

**Stopping Unethical Drug Promotion:  
To Prevent Economic Loss from Rising Healthcare Costs****Situation**

1. Drugs are moral commodities with positive and negative effects on the human body. Drug promotion contributes to greater use of drugs, which sometimes do not correspond to the health needs according to the principle of rational drug use. This could increase the risks or hazards to the consumer. Drug promotion has also led to a higher price of drugs. What is more, unethical drug promotion characterized by conflict of interests aggravates the problem even further.

2. The World Health Organization (WHO) attaches great importance to the problem of drug promotion with serious repercussions on drug use, as seen in a number of resolutions passed by the World Health Assembly. It has defined “medicinal drug promotion” as any action involving giving of information and persuasion or tempting in any way by the manufacturer or vendor leading to an order, procurement, purchase, and more use of drugs.

3. WHO provides a detailed definition of the ethical criteria for medicinal drug promotion. For example, promotion should comply with each country’s national public health policy and law. It should take into account the contents and format of presentation, ensuring the information given is reliable, true, accurate, comprehensive, up to date, verifiable and in good taste. It is emphasized that drug promotion should not lead to prescription in return for financial and/or material rewards requested by health personnel whether directly or indirectly. The reverse also applies; health personnel should not receive or seek any benefit whatsoever.

4. Thailand has been facing problems of medical expenses on drugs which have continued to rise, especially medical expenses under the civil servant medical benefits system covering about 5 million civil servants. In 2008 the amount soared double, representing 54,904 million baht, while the social security system and the universal health coverage system combined, covering 57 million people, cost only 98,700 million baht. Part of the reason is that the prescription system in the civil servant medical benefits system is open-ended, not in line with the principle of rational drug use, thus encouraging the unethical drug promotion.

5. The expenditure for Thailand’s drug advertisement is found to be very high. The drug advertisement to consumers alone over the three years between 2006 and 2008 is more than 2.5 billion baht/year. If one includes live programs on which the program hosts made reference to drugs, various types of rapidly increasing advertisement on the Internet, community radio, health programs, health columns and other latent advertisements, as well as drug advertisement to health professionals, the advertisement expenses will be many times more. For lack of monitoring systems, however, it is difficult to give the correct exact amount in the drug promotion.

6. The unethical drug promotion has involved physicians, pharmacists and other personnel, including the mass media, in various types of conflicts of interests with pharmaceutical companies both directly or latently. There are attempts to foster the relationship between physicians and pharmaceutical companies via medical representatives (pharmacists and non-pharmacists) in various forms such as giving benefits, presents, souvenirs, food items, entertainments, support for the organization

of conferences, trips abroad, grants given to individuals and institutions. All this is geared toward familiarizing the physicians concerned with the pharmaceutical products and paving the way for choosing them based on the benefits that might be received.

7. The drug promotion designed to strengthen such conflict of interests has become part of the routine situation in Thai society. It has led to an unfortunate result that some of the new generation of physicians, pharmacists and health personnel have mistaken that these benefits are something that they are entitled to or due to them. They do not realize how such promotion can affect health and drug prices, nor do they pay due attention to the attempts made by the WHO, NGOs, and professional organizations to reflect the multi-dimensions of the problem and to solve the problem at the international level.

8. Besides, there are some groups of physicians, health personnel, and medical representatives with clearly unethical behaviors, as seen in the form of “negotiation of benefits” and “prescription of unnecessarily expensive drugs”. These acts present an ethical issue on the part of people who offer the benefits as well as those who seek them. If one allows such practice to continue, it will only erode the confidence of the patients and the public trust in physicians, pharmacists and other related health personnel.

9. The WHO report on the assessment of the transparency of the drug systems in four countries finds that the transparency in medicines registration, selection and procurement<sup>1</sup> does not fare so well in the Thai case, which warrants further examination on the drug promotion in Thailand.

10. At present Thailand has no law that directly controls the drug promotion. The existing laws are inadequate and out of touch with reality. At the same time, the industry’s self-regulation system, revealing only 1-2 cases of malpractice a year, clearly does not cover the entire spectrum of the pharmaceutical industry. Professional councils may have developed their ethical criteria/codes of conduct but they do not cover the drug promotion or the relationship with the pharmaceutical industry. Thus, they are unable to reflect the real problems or serve as main mechanisms for problem solving.

## **Policy and law<sup>2</sup>**

11. *Ethical criteria for medicinal drug promotion:* At the international level, the World Health Assembly adopted a resolution on ethical criteria on medicinal drug promotion in 1988 (WHA 41.17), urging its member states to apply them accordingly. It was followed by a number of resolutions on the appropriate drug use. As far as Thailand is concerned, the criteria were translated into Thai and first disseminated by a drug problem study group with the financial support from the Ministry of Public Health. Efforts were also made in conjunction with the Plan to create surveillance mechanisms and develop the drug system which saw its third publication in 2009. The Food and Drug Administration worked with several sectors in the developing of the criteria for national medicinal drug promotion in 1994; however, it was not legally enforced.

