO since its establishment in 1995, imposing minimum standards of intellectual property protection while allowing countries to make use of certain flexibilities, including some relating to public health.

As per the Agreement, all WTO Members must provide patent protection for medicines unless they adopt and make use of those flexibilities to secure access to affordable drugs. An exemption period is given to least developed countries.

The Doha Declaration adopted in 2001, forms an authoritative interpretive guide for the use of TRIPS flexibilities, clarifying that the TRIPS Agreement does not prevent WTO Members from taking measures to protect public health. There is a variety of ways in which TRIPS flexibilities can be utilised:

PREVENTATIVE MEASURES:

‘Ever-greening’ is the practice whereby a drug’s patent duration is extended by the reapplication of patents for essentially the same drug with slightly modified formulations, presentations or compositions. This was identified as a major issue in most participant countries. In Thailand, more than 96% of patent applications have one or more characteristics of ever-greening patents.

Countries such as India, China and the Philippines have laws in place that limit the pool of patentable drug formulations. In China, provisions prevent the granting of patents that may ‘harm the public interest’, while India and the Philippines have strict patentability criteria that mitigate frivolous patents and ‘ever-greening’. Specifically, these laws clearly outline the definition and set rigorous standards for ‘the Inventive Step’.

These preventative measures can reduce the number of successful patent applications by allowing only truly innovative drugs to receive patent protection rights.

Having transparent patent application and pre-grant opposition process whereby the public may contest the granting of patents are also preventative measures, which ensure that public health needs are met through community engagement.

These preventatives mechanisms are an effective and often less politically sensitive first-line defence to limit the granting of patents on medicines.

REMEDIAL:

States can also enact remedial measures to reduce the impact of pharmaceutical patents on public health interests once granted. Chief among such flexibilities discussed, were the granting of compulsory licenses and government use orders, as well as the use of parallel importing and national completion laws. In particular, the compulsory licence (CL) or non-voluntary licences as referred in the TRIPS Agreement was discussed in depth.

With the exception of least developed countries Cambodia and Myanmar to whom the 2016 exemption period for pharmaceutical products still applies, all countries in the region have in place legislative frameworks that allow them to issue compulsory licenses on drugs in at least one on the following conditions: government use, public health interest or emergencies.

However, each country faces its own challenges to realise full and effective utilisation of this vital flexibility:

- *In some countries such as Thailand, intellectual property laws are not explicitly supporting the implementation of TRIPS flexibilities, while others such as India are having their compulsory licencing laws challenged.*
- *Other challenges are procedural and organisational, as some country lack of capacity and experience with CLs within departments and patent offices as China Malaysia and Vietnam have cited or a lack of inter-departmental coordination mechanisms to oversee the process of issuing CLs.*

All states can ensure they use CLs to full effect by:

Social mobilization and the Role of Civil Society.

As civil society, activists and People Living with HIV cannot be out of the responses to these challenges, governments and the UN must actively seek their support, consultation and guidance.

It was noted when academia, government and civil society maintain a cooperative yet independent relationship with each other, significant progress in reaching positive outcomes for access can be reached with countries like Thailand and India as model examples.

In both countries, civil society were instrumental in mobilising public support and input for the issuing of compulsory licences. Their presence and voice during FTA negotiations also give impetus for Thai and Indian negotiators to reach more access-friendly positions in bargaining with high income countries.

- *Strengthening legal frameworks, ensuring national legislation explicitly supports and provides for TRIPS flexibilities,*
- *Cooperating with Patent Offices of other countries to obtain up-to-date and accurate relevant patent information,*
- *Ensure a multi-sectorial response between government agencies with different mandates; e.g., public health, trade and commerce, foreign affairs.*

A point raised by international experts as well as various country delegates, was the need of having clear, easy-to-apply and transparent guidelines for negotiating with patent holders. Also, having clear remuneration or royalty rates for CLs will incentivise the granting of voluntary license by patent holders.

Results of Regional Mapping Exercise.

ART Coverage:
Results from the regional mapping survey conducted in the run-up to the workshop showed a general increase in ART coverage. However, some countries have not updated their estimates of the number of people in need of treatment or are not using a WHO/UNAIDS accepted methodology. This may lead to misrepresentation of actual ART coverage.

