Access to Medicines in Thailand

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According to the World Health Organization (WHO) "Health" is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.[1] While health is a fundamental human right indispensable for the exercise of other human rights. Thus individual health right must be protected. The right to health contains both freedoms and entitlements. The freedoms include the right to control one's health and body, including sexual and reproductive freedom, and the right to be free from interference, such as the right to be free from torture, non-consensual medical treatment and experimentation. The realization of the right to health may be pursued through numerous, complementary approaches, such as the formulation of health policies, or the implementation of health programmes developed by authorized agent or the adoption of specific legal instruments. Moreover, the right to health includes certain components which are legally enforceable.

Access to medicines and factors affecting health are well known among those in public health team. However, these topics are not well aware among general public, thus will benefit those who are concerned in their health and wish to be in a good health. This article aims to give a general idea for those aspects. Before giving a basic knowledge about the accessibility to medicines in Thailand, various factors that have either good or bad effect on one's health are reviewed. Such factor can be grouped as follows :

Environment

The environment includes both the physical environment we live in and the social fabric of the community, which significantly influence health. The physical environment plays an important role in many ways. A clean environment helps prevent the spread of disease and may reduce depression.

Awareness of health issues

The awareness of individuals about health is fundamental to promoting a healthier population. If people do not understand the causes of ill-health and how they can improve their health, they cannot make decisions about investing resources and time to improve their community, or about lobbying for outside assistance. Such awareness; for example health promotion, health prevention, health communication, and health protection, should be developed in all areas that influence health because the different influences are often interrelated. Both community leaders and governments play important roles in developing this awareness.

Personal hygiene

Personal hygiene is essential both for improving health and for sustaining the benefits of interventions. For example, if injuries and minor cuts are not kept clean, they may become infected and lead to further health problems.

Health care

All people suffer from disease at some point in their lives and may need to seek medical advice and treatment. In all cases, the health outcomes are profoundly affected by whether health care facilities are available to the people. As the population ages, health systems that formerly focused primarily on infectious disease are being asked to deliver new types of care, mostly for chronic illnesses and increasingly for mental illness. The major causes of the burden of disease will shift from pneumonia, diarrhea, and perinatal conditions to heart disease, mental illness (particularly depression), and road traffic accidents. Tobacco will kill more people than any other cause of diseases, including HIV.

Disease

The most common causative agents of diseases are disease-causing organisms or “pathogens” or inappropriate nutrition. Many of illnesses and deaths occur unnecessarily.

Many diseases can be effectively treated, managed, or prevented with pharmaceutical products. Medicines do not only help people live longer, but they also greatly improve the quality of their lives,

reduce stigma and discrimination that they might experience, and enable them to contribute to the economic and social welfare of their families, their communities, and their countries as a whole. People and governments willingly spend money on drugs because of the role they can play in saving lives, restoring health, preventing diseases and stopping epidemics. But, in order to do so, drugs must be safe, effective and of good quality, and used appropriately. This means, in turn, that their development, production, importation, exportation and subsequent distribution must be regulated to ensure that they meet prescribed standards. However, the limitation of access to medicine was reported over the world, especially in developing countries.[2] There are a lot of sick people in Thailand who need available medicines, as well as in poor or developing countries, who are threaten by potential new epidemics like HIV/AIDS and avian influenza.

Access to Medicines in Thailand

Various factors limit access to medicines in Thailand such as financial factor, procurement of medicines, regulation on medicines for use, etc.

Financial factor

In 2001, the main percentage of average monthly expenditure of Thai household is Food and Beverages (32.5%), Housing (22.4%), and Transportation and Communications (15.7%), respectively.[3] While Medical Care expenditure was only 2.6%. So insufficient financing for medicines is the main factor for the sick poor. It means that almost of their expenditure are not for health. Thus if they need medical care, it may be a financial barrier to access. Self care is the popular care for Thai when they have minor ailment. Drug store has important role for self care.[4-5] Medicines in the market, which formularies contain the same active ingredients can be classified into 2 groups : generic drug and patented drug. Patents afford drug producers monopolistic control over production and prices. The different prices between generic drugs

and patented drugs in Thailand are very high.[6] For example, in 2002, the Government Pharmaceutical Organization (GPO), a state enterprise under the Ministry of Public Health, successfully produced its first ARV 'cocktail' called GPO-vir. GPO-vir, a fixed-dose combination of three drugs (stavudine, lamivudine and nevirapine) has become a cheap and affordable ARV treatment for many people with HIV/AIDS in Thailand. GPO-vir costs 1,200 bath (US$31) per patient per month compared to 18,620 baht (US$490) per patient per month for imported, brand-name drugs, especially patented drugs.[7]

The key to reducing drug prices is to create competition among producers. The most effective way to reduce prices and increase access is to promote local generic competition. In Thailand, local generic production of medicines is legal if the medicines were invented before product-patent protection was introduced in 1992. Therefore, they could not be patented in the country.

