Unofficial Translation

Annex 1/2/1 Revised 1 13 December 2008

Strategies for Universal Access to Medicines for Thai People

Goals

1. The country has essential drugs available for general use in a timely and self-reliant manner and for public good.

2. People enjoy good health and can rely on themselves for basic medical care, with an emphasis on health and use of local health wisdom, Thai traditional medicine, folk medicine and alternative medicines.

Strategies

- 1) Coordinating partner networks for access to drugs
- 2) Supporting patients to get access to drugs and participate in health care and health promotion
- 3) Promoting local drug prices that correspond with the local cost of living
- 4) Developing the local pharmaceutical industry
- 5) Making use of legal provisions and/or reducing barriers deriving thereof
- 6) Proper use of drugs
- 7) Research and development of new drugs.

Strategy 1: Coordinating partner networks for access to drugs

Partner networks (health personnel, academia and patients/drug users) jointly develop systems, mechanisms, and processes as follows:

- 1.1 To ensure proper use of drugs.
- 1.2 To ensure effective drug system administration.
- 1.3 To advocate policy implementation and improvement and/or legislative amendments to ensure universal access to drugs.
- 1.4 To encourage coordination and networking among drug service units of acceptable standards at the community level.
- 1.5 To ensure a long-term sustainable access to quality drugs.

Strategy 2: Supporting patients to get access to drugs and participate in health care and health promotion

2.1 The public sector must support the formation of patient groups, especially patients suffering from diseases that involve high medical expenses and are the nation's public health problems, as well as diseases with low prevalence, in order to empower them to propose to relevant agencies recommendations for access to service and drugs.

2.2 The public sector must support people joining together for healthcare and health promotion purposes including physical and mental rehabilitation and help reduce social discrimination..

Strategy 3: Promoting local drugs prices that correspond with the local cost of living

- 3.1 Drug price control measures shall be put in place on a rational and transparent basis and efficiently enforced, especially for patented drugs and drugs under market monopoly or oligopoly.
- 3.2 The flexibility of TRIPs agreement that appears in the Patent Act shall be used to efficiently and rationally solve the problem of access to drugs.

Strategy 4: Developing the local pharmaceutical industry

- 4.1 Encouraging production of essential drugs, pharmaceutical raw materials and herbs in healthcare to replace imported drugs, and promoting research and development of essential pharmacopoeia.
- 4.2 Where there is a patent-related problem, the government shall have supportive measures, e.g., facilitating voluntary licensing by fixing appropriate compensation and providing other forms of support such as tax and marketing measures.
- 4.3 Encouraging the generic drug industry to engage in research and development of pharmacopoeia whose patents are about to expire, and getting relevant agencies to accelerate the pharmacopoeia registration process.
- 4.4 Promoting the establishment of clinical research centres and bioequivalence testing centres of acceptable standards.
- 4.5 The State shall support the creation of a fund for research and development of the domestic pharmaceutical industry, by creating National Pharmaceutical Industry Development Institute as a mechanism to manage the fund and serve as a linkage between pharmaceutical research and development agencies, academic institutes and pharmaceutical industry.
- 4.6 Promoting cooperation between the Government Pharmaceutical Organization and domestic pharmaceutical manufacturers and expanding the cooperation to other countries in the region with a view to enlarging the pharmaceutical market worthy of investment, especially the market for orphan drugs, alongside appropriate standard setting and consumer protection.
- 4.7 The government shall promote investment in the local pharmaceutical manufacturing industry for modern as well as traditional medicines at national level.

Strategy 5: Making use of legal provisions and/or reducing barriers deriving thereof to ensure that there is no barrier to access to drugs

- 5.1 Obligations under free trade agreements must not exceed those under 1994 Trade-Related Aspects of intellectual Property Rights Agreement (TRIPs Agreement).
- 5.2 Using WHO's criteria for registering drug patents as guidelines for consideration of technologies that should be granted patents.
- 5.3 Developing a database of drug patents in Thai and English to facilitate easy, quick, and complete access to information.
- 5.4 Amending the Patent Act to ensure fairness according to the spirit of the law especially in the following matters:
 - 1) Setting detailed procedures for an "inventive step" to prevent applications for patents that are not really inventive steps but only minor changes of claims.
 - 2) Establishing the "Pharmaceutical Product Patents Committee" whose members have specialized expertise, to consider, pass decisions on, and perform other acts relating to pharmaceutical product patents.
- 5.5 Import taxes shall be abolished on life-saving drugs on the National List of Essential Drugs and on active pharmaceutical ingredients (API) used in the manufacturing of drugs on the National List of Essential Drugs.

Strategy 6: Proper use of drugs

- 6.1 Updating the National List of Essential Drugs using information on costeffectiveness of health economics.
- 6.2 Requiring medical health establishments to seriously use the National List of Essential Drugs and to prescribe drugs properly
- 6.3 Promoting the use of generic drugs at all levels:
 - 1) Requiring that the size of the generic name and that of the trade name on a label and a fact sheet be the same.
 - 2) Focusing on generic names in the teaching and training of all public health personnel.
 - 3) Requiring that the same drug list be used in the same health facilities for treatments of patients under the universal coverage scheme, the social security system, and the medical welfare system for government officials. For drugs with the same active ingredients, only one item will be used, based on economic cost-effectiveness and negative side effects of the drugs. A follow-up mechanism shall be put in place to monitor quality assessment on a regular basis.
 - 4) Requiring that public health personnel of all levels use generic names and inform the consumers of the generic names of the drugs.
- 6.4 A mechanism shall be provided to promote self-reliance in healthcare among the people and the communities, with emphasis on health promotion and use of local folk wisdom on health, traditional Thai medicine, folk medicine and alternative medicines.
- 6.5 Developing and promoting a surveillance system on drug safety and quality in an efficient and timely manner.
- 6.6 Developing and revising an efficient registration system for pharmacopoeia

- 6.7 For new pharmacopoeia registration, the following additional information is required:
 - 1) Patent status of the new drug upon registration.
 - 2) Information on the cost-effectiveness of health economics together with the procedure of the development process
 - 3) Information on drug prices¹
- 6.8 Providing information on drug usage in Braille code for visuallyimpaired patients.

Strategy 7: Research and Development of New Drugs

- 7.1 Participating proactively with inter-governmental working committees on public health, innovation and intellectual property to formulate a plan to encourage research on new drugs for diseases that are public health problems in under-developed and developing countries.
- 7.2 Promoting new alternative systems to support research and development of new drugs and new pharmacopoeia other than the patent system (e.g. joint management of continuing patents, Fund for Research Awards, and futures contracts for research and development.)

¹ Meaning the proportion between research & development costs, manufacturing costs, management costs, marketing costs, and profit distribution costs