WHO Guidelines:
Myanmar, Thailand and Vietnam have fully adopted the 2010 WHO ART guidelines on treatment of adults and adolescent and infants and children. China also adopted the guidelines pending Ministry of Health endorsement. In Cambodia and Malaysia, various constraints have led to partial adoption while in the Philippines guidelines are being applied while not yet being officially endorsed. Neither new guidelines nor changes in treatment programmes have taken place yet in India.

ART Funding and Expenditure:
While Indonesia, Malaysia , the Philippines and Thailand fund the majority of their ART programmes from domestic sources, Vietnam, Myanmar and Cambodia remain heavily dependent on international (bilateral or Global Fund) funding. India is planning a rapid increase

ARV Sources:
India (exporter), Thailand and China have achieved majority domestic production with some imported patented ARVs, mostly for 2nd line drugs. Malaysia and Vietnam have some domestic production capacity while Cambodia, Myanmar and the Philippines have no domestic production and import both generic and patented ARVs.

ARV patent Status:
In general, patents on the most recommended first-line ARVs either have expired or are about to in most countries. However, patent applications on newer generation first-line ARVs, in particularly, TDF and related formulations, have already been filed or granted in China, India, Philippines and Thailand. Although there were no patents on TDF in Vietnam prior to 2011, it was subsequently included in the Voluntary Licensing Agreement between Gilead Sciences and the Medicine Patent Pool as one of the few countries in the region where generic TDF can be supplies. No TDF-related application was found in Malaysia.

Legal environment:
Cambodia, China, India, Indonesia, Malaysia, the Philippines, Thailand and Vietnam have either created or amended their IPR to be in line with the WTO TRIPS Agreement. With the exception of Cambodia, national patent laws in the other seven countries also create legal space for the use of TRIPS flexibilities. Cambodia's IPR Law specifies that no patents will be granted on pharmaceutical products before 2016. Myanmar is currently in the process of developing its IPR Law, including laws on patents.

The Challenges of TRIPS+ Provisions.

On the second day, delegates discussed the current state of free trade negotiations in the region and their potential effects on access to affordable drugs.

International experts identified and explained specific TRIPS+ provisions that states are being pressured to agree to as part of on-going FTA negotiations. The following session had country delegates sharing experiences in dealing with such provisions.

TRADE AGREEMENTS AND TRIPS+ PROVISONS

While the region have acknowledged the need to utilise TRIPS flexibilities in the ASEAN 2011 Declaration of Commitment to Get to Zero, some countries negotiating bilateral or multilateral free trade agreements (FTAs) with high income countries are being asked to increase intellectual property protections beyond the agreed standards under the TRIPS Agreement. These provisions are known as 'TRIPS+ provisions'.

Dr. Jiraporn Limpananont of University of Chulalongkorn conducted a study on the economic and public health impacts of potential TRIPS+ provisions in Thailand. The study found that should TRIPS+ provisions be enacted, Thailand would experience significant increases of average drug prices leading to a large increase in domestic drug expenditure; moreover, there would be a significant decrease in the market share of locally produced ARVS, leading to a decrease in ARV affordability and accessibility. While other countries in the region should conduct their own impact assessment, there is no reason to believe that TRIPS+ measures would affect other countries differently.

While countries in the region are in different stages of negotiations for FTAs with different parties, similar TRIPS+ provisions are being advocated by the USA, the EU and Japan (the main proponents of such agreements). TRIPS+ Provisions comes in many forms, they may:

- *Increase the number of patents that must be granted across the region by **Patent Cooperation Treaties** or **region wide patents**,*
- *Increase the ease of new patents being granted and ever-greening old ones by **lowering patentability criteria (standards)** or allowing '**new uses'** for old patents,*
- *Limit the ways civil society or the general public may challenge the patenting process by **prohibition of pre-grant patent opposition,***
- *Extend patent rights beyond the 20 year period agreed under the TRIPS Agreement **('Patent Term Extensions')**,*
- *Keep clinical trial data held in exclusive rights of the patent holder, thereby delaying the production of generics and/or requiring unethical repeated drug trials **('Data Exclusivity')***
- *Link medicine registration in drug and food authorities on the drug's patent status in patent offices, thereby blocking or delaying marketability of generics. **('Patent Linkage')**.*

