# Access to Medicine for All: Civil Society's Strategies

## Introduction

Medicine is one of the key components in national public health service system. It is the public goods, which incorporating largely rapid, innovative technological development. Unlike other goods in market, patients and consumers cannot decide which medicine to prescribe for themselves, besides ones cannot tell its efficacy and quality from the appearance. In addition an exclusive essence endowed by patent system, create longer period of monopoly market. As the result, the price is too high and unaffordable for people in developing and least developed countries. In addition, drug industry is a huge, international business with monopoly power in global market. In Thailand, drug spending accounts for one-third of national health care expenditures, costing an estimated 100 billion Baths a year.

Access to health care is a constitutional right of the Thai people, as stated in Chapter 3 Part 9 Section 51 of the Constitution of the Kingdom of Thailand B.E. 2550 (equivalent with Section 52 of the Constitution of the Kingdom of Thailand B.E. 2540).

"A person shall enjoy an equal right to receive standard public health service, and the indigent shall have the right to receive free medical treatment from public health centres of the State.

The public health service by the State shall be provided thoroughly and efficiently.

The State shall prevent and eradicate harmful contagious diseases for the public without charge in a timely manner".

In Thailand, the first "National Drug Policy B.E. 2524" was introduced as part of National Development Plan of Economy and Society Issue 5 (1982-1986) on public health. It contained 5 key components as follows: 1) distribution of essential drugs; 2) promotion of rational use of drugs; 3) quality assurance of all drugs; 4) promotion of the use of local raw materials for drug manufacturing; and 5) utilization of herbal medicine and traditional medicine. To implement the policy, Minister of Public Health, Dr. Sem Pringpuangkeo published, on October 1st, B.E. 2524, National List of Essential Drugs(NLED) 1981, included a List of Hospital Formulary, and issued the Regulation on drug procurement under the Ministry of Public Health's budget B.E. 2524, where the National List of Essential Drugs was adopted as criteria for the selection of drugs to be used in public health facilities. The main objective was to ensure availability of essential medicine for all Thais - even the poor who live in remote areas - at affordable price.

Following some amendments to the policy, "National Drug Policy B.E. 2536" was announced with two additional components: 1) encouragement and supporting the National Essential Drug List in both government and private sectors; and 2) improvement of efficiency in drug administration and legislative procedures, rules and regulations in favor of consumer protection. The amended policy put particular emphasis on establishing relevant provisions, strategic and operational mechanisms as well as responsible authorities, all to achieve concrete outcomes. This led to some modifications to the

National List of Essential Drugs B.E. 2542 to cover necessary drugs for treatment and prevention - drugs that were indispensable in addressing health care needs of the Thai people. Additionally, a National List of Herbal Medicinal Products B.E. 2542 was first created with respect to the amended policy. The two lists thus laid down drug criteria - on a sustainable and equitable basis - for health benefits provided under the National Health Security Scheme (Universal Coverage,UC), the Social Security Scheme (SSS) and the Civil Servant Medical Benefit Scheme (CSMBS).

In 2002, National Health Security Act B.E. 2545 was promulgated, in light of the Constitution of the Kingdom of Thailand B.E. 2540, and came into force since November 19th, 2002. According to the Act, the government implemented universal coverage policy to provide health care coverage for all Thais. However, given the universal coverage scheme and other interventions like the National Access to Antiretroviral Program for People Living with HIV/AIDS, a large number of people and patients still lack access to medicine. This is due to the fact that many medicines are prohibitively expensive for most people. Moreover, with such excessively high prices, the government cannot allocate enough health budget. The heart of the problem is these medicines are patented, despite the fact that access to medicine is a fundamental human right and that medicine is one of the four basic necessities of life.

With collective strength of the civil society, particularly the network of people living with HIV/AIDS, advocacy groups, social pharmacy network, academics, and orther network, combined with systematic approach to preparation the issue, and collaboration with the National Health Security Office, and the Food and Drug Administration, the Ministry of Public Health, Dr. Mongkol Na Songkhla, under the new government that took office in late 2006,

announced to issue "compulsory licensing for government use" of three patented drugs for the first time. They are an antiretroviral drug 'efavirenz' on November 29th, 2006, a second-line anti-retroviral drug 'lopinavir/ritonavir' on January 25th, 2007, and a heart disease drug 'clopidogrel' on January 25th, 2007. This radical move was in compliance with Section 51 of the Thai Patent Act B.E. 2522 as amended by the Patent Act B.E. 2535 and the Patent Act B.E. 2542. The decision was also consistent with the WTO TRIPS Agreement and the Doha

Declaration on TRIPS and Public Health, which reaffirmed the right of each member country to grant compulsory licenses to protect public health and enhance access to medicine for all, in case of emergency, urgent need and public non-commercial use, and for the public interest..