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<sup>1</sup> WHO (2006): Measuring transparency in medicines registration, selection and procurement: Four country assessment studies. WHO/PSM/PAR/2006.7.

<sup>2</sup> See details of various laws in Annex: Technical Documents.

12. *Laws on medicinal drug advertisement*: The laws are not up to date, out of touch with reality, ineffective, and with weak penalty provisions. There are no provisions for direct or indirect control of medicinal drug promotion.

12.1 *The Drug Act B.E. 2510 (1967) and its subsequent amendments*: Under this Act, permission must be obtained for drug advertisement. Advertisement must not be boastful of its therapeutic properties. It shall not show the therapeutic properties of a dangerous or a specially-controlled drug. It shall not lead to an understanding that it is an abortifacient or emmanagogue, aphrodisiac or birth-control drug. It shall contain no certification or laudation of its therapeutic properties made by any person other than a professional practitioner. It shall not advertise falsely or exaggeratedly. No sale of drugs shall be advertised impolitely or by means of showing the distress or suffering of a patient. No sale of drugs shall be advertised by means of a gift or lottery drawing. Yet, in all this no mention is made of control of drug promotion. Besides, the control of advertisement under this Act cannot be effectively enforced in unclear cases, ethically-related issues, and manipulated communication techniques like latent advertisement/promotion. Therefore, unethical advertisement does not come under the direct control of any law, coupled with a weak surveillance system and penalty regime. It is only recently that an agreement on advertisement was developed and administered by the Food and Drug Administration in conjunction with the business sector concerned with the advertisement of drugs and health products.

12.2 *Direct Sale and Marketing Act B.E. 2545 (2002)*: It contains no provision on advertisement and sale promotion whether directly or indirectly.

12.3 *Consumer Protection Act B.E. 2522 (1979) and its subsequent amendments*: Mention is made of advertisement of products and services, but no direct or indirect mention of advertisement and sale promotion.

13. *Professional control laws*: There exist some ethical criteria or codes of conduct, but no provision on control or criteria on how to interact in the relationship when it comes to sale promotion.

13.1 *Act on Medical Profession B.E. 2525 (1982) and Medical Council's Regulations on Maintenance of Ethics of Medical Profession*: Under these law and regulations medical professionals shall not advertise, hire or allow other persons to advertise medical practice, knowledge or expertise of self or others. They shall not practice without consideration of the patient's possible loss or waste. They are also required to display their technical achievements. There are provisions on advertisement of medical establishments in relation to the profession. For example, they shall not boast of their professional practice or activities in an exaggerated manner. They shall not boast of their equipment or offer discount in order to attract people to mistakenly use their service.

13.2 *Act on Pharmaceutical Profession B.E. 2537 (1994) and Pharmaceutical Council's Regulations on Maintenance of Ethics of Pharmaceutical Profession*: Under these law and regulations pharmaceutical professionals shall not advertise, hire or allow other persons to advertise pharmaceutical practice, knowledge or expertise of self or others. They are also required to display their technical achievements and shall refrain from seeking benefits in their individual pharmaceutical practice. They shall take care not to let their pharmaceutical practice publicized in the mass media in the manner suggestive of advertising their knowledge and expertise. In addition, there are provisions on advertisement of medical establishments or workplace in relation to the profession.

#### 14. Acts still in the drafting process

14.1 *Draft Drug Act B.E....(the people's version)* proposes improving control of drug advertisement and adding control of drug promotion for consumer protection in light of the changing situation, technology and market.

14.2 *Draft Drug Act B.E....(the version already considered by the Juridical Council)*: Several attempts have been made to amend the version to make it more in line with the current situation, but to no avail. Some of the substance in the draft act is concerned with the advertisement and promotion of drug sale.

#### **Important problems and impacts<sup>3</sup>**

15. Thailand's drug expenditure has considerably increased during the past several years. In 2005 the retail value was 186,330 million baht and is likely to exceed 200,000 million baht by the end of 2009, representing 42% of the health expenditure<sup>4</sup>. The civil servant group registers the highest drug expenses/person with a 3,600 baht/person/year. It is also found that Thailand's drug expenses are greater than the overall national economic growth. The increase in expenditure was about 13-20% during 2000-2005, while the overall national economic growth was only 2.2-7.1%. The value of the Thai drug market goes against the trend of the overall international drug market which registered a reduced increase from 11.7% in 2000 to 6.8% in 2005.

16. Drug promotion including drug advertisement is related to prescription behaviors of the health personnel while more unethical drug promotions have been reported<sup>5 6</sup>. Much inappropriate drug use has also been noted, including antihyperlipidemic drug, diabetes drug, antibiotic drug or expensive drugs. For instance, more than 85% of the antihyperlipidemic drug use did not comply with the treatment standard.