The following experiences with TRIPS+ provision negotiations were shared by delegates from India, Malaysia, Thailand and Vietnam:

- *The United States advocates for data exclusivity and diluted patentability criteria through the Trans-Pacific Partnership Agreement.*
- *The European Union, though not traditionally an advocate of TRIPS+ measures, have in recent years advocated for stronger enforcement measures, including criminalization of patent infringement.*
- *Japan has been known to advocate for having TRIPS+ patent office procedures to increase the ease of patentability.*

TRIPS+ Enforcement

While Article 41 of the TRIPS agreement set out that enforcing procedures must be applied to avoid the creation of illegitimate barriers to trade, some TRIPS+ provisions being negotiated would put in place more restrictive measures in the ways IP is being enforced.

Unilateral measures - Some high-income countries such as the United States have established watch-lists for countries which they determine as non-compliant with IP protection provisions. These countries are threatened with trade sanctions or withdrawal of trade preferences. This year, the Philippines and Vietnam have been placed on the watch list, while China, India, Indonesia and Thailand were already on the 'priority' list. Malaysia has been removed after complying with certain conditions.

Conflation of generic and counterfeit medicines (trademark) - Substandard and/or counterfeit medicines pose a real threat to patients. They not only decrease treatment effectiveness or even damage patient's health, but also threaten access to generic drugs as these are often confused and conflated with counterfeits trademark goods.

By the TRIPS Agreement definition, "counterfeit trademark goods (drugs)" are goods (drugs), including packaging, which are bearing, without authorization, a trademark which is identical to the trademark validly already registered". While counterfeit trademark and copyright violations are rather easily established through visual inspection by customs and IP enforcement officials on the ground, determining whether goods infringe a product/process patent is far more difficult and requires significant technical and legal expertise and testing that are beyond practicality for most customs and IP enforcement agencies.

Seizure of goods in transit - Article 51 of TRIPS requires Members to control imported goods protected by trademarks and copyrights. In 2008, the European Commission argued that Article 51 can be extended to include goods in transit and adopted policies that authorize seizure of generic medicines in transit. This resulted in 17 incidents of detention of medicines at various EU ports in France, UK, Holland and Germany including AZT and Abacavir from India destined to Africa and South America.

Instead, countries should develop adequate measures showing zero tolerance for all substandard medicines, regardless of whether they are brand or generic.

Enabling South-South Collaboration

The morning of the third day focused on ways and opportunities in which countries can collaborate on securing access to generic drugs.

The World Health Assembly's Consultative Expert Working Group (CEWG) reported in April 2012 that the 10/90 gap well and truly exists. The current modality of intellectual property rights and sales do not provide enough incentive for innovators in high-income countries to invest in research in diseases that affect people in developing countries. If the ARV needs of countries in the region are to be met, there is a need to uncouple the cost of research from the price of the product and to develop mechanisms in addition to intellectual property rights to effectively incentivize research investment.

As most states present at the meeting were ASEAN member states, the ASEAN Strategic Framework on Health Development was identified as a regional mechanism to facilitate coordination and dialogue on this issue at the senior political and policy level.

The following areas where identified as key opportunities for collaboration:

Regulatory Cooperation

Having a common, region-wide regulatory environment that encourages generic competition would incentivise global generic companies to start producing locally in each country. To do so, countries in the region must:

- *Fully realize TRIPS flexibilities in national legislation with common definitions and patentability standards.*
- *Have a harmonized negotiating position at WTO TRIPS Council e.g. for least developed countries extension.*
- *Share global best practice in using flexibilities, e.g. Competition policy in South Africa, India's Section 3(d) or Argentina's patentability criteria.*

Research Gap

It was highlighted that the Global Research and Development Treaty was one of the potential avenues of collaboration on innovation to reduce the region's dependence on traditional sources of technological innovation.