Even though in 2002, the Thai government initiated a national health insurance system which covers 95 per cent of the population. The health insurance system provides basic health insurance for a fee of 30 baht (US$ 0.79) per visit to a clinic. The quality of medicines in the '30 baht' scheme are questioned, because of the limited public budgets.[8] So there are many Thais who under the '30 baht' scheme deny to exercise their right.

Procurement of medicines

Medicines are developed as a result of innovation by researchers and pharmaceutical companies. The global pharmaceutical market was worth more than US$400 billion in 2004, and more than 80 percent of this market is in North America, Europe, and Japan. Thus procurement of medicines depends on research and development (R&D). But R&D on the breakthrough (innovative) medicine is a high risk process for failure, has very high cost and needed high technology and length of time.[9-10] Research incentives must be available to both the public and the private sector. The concept of patents to encourage for researching

innovative medicines is likely occurred. Drug companies introduce minor changes to drugs(such as salt form, new indication or new dosage form) in order to extend patents. For medicines needed in both rich and poor countries, such as anti retroviral, companies recoup their expenses in the profitable market in developed countries. Developing countries in Asia, Africa and Latin America together account for only about 11 per cent of the world pharmaceutical market. So there is little private research into health problems specific to developing countries because they are not lucrative markets. Then medicine accessibility is difficult and it is impossible for developing country to get a complete R&D on medicine. Pharmaceutical industries in Thailand as well as in other developing countries have invested not much on R&D, of which the most investment is on formulation development. Almost all of local manufacturers produce 'me-too' or 'follow-on' drugs*

Intellectual property right protection (patent) is necessary in order to initiate incentive innovative creation and to generate revenues to finance research and development. However patent barriers to access medicine are the major factors for medicine Procurement in Thailand. Since 1985, as a result of complaints by the Pharmaceutical Research and Manufacturers Association of America (PhRMA), claiming that weak patent protection was costing them millions of dollars in lost revenue, the Office of the United States Trade Representative (USTP) has pressured Thailand to strengthen its patent laws. Consequently, the US trade preferences under the General System of Preferences (GSP) have denied to import from Thailand in 1989 and 1991. Facing intense pressure, The Thai government amended its existing patent laws in 1992 to allow patents on pharmaceuticals, to extend patent life from 15 to 20 years. The law was amended again in 1999 to comply with obligations under the World Trade Organization

* referred to a new entity with a similar chemical structure or the same mechanism of action as that of a drug already in the market.

(WTO) Trade Related Intellectual Property Rights (TRIPS) agreement. Thus Thailand has forfeited the possibility of producing or importing cheap generic versions of patented medicines, except under a compulsory license. As permitted by TRIPS, the Thai patent law currently allows flexibilities that help lower the price of medicines, such as compulsory licensing and parallel importation. Even though compulsory licenses are rarely invoked, their use remains an important policy tool for government - and the threat of issuing such a license often serves as bargaining leverage in negotiations with pharmaceutical companies to induce them to reduce their prices. For example, in 2001, Canada threatened to issue a compulsory license for a supply of the antibiotic Cipro to respond to an anthrax scare. Eventually, Bayer, the maker of Cipro, agreed to provide the drug at discounted prices. Moreover in October 2005, US Senator Charles Schumer threatened to push for a compulsory license on the avian influenza drug, oseltamivir (Tamiflu®), if its patent holder, Roche, did not agree to allow generic companies to produce the drug in order to increase its supply. Roche entered negotiations and reached agreement with several generic producers shortly thereafter.[7] The other patent barrier example, in 2006, German physician has desperately tried to order oseltamivir (Tamiflu®) form Roche, the medicine producer for more than 6 months. He did not get it from the company but he eventually picked up 500 doses from a Dutch wholesaler.[11]

Despite pressure from Thai civil society, the Thai government has not so far used these TRIPS “flexibilities”. According to a recent World Bank report, by exercising compulsory licensing to reduce the cost of second - line HIV/AIDS therapy by 90%, the Royal Thai Government would reduce its future budgetary obligations by 3.2 billion discounted dollars (127 billion discounted baht) through the year 2025 and cut by more than half the cost per life-year saved of the National Access to Antiretroviral Program for People Living with HIV / AIDS, from $2,145 to $940 per life year saved.[7]

However, provisions in a US-Thailand FTA(Free Trade Agreement) are likely to limit the government's flexibility to issue compulsory licenses and would create a number of other obstacles to production and marketing of generic drugs by extending patent protection beyound the maximum 20-year period established under TRIPS. This means that the monopoly period will further delay the introduction of affordable generic medicines which produced by local company in Thailand. Furthermore, it could become more difficult to challenge the validity of a patent.

