



# **Intellectual Property and Public Health Cambodian Perspective**

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## ***Basic Principles of Cambodia's policy on IPRs and Public Health***

- Constitution of the Kingdom of Cambodia endorsed the advocacy of public health and access to medicines for people of all echelons.

*Article 72 “The health of the people shall be guaranteed. The State shall give full consideration to disease prevention and medical treatment. Poor citizen shall receive free medical consultation in public hospitals, infirmaries and maternities”*

## *Basic Principles (cont'd)*

### **Government's policy on public health:**

*“Promote better public health system to ensure safety, efficacy, and quality services to the people and uphold the Human Rights principle through the increased access of essential medicines to the public”.*

## *Basic Principles (Cont'd)*

### **Doha Declaration on TRIPS and Public Health (paragraph 5)**

*“Member has right to grant compulsory license and freedom to determine grounds upon which such licenses are granted”*

*“Member has right to determine what constitutes a national emergency or other circumstances of extreme urgency...”*

*“Effect of TRIPS to the exhaustion of IPRs is to leave member free to establish its own regime for such exhaustion...”*

## *Basic Principles (Cont'd)*

### **Government's policy on IPRs:**

- *As a member of WTO, the Government of Cambodia has clearly defined its position to strengthen the protection of IPRs and promote the use of IPRs as a tool for wealth creation and development of national economy.*
- *Cambodia's commitment during its accession to WTO – TRIPs Compliance*
  - Development of IP Legislations
  - Modernization of IP System
  - Strengthening of IP Enforcement
  - Enhancing the promotion and dissemination of IP knowledge including IP education and awareness.

## ***Enacting Legislations to protect IPRs (cont'd)***

### **Law on Patent, Utility Model Certificates, and Industrial Designs**

- Promote technological development
- Create trust and promote sound investment climate thus attract FDI into the country.
- Promote transfer of technology and know how.
- Encourage innovation through research and development activities.
- important factor to enhance industrial development.

## ***Enacting Legislations to protect IPRs (Cont'd)***

- **Importance of Law on Marks, Trade Names, and Acts of Unfair Competition**
  - Ensure fair competition and secure safe and prospective trading environment in the country.
  - Promote concept of national brand and ensure quality of products and services attached to particular brand name.
  - Registered commercial name helps to prolong exclusive rights of right holder on special product like medicines after the expiration of patent.



## ***Balancing between TRIPS Obligations and Public Health Policy***

- We must respect our commitment to TRIPS but we should recognize the public health problem in our country, especially the necessity to access to essential medicines.
- Look at possibilities to implement some flexibilities provided by TRIPS and reconfirmed by Doha Declaration.
- Establish remuneration system to ensure fair encouragement to patent holder.
- Create coherent approach taking into account issues on the access to medicines, competition, technology transfer, and ability of local production

## *Public health situation in Cambodia*

- Total population: 14 million
- Life expectancy at birth 63 years
- 27% of the population lives below the poverty line
- Infant Mortality Rate in 2010
  - Age 0-1 year (per 1000 live births= 45 People)
  - Age 1-5 year (per 1000 live births= 9 People)
- Limited resources for health and reproductive health services
- Low skill of health care staffs
- 63,000: Estimated number of people living with HIV/AIDS in 2009
- Others pandemics: malaria, tuberculosis....
- Few pharmaceutical enterprises, produce only generic medicines rather than patented ones
- No issuance of compulsory license for pharmaceutical products in Cambodia so far.

## **Using TRIPS flexibilities and Doha Declaration to obtain further benefits for Public Health**

All patented pharmaceutical products and products produced through pharmaceutical patented process are required when dealing with public health problem. Then what to do?

- Possible legal mechanism:
  - **Using Art. 30 of TRIPS – Exceptions to Rights Conferred:** *Member may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third party.* **With Authoritative interpretation:** the issue of public health stands clear out of the normal exploitation of patent and doesn't prejudice the interest of patent owner – it is a common interest with the nature of utmost urgency which require holistic solution, thus exceptions to exclusive rights conferred by a patent could be applied.