- *It was recommended that all countries should allocate specified levels of public funding (at least 0.01% of GDP) on health R&D relevant to the needs of developing countries including the promotion of domestic capacity.*
- *In this framework, the WHO was recommended to play a stronger central role in improving coordination for R&D directed at health needs of developing countries.*
- *The promotion of technology transfers in developing economies by other economies in the region was also a key recommendation in the report findings.*

Production and Legal Capacity Gap.

For countries with low domestic production capacity or with new legislative and regulatory frameworks on intellectual property, south-south collaboration and assistance was identified as priorities.

Specific types of assistance identified were the build-up local capacity to produce generic medicines and manage patent laws in step with TRIPS flexibilities as well as diversifying from traditional forms/sources of assistance by high-income countries.

The following were highlighted as priority areas for capacity building especially least developed countries Cambodia and Myanmar: Human resource capacity building, in legal knowledge and patent assessment; technical assistance in drug regulatory policy and procedures and basic infrastructure and technology transfers.

As the key producer and supplier of generic medication to the region, India's role in reducing the regional capacity gap cannot be overstated. Generic companies from India are already beginning to expand offshore with manufacturing facilities overseas, providing for vital technology transfers. China, holding 80% of global market share on producing Active Pharmaceutical Ingredients (APIs) for ARVs, is a vital player in the region as well.

A key underlying message throughout the day was the need for strong cooperation between these two countries. The BRICS health cooperation framework was identified as a possible mechanism through which this can be achieved.

Furthermore it was identified current local producers, China, India and Thailand need to be a more positive force to bring about technology transfers and capacity building the rest of the region. While India and China both have partnerships in overseas capacity building, technology transfers or technical assistance, much of it is centred on Africa and South America and not it the Asia Pacific. On the other side, it was noted that other countries should at the same time proactively seek out possible regional partnerships and produce enabling environments to encourage investments from generic companies to set up locally.

Country Action Plans

The final session of the workshop involved country delegations taking stock of their newly acquired understanding of TRIPS related issues and with assistance from international experts and resource persons, draft a tentative country action plan including support request/needs. The following is a brief summary of key actions proposed from each country:

Cambodia

Cambodia plans to establish a country coordination-working group that will seek to revise patent laws to dismantle various TRIPS+ measures already in place, including criminalization of patent infringement and weak patentability criteria. Cambodia will also seek to pass a law on compulsory licenses. The training of patent examiners on health related intellectual property is also being planned.

Cambodia identified a need for assistance with legal expertise, support for training of patent examiners, developing civil society capacity and to explore technology transfer opportunities.

China

China plans to strengthen quality control and management of current generic ARVs to meet WHO prequalification standards in preparation for export. This has significant potential in changing the availability of generic ARVs in the future. China also plans to start political advocacy measures, using the BRIC Health Cooperation Framework as an entry point for political advocacy. China is also planning study tours to improve the understanding of various government sectors. In parallel, China also plans to revisit its patent laws to ensure it can fully utilize CLs and other TRIPS flexibilities, using the Doha delectation as the key interpretive guide.

China requires technical support in training of officials and hosts for the study tours. They will also look towards the WHO on the requirements on prequalification standards.

India

As the main global producer of generics, Indian has seen significant pressure from high-income countries to dilute Section 3d of its Patent Act as well as its compulsory licencing provisions. As such, it plans to strengthen capacities of stakeholders including patent officers, examiners, civil society, media etc. It also plans to raise awareness through workshops for judiciary and parliamentarians on the issue and to sensitize them on the continual need to protect access. Furthermore, India plans to increase its capacity building efforts in the region and is calling for expressions of interest by regional states that require assistance for building local production capacity.

From the UN family, India is requesting information about global best practices and facilitation of dialogue at international/multi-country fora.

Malaysia

Current pre-grant opposition provisions place an administrative burden on the IP office with limited technical capacity. Malaysia is exploring possible amendments to its Patent Act to enable an avenue for interested parties to formally submit information to the IP office on patent application. Malaysia is also exploring the possibilities of pursuing generic export opportunities in the future. Malaysia has also identified the need for region wide reference pricing of imported drugs for common reference and would support an inter-governmental mechanism for sharing such information.