17. Drug promotion contributes to higher drug prices. The prices of many drugs in Thailand are greater than those in developed countries<sup>7</sup>. Currently, Thailand has no drug pricing policy that reflects real costs, and there is no law that requires the industry to report figures in relation to drug promotion. Reports from other countries show that the drug promotion expenses are twice as high as the budget for pharmaceutical research and development.

18. There are a number of violations of the Drug Act B.E. 2510 (1967) and Food and Drug Administration Regulations on the Criteria on Drug Advertisement B.E. 2549 (2006). The following are major offenses. On the Internet 85% advertised without permission from the Food and Drug Administration. Out of 525 drugs advertised on radio covering five provinces, 56.4% breached the law, 8.9% exaggerated their therapeutic properties, 13.17% showed incorrect messages, and 21.88% showed messages that could cause misunderstanding. Community radio tended to advertise drugs without permission or host live programs through which the public received information about drugs. Such practices caused the consumers to receive incorrect information, misunderstand the real contents, and use drugs more than necessarily, leading to economic waste and possibly harming their health.

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<sup>3</sup> See more details on problems and impacts in Annex: Technical Documents.

<sup>4</sup> Suwit Wibulpolprasert (editor): Thai Health 2005-2007, ISBN 978-974-8072-76-0.

<sup>5</sup> Paper for "Technical Meeting for Drug System Development for 2009", organized by the Plan to create surveillance mechanisms and develop the drug system.

<sup>6</sup> Ya Wiphak, Year 1 (Vol. 2), June 2009.

<sup>7</sup> Ya Wiphak, Year 1 (Vol. 1), March 2009.

19. Drug advertisement and sale via the Internet are against the law according to the Drug Act B.E. 2510 (1967). The wellbeing of many women and children has been affected by sale of such drugs as abortifacient drugs, aphrodisiacs, anesthetic or hypnotic drugs that lead to sexual offenses, and AIDS medications. It is very difficult to arrest the wrongdoers and take action against them.

20. There are conflicting problems concerning advertisement in Thai medical journals compared to the world's leading medical counterparts. Significant problems that occur are latent advertisements in various guises, including education programs through health foundations or centers, health programs, and Q & A columns. Unlike international practice, Thailand is yet to have a supervisory mechanism put in place. The Food and Drug Administration has developed draft criteria for control of latent advertisement which are yet to be enforced.

21. Although the World Health Organization has developed ethical criteria for medicinal drug promotion and urged the member states to legislate accordingly. However, Thailand has no such law or adequate measures to monitor or supervise the sale promotion, thus causing the problem of ethical promotion to be more acute. Many academics have brought to light the issue and come up with a host of recommendations. Some of the problems highlighted are provision of support for technical conferences in the form of entertainments and souvenirs, support for participation in conferences abroad cum pleasure trips, or other kinds of packages depending on the sale order volume. All this can be found in research reports, technical papers, and private interviews. However, to date there are no measures to handle the problems in a systematic manner<sup>8 9</sup>.

22. Thailand falls short of good governance practice in many areas when it comes to the drug system, especially in the control of drug system and transparency of the supervisory system. With regard to the corporate governance of pharmaceutical companies, even though there have been attempts to present a good image in the form of corporate social responsibility (CSR), no effort has been made to disclose market information, including the value and activities of advertisement and sale promotion as well as drug marketing techniques.

23. The WHO has identified several sectors concerned with drug promotion that contribute to the worsening of the unethical promotion in several ways. For instance, some are not aware of the situation, while others pay no attention. Some are even part of the cause of the problem. At individual level, there are drug agents, prescribers, and procurers. At institutional level, there are hospitals and pharmaceutical and therapeutic committees. At the level of associations and professional councils, there are industry associations, the Medical Council, and the Pharmaceutical Council. One could even include veterinary science, dentistry and medical technology. At the regulatory level there is the Food and Drug Administration. At the insurance level, there are executive committees of the three security systems. Finally, there are mass media, people, and non-governmental organizations.

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<sup>8</sup> A participatory evaluation of the implementation of WHO's ethical criteria for medicinal drug promotion in multiple countries (2004), final report presented at Second ICIUM (2004).

<sup>9</sup> Summary of the joint analytical meeting on "Guidelines for Appropriate Action Concerning the relationship between physicians and pharmaceutical companies", 29 April 2009.

24. Therefore, as a whole, the inappropriate drug promotion is not confined only to the issue of expensive drugs or exploitation of any one group of consumers. It is a public problem that challenges and threatens the confidence and trust in physicians, pharmacists and health personnel, as well as ethical and moral foundations in Thai society.

**Issue for Consideration by the National Health Assembly**

The National Health Assembly is requested to consider document: Health Assembly 2/Draft Resolution 8.