Unofficial Translation

First National Health Assembly **Main 1/2**
Agenda 3.2 **21 November 2008**

Universal Access to Essential Medicines

1. Situation

1.1 Medicines are moral goods. It is necessary to have essential medicines commonly available in the country to be used in the time of need, so that the country can be self-reliant to a certain extent during a war or crisis and for the public interest. Access to essential medicines is related to rational use, efficacy, quality, distribution, and price of medicines.

1.2 The medicinal expenses in Thailand have gone up over the past several years. The drug market expanded from 32 billion baht in 2000 to 63 billion baht in 2005 in terms of exfactory's prices. Between 2000 and 2005, drug expenditures went up by 13 – 20 %. During this period, Thailand's spending on medicines increased at three times higher than the rate of economic growth which is only 2.2-7.1%. The increase rate of medicinal expenses in Thailand is against that of international drug market, whose expenses have been decreasing from 11.7 % in 2000 to 6.8 % in 2005.

1.3 The Thai government has implemented its universal health coverage policy to ensure that all Thais have access to essential health care. A study on expenditures at hospitals under the Universal Health Coverage scheme shows that drug expenditures account for 20.4 % and 65% of the total expenditures of inpatients and outpatients respectively, with likely increases in the future. A study on medical expenses of the civil servants medical benefit scheme indicates that outpatients' drug expenditures went up from 7,007 million baht in 2000 to 21,896 million Baht in 2005, resulting in a huge public financial burden. The increase was due to the increase in consumption as well as inflated prices for new patented medicines.

However, despite a number of special programs such as the government subsidized Anti-retroviral Drugs for People Living with HIV/AIDS Project, a large number of people still do not have access to essential drugs. The government, with limited resources, cannot supply sufficient essential medicines to meet the demand, while the medicine prices are too expensive for most people. The main reason is that these medicines are patented or monopolized. The patent system applied to medicines results in the distortion of the intention of the law to promote research and development. The outcome is that the monopolistic pharmaceutical business causes medicine prices to be too high for many consumers to afford.

2. Relevant Policies and laws

2.1 *The National Drug Policy 1981* covered five major aspects: 1) Distribution of essential medicines; 2) Promotion of proper use of medicines; 3) Medicine quality assurance; 4) Production of medicines from local raw materials, and 5) Promotion of the use of herbs in Thai traditional medicine, by introducing the National List of Essential Drugs 1981. Later, *The National Drug Policy 1993* was

pursued. The policy emphasized comprehensive measures and defined the strategies of agencies responsible to make the policy more concrete. Two more aspects were added to the existing policy: 1) Promotion and support for the use of medicines on the National Essential Drug List by the public and private sector; and 2) Improvement of efficiency of drug administration and provisions of laws, rules, and regulations that contribute to drug consumer protection. This resulted in revision of the National Essential Drug List to include medicines to prevent and resolve health problems of Thai people. The list was to include essential and cost effective medicines for the treatment of illnesses. The Policy also called for the preparation of a list of herbal medicines to be used, in a sustainable and equal manner, by the universal coverage scheme, the social security system, and the medical welfare system for government officials, as references to claim for benefits

2.2 *The regulations of the Ministry of Public Health on Procurement of Drugs Using the Budget of Government Agencies under the Ministry of Public Health 1981, dated 1 October 1981* stipulated that the National Essential Drug List be used as the reference in selection of medicines for public health care facilities, so that all the people, including poor people living in remote areas, would have access to essential medicines at affordable prices.

2.3 *Trade Related Aspects of Intellectual Property Rights Agreements (TRIPs).* These are agreements on trade-related aspects of intellectual property nights that set minimum standards that all member states of the World Trade Organization have to comply with, by amending their national laws to meet these requirements within the designated time frames.[1]

2.4 *The Doha Declaration* was adopted to underline the objectives of TRIPs to strike a balance between intellectual property protection to promote inventions, and protection of public health and rectification of public health problems. The Doha Declaration emphasizes that each country can produce medicines or use compulsory licensing and/or parallel imports to solve public health problems.

2.5 The *Patent Act, B.E. 2522 (1979) and the Patent System*. Under this Act, medicines were granted patents for 15 years and they were process patents[2] providing production process protection. Then in 1992, the Patent Act, 1979 was amended, as a result of pressure from the U.S., to provide protection for medicines

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[1] By 1995 for developed countries, by 2000 for developing countries, and by 2005 for the least developed countries.