The patent system for pharmaceuticals abuses the spirit of patent law aimed at providing incentives for innovation benefit to people, in order to investment in research and development. It thus creates monopoly, causing extortionate prices that make drugs unaffordable for many. The costs per unit of most patented drugs are over 10 times higher than daily cost of living, posing the grave problem of inaccessibility of drugs for most people in the country. Now Thailand has more developed health care system than other countries in the region, and every Thai citizen is under one of the national public health insurance schemes: National Health Security Scheme, Social Security Scheme and Civil Servant Medical Benefit Scheme. Unfortunately, however, such excessively high prices have put limitations on the national public health insurance schemes: the benefits package cannot cover every disease, particularly those expensive ones that impose high-cost treatment and



medicine.

Moreover, the patent granting process, operated by Department of Intellectual Property (DIP),Ministry of Commerce, is rather cumbersome and complicated, further aggravated by the lack of competent patent profession and workforce as well as the in-efficient patent database. These have led to many frivolous patents and ever-greening patents. As a result, the World Health Organization (WHO) developed guidelines for the examination of pharmaceutical patents to provide patentability criteria for pharmaceutical inventions. However, these guidelines have not been adopted or applied rigorously enough.

Patents create market-based incentives for the drug industry to invest in pharmaceutical research and development (R&D). But such market driven R&D do not address public health needs: there is no R&D for particular diseases, especially those prevalent in developing and least developed countries. Recognizing the issue as top priority, the World Health Organization mandated the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) to look into the issue and publish a report on it. This report was presented at the World Health Assembly, who later passed a resolution establishing the

Inter-Governmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) to prepare "Draft Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property". The IGWG met for the first time in Geneva between 4th-8th December, 2006. The second IGWG meeting is scheduled on 5th-10th December, 2007 in Geneva, Switzerland.

The problem of inaccessibility to pharmaceuticals is paramount so the civil society led by Health Consumer Protection Programme (HCP), Chulalongkorn University, Pharmacy Network for Health Promotion Programme (PNHP) - Chulalongkorn University, Social Pharmacy Research Unit (SPR) - Chulalongkorn University, Faculty of Pharmaceutical Sciences - Chulalongkorn University, Health and Development Foundation (H&DF), AIDS Access Foundation, Foundation for Consumers, Drug Study Group (DSG) and Thai Network of People Living with HIV/AIDS (TNP+) had organized the forum, on October 1st, 2007, to draw up the Strategies for Access to Medicine. Altogether 40 participants, being government authorities, domestic drug manufacturers, and non-governmental organizations on consumer protection, gathered at the preparatory meeting to work out this civil society version of strategic plan for access to medicine for all.



## Strategies for Access to Medicine

## Objectives:

1. Medicine is the ethical and moral goods. It is necessary to have essential medicine available for public use on an equitable basis and in a timely manner. Additionally, the country should be self-reliant in medicine at certain levels, in case of war or emergency and in the public interest.

2. People maintain good health and can be self-reliant in health care, with particular emphasis on health promotion and utilization of health related local know-how, Thai traditional medicine, local medicine and other alternative medicine.

## Policy:

Health comes before trade interest

## The 7 Strategies:

### 1. Development of networking for access to health care

Develop the networking of health workers, academics and patient groups to create systems and mechanisms for

1.1. Rational use of drug

1.2. Effective drug system management

1.3. Pushes for policies and improvements to legislation that affects access to medicine such as Patent Act, Drug Act etc.

**2. Coalition of patients of the same diseases**

The government shall promote coalition of patients of the same diseases, particularly those costly diseases that become national public health problems. With such collective strengths, these patients can have bargaining power, like the Thai Network of People Living with HIV/AIDS (TNP+) or Network of Cancer patients, in making suggestions regarding access to health care to relevant authorities. Furthermore, the coalition can promote support and care, both physically and emotionally, as well as strengthen relationships among patients of the same diseases.