## ***Using TRIPS flexibilities (Cont'd)***

- Interpretation of Art. 31(f) – “Other use without the authorization of the Right Holder” – *Where the law of member allows for such use, in Art. 31(f) the use shall be authorized predominantly for the supply of domestic market of the member authorizing such use.* In this case the interpretation could be enlarged to amend the meaning of this provision to allow the scope of supply beyond domestic market of the authorized member to allow the export to the country in needs by taking into account of the public health interests.

## **Using TRIPS Flexibilities (Cont'd)**

- *Cambodia is a country among LDCs who are eligible for grace period until 2016 for the protection of patent on medicines.*
- *Eligible to be a supplying or importing country in case of using compulsory license.*
- *What we have to do is to ensure clarity and transparency in the implementation of these flexibilities through the involvement of right holder.*
  - Allow the monitoring and reviewing of the efficiency of the system
  - Help identify and inform potential suppliers
  - Increase competition among potential suppliers.

## ***Using TRIPS Flexibilities (Cont'd)***

- Introducing safeguard mechanism against product diversion.
  - All products have to be used domestically or exported to the beneficiary members.
  - Ensuring no re-exportation.
  - Requiring to use special labeling, packaging, coloring, shaping for those medicines produced under compulsory license.

## *Challenges of Cambodia on the application of TRIPS flexibilities*

- To amend the law on the Patents, Utility Model Certificates and Industrial Designs of Cambodia to get broader flexibilities concerning ability to acquire more sources of medicines through importation.
- Lack of capacity to avail of TRIPS flexibility (e.g., lack of drug manufacturing capacity to use compulsory licensing)
- Pressure by developed countries to enact TRIPS-plus legislation

## *The challenge of Cambodia to implement TRIPS Plus*

The main “TRIPS Plus” obligations that have been imposed upon Cambodia include:

- A fixed duration of five years for the protection of data exclusivity for pharmaceutical products;
- The approval of the original applicant must be obtained, suggesting that a data exclusivity obligation has been recognized; and
- The Minister of Health must police patents.



## *Solution*

Article 136 of the *Law on Patents, Utility Model Certificates and Industrial Designs* provides:

“The pharmaceutical products mentioned in the Article 4 of this Law shall be excluded from patent protection until January 1, 2016 according to the Declaration on TRIPS and Public Health of the Ministerial Conference of World Trade Organization dated November 14, 2001 in Doha”.

## *Solution*

### **Article 4. Deferral of Enforcement**

- Parts One through Three of the draft Law on Undisclosed Information and Trade Secrets shall be excluded from enforcement until July 1, 2013, in accordance with the *Extension of Transitional Period under Article 66.1 for LDC Members*, Decision of the Council for TRIPS of 29 November, 2005, unless:
  - (a)- the Kingdom of Cambodia is no longer listed as a “Least-Developed Country” by the World Trade Organization; or
  - (b)- the National Assembly declares the Law or any part thereof to be enforceable.

## **Conclusion**

- The Cambodian pharmaceutical industry remains at the nascent stage, the supply of medicines is largely relied on import.
- Based on the benefits of Doha spirit, we have included in our Law on Patent, Utility Model Certificates, and Industrial Designs, the provision which allows us to exempt the protection of Patent for pharmaceutical product until 1 January 2016.
- As an LDC, Cambodia could also take advantages of TRIPS flexibilities to implement Compulsory Licensing for the sake of Public Health which allow us to issue this possibility for the import of generic medicines from export countries where the production is made under Compulsory Licensing conditions.
- This benefits will help us to strengthen capacity of our local pharmaceutical production and become an attractive place for developing countries where the obligations for protecting patent has to be implemented after the exhaustion of grace period.

**Thank You**