[2] Provisions of the Patent Act 1979 that granted 15-year process patents corresponded with the level of production technology development in Thailand. This was because the local pharmaceutical industry at that time was a downstream industry, i.e. regimen development, and not research and development of new drugs. Thus protection of production processes allowed local pharmaceutical companies to develop drug production processes that were different from the patented ones. The Patent Act (2nd Amendment), B.E. 2535 (1992), which provides protection for drugs and pharmaceutical products, has prevented local pharmaceutical companies from developing production processes using the original drugs before their patents expire. At present, ever-greening patents are more common, and drug patents are constantly renewed. Moreover, patents have been registered for minor development, i.e., in the form of crystals, salt, or new formula. As a result, the local pharmaceutical industry has no opportunity for development and the industry has become weakened.

and pharmaceutical products, and the protection period was extended to 20 years. The Drug Patents Commission was established to oversee drug pricing and compulsory licensing and government use, a measure necessary for public health protection from patent holders. Then in 1999, the third amendment of the Patent Act 1979 took effect whereby provisions on the Drug Patents Commission were removed. Other amendments were also made to comply with the TRIPs Agreement and safeguard provisions were added to balance patent holders' interest and the public interest. However, such measures have not been used effectively in Thailand, and amendments have not yet been made to the Act to accommodate Paragraph 6 of the Doha Declaration and WTO's Decision on 30 August 2003.

2.6 *The Drug Act B.E. 2510 (1967)* and other subsequent amendments were focused on controlling drug manufacturing plants, import and export. There were provisions on safety, quality and efficacy. What was missing was, however, had an impact on the public access to medicine. The Act covers such matters as the national drug policy, drug price control (through disclosure of drug pricing structure to reflect the actual costs when the drugs were registered), drug promotion control (to save the costs of the drug companies), promotion of the use of generic names and national lists of essential drugs, as well as promotion of domestic pharmaceutical industry and development of Thai medicine.

2.7 Under *the Prices of Goods and Services Act B.E. 2542 (1999)*, drugs are considered controlled goods, which has been the case since 1979 when the Act on Price Fixing and Prevention of Monopoly was passed together with the Announcement No. 1 of the Central Committee on Price Fixing and Prevention of Monopoly (now abrogated). The Central Committee on Goods and Services, established by the 1999 Act, still maintain that drugs are controlled goods required to display retail or wholesale prices. Prices are to be displayed on labels. However, there has been no announcement on price control. As a result, price fixing is not realistic. Drugs with prices marked on the labels are sold in Thailand differently. Evidently, prices on the labels are not the central prices but the highest and most expensive for consumers.

2.8 *Trade Competition Act B.E. 2542 (1999)*: In 2007 the Trade Competition Commission set criteria identifying business operators as holding dominant market positions over all goods in Thailand as follows: any business operation that has a market share of more than 50% in the previous year and a total sales volume of more than one billion baht, or the first three business operators in any market that have a combined market share of at least 75% with a total sales volume by any one of the operators of more than one billion baht. They are considered to hold dominant positions over the market except any business operator with the market share of the previous year less than 10% or with a total sales volume less than one million baht. In other words, such criteria do not take into account drugs as necessary goods with their own peculiarity. Drug monopoly is decided on whether or not there are alternatives to the products on sale. In actual fact, if the business operator is both the sole manufacturer and distributor and even if the sales volume is small, the monopoly that he/she enjoys is enough to exercise enormous control of the market. Any action by such a person has a direct and serious effect on the consumers, especially with regard to the access to drugs.

Problems of access to essential medicines

The drug access problems include the following. (1) Drugs are not sold at affordable prices. (2) Orphan drugs are essential imported drugs with no domestic manufacturers or proper channels of distribution. (3) Drugs are used without good reasons or caution for safety. And (4) the quality of drugs poses great concerns with low quality or fake medicines widely sold in the market. The problem facing Thailand at the moment is the price of drugs due to the impacts of the WTO's TRIPS agreement under which protection is provided for drugs patents and their processes for 20 years, resulting in higher prices because of monopoly, and posing considerable barriers to the development of the country's pharmaceutical industry.

Thailand has had to rely on imported new medicines and had to bear the burden of drug expenditures that went up sharply in the past decade due to rules on IP, or drug patents, protection. From 1991 to 1999, 742 original drugs were approved for registration. Due to market monopoly, Thailand had to buy several expensive medicines. Moreover, the manufacturers of original medicines were able to extend the protection period of their medicines by slightly modifying their molecular structures shortly before the patents expire and reapplying for patents. It is a known fact that the properties of a substantial number of new medicines are no better than the original medicines but the prices are much higher. Moreover pharmaceutical companies will launch such intensive sales promotion campaigns of new medicines that many doctors will prescribe expensive medicines under trade names. The result has been a sharp increase in the import value of modern medicines over the past 3-4 years, especially in 2005.

Thailand has no clear drug pricing policy, no efficient drug price control system, and no regulatory body to ensure that drug prices are reasonable, fair, and reflect their true cost. Price fixing is only from the manufacturers' side.

4. Strategies for Universal Access to Medicines for All Thais

There is an urgent need for a national strategies to ensure universal access to essential medicines. Through extensive consultation processes among related parties such as WHO representatives, government sector (Thai Food and Drug Administration, governmental/university hospitals and medical science centers), service management agencies (National Health Security Office and Social Security Office), professional network (doctors and pharmacists), business sector and patient network, *a draft national strategies for universal access to essential medicines* has been proposed in the Annex 1/1/2.

5. Action by the National Health Assembly

The National Health Assembly is invited to consider the *Draft Resolution 1/2*.