**3. Bringing medicine prices down to match the cost of living of the people in the country**

3.1. Promotes efficacious enforcement of drug price control law, particularly on patented drugs and drugs with monopoly power

3.2. Encourages the use of TRIPS flexibilities incorporated in the Thai Patent Act to effectively address the problem of access to medicine. These flexibilities include compulsory licensing (CL) for government use, as provided under the TRIPS agreement, to import, produce, and export drugs to countries without manufacturing capacity

**4. Capacity building of domestic drug manufactures**

To become self-reliant in medicine in case of war or emergencies by

4.1. Enhancing the availability of essential drugs to solve health problems and production of import substitute drugs which are not domestically manufactured as yet, as well as providing support for research and development of the essential drugs. The government should formulate clear policy to encourage production of medicine for public consumption at reasonable prices. In the event that problems associated with drug patent

arise, the government should provide support mechanisms such as coordinating license agreements, in which reasonable royalty rates are established, and implementing incentive schemes like tax incentives and the market mechanism

4.2. Promoting the use of Bolar Provision that allows generic manufacturers to use technology of patented drugs to conduct research and development to accelerate registration of generic versions before the patent protection expires. This provision enables generic manufacturers to market their products as soon as the patent expires.

4.3. Encouraging establishment of clinical research centers, for instance, Bioequivalence Center etc

4.4. Ensuring effective implementation of drug registration system in a timely manner

4.5. Specific requirements for new drugs registration:

4.5.1. Notification of the patent status of pharmaceutical products when filing for marketing approval; otherwise, the products are regarded as non-patented



4.5.2. Evaluation of cost-effectiveness of pharmaceutical products must also be incorporated into marketing approval, besides efficacy and safety considerations.

4.5.3. Presentation of drug pricing structure

4.6. Developing regional cooperation among countries in this region to expand market size to create a profitable market for investment

**5. Patent-related strategy**

Patent should be less of a hindrance to access to medicine

5.1. Free trade agreements shall not impose obligations beyond those otherwise stated in the WTO TRIPS Agreement (No TRIPS-Plus)

5.2. Adopts the WHO's patentability criteria for pharmaceutical products as guidelines for determining whether a claimed invention is eligible for patent protection

5.3. Develops patent database to facilitate quick, easy and comprehensive searching, particularly for

pharmaceutical patents; the database should yield search results in both English and Thai

5.4. Amends the Patent Act to promote just and fair practices that are consistent with the principles of the law, with special emphasis on the following areas:

5.4.1. The law shall set forth patentability requirements for pharmaceutical inventions, namely inventive step, in an attempt to prevent the practice of evergreening of a claimed invention that lacks inventive step to qualify for patent protection.

5.4.2. The law shall facilitate the implementation of compulsory licensing of patented drugs for government use, pursuant to the TRIPS Agreement, to import, manufacture, and export compulsory licensed drugs to countries without manufacturing capacity

5.4.3. No amendments shall be made to particularly good principles or provisions, namely pre-grant opposition. Also, the law shall provide also post-grant opposition protocol

5.4.4. Establish 'Pharmaceutical Patent Committee' to review, examine and perform any functions in relation to pharmaceutical patents, in particular, similar to duties of the Board of Drug Patent under the Patent Act (no. 2) B.E. 2535. This is due to the fact that the examination of drug patents is of vital importance and requires specific expertise.

## 6. Promotion of rational drug use

6.1. Updates the National List of Essential Medicine (NLEM) B.E. 2547, the National List of Herbal Medicinal Products B.E. 2549, and the List of Hospital Formulary B.E. 2549 to be most current and comprehensive enough to cover a great number of diseases

6.2. Calls on the adoption of the National List of Essential Medicine in a rigorous manner

6.3. Promotes the use of International Nonproprietary Names (INN) or generic names - in all levels - to identify every pharmaceutical substance

6.3.1. Mandates the use of the same font size for both proprietary names and generic names on both container labels and patient package inserts

6.3.2. Emphasizes the use of generic names across the curriculums for health care professional of all disciplines

6.3.3. Enforces the use of the same essential medicine list in the same health facilities under the National Health Security Scheme, the Social Security Scheme and the Civil Servant Medical Benefit Scheme. For drugs containing the same active ingredients, use cost-effectiveness consideration as key determinant of which only one brand drug to use, where a system for drug quality monitoring and evaluation is established and implemented on a regular basis

6.3.4. Health care professional should take the leading role in promoting proper and rational use of drugs, notably the use of generic drugs



## 7. New Drug Research and Development

7.1. Takes proactive approach to collaborating with IGWG to plan and push for research and develop-ment of new drugs for diseases that cause public health problems in developing and least developed countries

7.2. Feasibility study for alternative approaches or methods apart from patent system to promote research on new drugs. For example,

7.2.1. Research Prize Fund

7.2.2. Medical Research and Development Treaty

7.2.3. Advance Market Commitment

7.2.4. Patent Pool

7.2.5. Drug researchers pool