Regulation on medicines for use

Medicines are not normal 'commodities'; they meet fundamental health needs, and access to essential medicines, according to the World Health Organization, is a fundamental human right. Thus, medicines have additional social value. Appropriate use of medicines requires a 'learned intermediary' to prescribe them and a trained person to dispense them appropriately before the consumer takes them. The market for pharmaceuticals is therefore not a usual market in economic terms; there are major informational asymmetries and monopoly behaviours by suppliers that include patent rights and 'data exclusivity' clauses that further strengthen monopolies. In addition to the quality, safety and efficacy requirements for regulation, it means regulating supplies of the pharmaceutical industry.

The marketplace for pharmaceuticals is one of the most highly regulated industries in Thailand. To use any new pharmaceutical product, the patient must secure the approval of Food and Drug Administration (FDA). Before medicines were released to market for consumption, they must be approved by regulatory agencies. The drug regulatory system based on principles of consumer and public health protection through drug efficacy, quality and safety.[12] The initial regulatory standards were primarily related to ensuring the pharmaceutical quality of medicinal products and subsequent developments led to the development of standards for testing

efficacy and safety of new medicines as well. The fact about drug is that even the most successful clinical trials cannot eliminate the possibility that a drug will turn out to be unsafe or inefficacious. Because no pharmacologically active drug substance is entirely free of risk, the conclusion that a drug has been shown to be "safe for use," is actually no more than an opinion. Accordingly, risk to benefit assessments are inherently arguable, all the more so because each turns not only on personal sentiments about the nature of risks and benefits of a drug, but upon incomplete and imperfect information concerning the drug's risks. The timeliness with which national regulatory agencies approve new medicines for marketing affects health care professionals and patients. Namely, if this process takes time, it will delay entry of needed medicines in a particular market. But if it is a rapid process, it may be increase consumption of useless and risky drugs. While approval times for new medication (especially priority drugs) have become shorter during the past fifteen years, one implication of the perspective is that further reduction (if they can be generated at all) are likely to come at a much higher marginal cost.[13] This process is the difficult task of needing to convey as accurately (balanced) as possible the benefits of a new drug. Registration should not be seen as a detrimental hurdle to be avoided; it needs to be seen as a critical step in ensuring access to effective and safe medicines. Regulation has been seen as an 'impediment' to profits and industry development.[14] The resulting pressure on regulators has been to approve new medicines quickly - sometimes on the basis of what can only be described as preliminary data (e.g. in the case of imatinib for acute leukaemia, there were no high quality trials completed at the time of initial approval) - to remove regulatory 'bottlenecks', to carry out reviews and evaluations of data in the shortest possible time. There has also been pressure from patient groups to speed up access to new, 'breakthrough' medicines, for example in the field of HIV/AIDS.[15]

However, there are many issues that must be concerned in drug regulation policy, such as balancing between health and commercial objectives, transparent, pediatric indication, risk and benefit on medicine consumption. Because the political climate is currently in favor of multinational companies continuing to monopolize supply through uses of free trade agreements, patent legislation, political lobbying and legal pressures. In the context of concerns about improving access to effective and safe medicines, it is clear to consider how drug regulation 'fits' with other policies in relation to health and medicines supply.

Regulatory decision should be based on scientific reasoning from dossier which deals not only with the production and the physicochemical characteristics of drug but also with its pharmacological and clinical characteristics, including evaluation of efficacy and adverse effects in relation to existing therapies, not to facilitate profit of pharmaceutical manufacturers. Under bilateral trade agreement, the clinical data protection issue is the main topic to be raised in pharmaceutical section for trade fair. Namely, the local drug manufacturer will not use clinical information of original drug for approval of their 'me-too' drugs. So this agreement means to extend original patent drug and it will affect medication access in developing country. Moreover, availability of drug clinical trial information is important for informing decision-making to patients, prescribers, and researchers for rational use of drug.

For solving this problem, the medication regulation system should be requested to share experiences on medicine policy issues between various countries. Especially, if there is the coordination of WHO at country level, working on medicines closely with Ministries of Health and other stakeholders involved in the pharmaceutical sectors, access to medicines will be improved. This important network of country-based experts communicate with each other by exchange of information on key issues and sharing innovative solutions to common problems. For example, the barriers to providing highly active anti-retroviral therapy in poor countries have until recently seemed insurmountable.

Conclusion

Access to effective medicines requires a complex and coordinated system. It must encompass production that ensures good quality, selection, procurement, and distribution; correct prescription and dispensing and correct use by patients; adequate financing; and effective monitoring of the system. Ensuring that needed medicines are available is critical for the success of any disease control program. A great FTA deal is known about what works and what does not work.

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