Myanmar

Establishing/strengthening a multisectoral core working group with participation from government, UN, parliamentarians, the private sector and civil society will be top of Myanmar's priorities. The working group will facilitate inputs on Myanmar's draft IP law to ensure that policy space for utilisation of flexibilities is protected. Myanmar will also actively seek regional cooperation and collaboration in technology transfer and local production, including through the ASEAN framework.

While needs that are more specific will be identified by the core-working group, capacity building, technical and financial assistance were identified as potential areas that support was needed.

The Philippines

Currently there are wide varieties of challenges that hinder implementation of CLs to the fullest in the Cheaper Medicines Act.

The Philippines plans to start with gathering experiences on using TRIPS flexibilities to maximum effect. Currently, The Philippines have no TRIPS+ provisions, but will carefully monitor the implementation of the existing Partnership & Cooperation Agreement with the EU for any impacts on access to medicines.

Thailand

Protecting the Thai Patent Act against any dilution of its TRIPS flexibilities is a priority for Thailand. It also is looking to amend its IP law to further support the use of TRIPS Flexibilities. Thailand is also planning to streamline patent information by developing a pharmaceutical database and a manual for registration.

The Thailand delegation has identified the need for all levels of government and civil society to be sensitized and unified under a single country strategy and requests UN support for this. Thailand also requests the UN or WHO to advocate to high income countries not to push for TRIPS-Plus provisions during free trade agreement negotiations.

Viet Nam

Training of patents examiners, industry awareness raising and social mobilization, stake holder consultation as well as inter-ministerial coordination are key priorities for Viet Nam in protecting and enhancing their TRIPs Flexibilities.

As such Vietnam requests assistance in technical expertise to organize workshops training and facilitate south-south dialogue.

Key Themes and Messages

Legislative strengthening at the country level.

In order to maximize the utilities of flexibilities under TRIPS, countries must take measures to ensure these TRIPS-Flexibilities are enshrined in national legislation.

Specifically provisions for high patentability criteria, compulsory licenses should explicitly be stated in national laws.

Least developed countries, should take full advantage of the exemption period and ensure inclusion of ‘sunrise clauses’ in their patent laws so that provisions take effect only after the exemption period expires, with room for possible extensions.

At the same time, countries in the region should look to revising legislative and procedural elements containing TRIPS+ provisions that may harm access. For example, provisions such as criminalization of patent infringements can prove to be a significant deterrent for generic companies to invest in local markets, while in least developed countries, implementing a mailbox system where patent applications are accepted and filed before the 2016 exemption period expires can mean large amounts of patents to be in force retroactively.

Stronger and more coordinated national response, with PLHIV and MARPS civil society voices.

Navigating the implications of TRIPS to ensure optimum access to medicines is a complex and intricate process that requires input and participation from various parts of government, academia, business and civil society.

It is crucial for all countries in the region to establish a multisectoral task-force to work on the issue. Such task force should include relevant ministries and government departments and ministries. (National AIDS Authorities, Health, Commerce, Foreign Affairs, Patent Office, etc.)

Learning from the successes from India and Thailand, civil society organisations must take on a proactive leadership role in shaping the public agenda and debate around the issue, locally and regionally. Furthermore, governments must include the voice of civil society in national and regional dialogues on issues that affect to the medicines that they themselves receive.

PLHIV networks and their partners must continue joint action to advocate for continued access on all levels.

The need for stronger south-south collaboration at the regional level.

Countries in the region need to strengthen regional collaboration and partnerships to meet current and future challenges to low cost access and to the make full use of TRIP-flexibilities.

Cooperation in regional diplomacy leading to a common negotiating position around intellectual property and trade negotiations with high income countries is a vital step. States need to make sure ASEAN mechanisms for dialogue and coordination are being utilized effectively.

Having a common, region-wide regulatory environment that encourages generic competition would reduce barriers of entry for global generic companies to increase exports or start producing locally.

Providing technical legal assistance, human resource capacity building, basic infrastructure and technology transfers are all areas that countries in the region can cooperate on.

Participants called upon the United Nations family to play an active role in facilitating coordinated action at the global, regional and country level. This can involve various activities such as the establishment of inclusive country coordinating platforms, support to the review, strengthening and alignment of legal frameworks, developing common procurement policies and research agendas, and stimulating economic partnerships for improving local production capacity.