The 10 burning questions on the Government Use of Patents on the four anti-cancer drugs in Thailand

By
The Ministry of Public Health
And
The National Health Security Office
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NHSO
National Health Security Office

กระทรวงสาธารณสุข
MINISTRY OF PUBLIC HEALTH

Preface

Cancer is a serious disease, bringing great suffering and pain to people in terms of its fatality and its high expense of care, both for the poor and the rich alike.

When President Clinton took office during his first term, he tried to reform the U.S. healthcare system, according to the policy stated during his election campaigns. Cancer patients were cited as an example to justify the reform. When people were diagnosed as suffering from cancer, it would be their first verdict of death sentence. Later, when they learned that their healthcare policy did not cover cancer treatment expenses, it would be like being sentenced to death for the second time. Because the patients could not shoulder the exorbitant expenditure, they died more rapidly. Although there were medicines to cure or alleviate the disease, access to them were barred by the extremely high prices.

In Thailand, a similarly sad case was about a young engineer suffering from Gastro-Intestinal Stromal Tumor (GIST). This engineer was covered under the Social Security Scheme (SSS). But when he was diagnosed as suffering from cancer, the hospital he registered with and obliged to provide him with anti-cancer drugs, Imatinib, refused to do so, citing a number of excuses. The patient humbly sought help from the Social Security Office, whose executives insisted that the hospital had to provide its treatment. The hospital then resorted to the SSS's medical panel, which decided that the hospital was not to pay for the patient. The buck was being passed despite the medical ethics--taught to his medical students by HRH Prince Father Mahidol Adulyadej, Prince of Songkhla and the father of modern medicine of Thailand—affirmed that the interests of patients had to come first. Moreover, the basic principle of the SSS was to help, particularly those patients who could not afford to pay. The case in point became a tragedy because the medicines were highly priced, costing the patient an annual expense of about 1.3 million baht. Responsible parties were irresponsible. As the drug expenses were too high for the patient to pay, he had to turn to traditional medicines instead. When this patient's story was reported, Dr. Mongkol Na Songkhla, Minister of Public Health, invited the man to meet him. The required drugs provided by the drug company were given to him, but the disease had spread extensively because he had stopped his medication for a long time.

Such cases in point usually take place in Thailand and many developing countries, as well as the developed countries. It is one of the big problems for those conscientiously responsible. This prompted Dr. Sanguan Nitayarumphong, former secretary general of the National Health Security Office, who passed away recently from lung cancer, to propose that the Ministry of Public Health exercise government use of patent on four anti-cancer drugs since 25 September 2007. Due procedures were carried out and the government use of patent on the four drugs were eventually announced on 4 January 2008.

Gladly, the patent holders of Imatinib—used for the treatment of Chronic Myeloid Leukemia and GIST—decided to provide the drug to all of the 48 millions of patients under the Universal Coverage Scheme free of charge. Thus, the exercise of compulsory licensing on this drug was announced with a proviso. The remaining three anti-cancer drugs are used for the treatment highest prevalent cancers among Thai people, i.e., lung cancer in males and breast cancer in females.

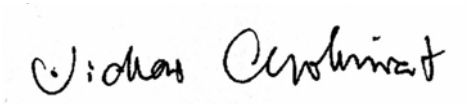
In summary, the differences between the original prices of the four drugs and the reduced prices of their generic versions can be compared, as follows:

1) Imatinib: from an annual expense of 1.3 million baht to almost free of charge for the patients under the Universal Coverage Scheme, except the very high-income earners;
2) Docetaxel: from 25,000 baht to around 4,000 baht per an injection (the Government Pharmaceutical Organization could negotiate for the final reduction of the price to 1,245 baht per injection);
3) Letrozole: from 230 baht per tablet to 6-7 baht; and
4) Erlotinib: from 2,750 baht per tablet to 735 baht.

It is evident that the patent holders, with market exclusivity, can set their drug prices as they please. But such rights on market exclusivity, do have limitations. According to the WTO's TRIPS Agreement, countries are permitted to exercise government use of patent to bring about a balance between the promotion of invention and the public access to innovation. Such permission was further reconfirmed in the Doha Declaration signed by ministers of commerce of over 140 WTO member countries, including the US. The Declaration entitles each country to exercise government use of patent in accordance with its appropriate reasons and needs. In the case that it is necessary to weigh commercial interests against public health, the Declaration reiterates that public health must take priority.

The implementation of the government use of patent on the four anti-cancer drugs was therefore genuinely carried out in compliance with international rules and Thai laws, for the public benefits and on humanitarian grounds.

This white paper provides all the facts relate to 10 burning questions regarding the implementation of the government use of patent of the four drugs. It is considered as a historical record for social learning and strengthening, to achieve more social equity and justice.



Dr. Vichai Chokevivat
Chairman, Committee to Support the Implementation of
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5 February 2008

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Question 1: What is the rationale for the implementation of the Government Use of Patents on the four anti-cancer drugs?

Cancer has been one of the top killers among Thai people for over a decade. It is the cause of more than 30,000 deaths annually in Thailand, with more than 100,000 new cases reported each year. Cancer is no less serious than HIV/AIDS. The leading types of cancer in Thailand are lung and breast cancer. There are many new "chemotherapeutic and targeted therapies" that have been developed in the last decade. Most of these new anti-cancer drugs are patented, costly, and cannot be accessed by the poor, nor by many members of the middle class. Many of these new drugs are not included in the National List of Essential Drugs (NLED) due to their high price, nor are they covered by the National Health Insurance system. Patients who try to pay their expenses out of pocket will soon face catastrophic illnesses and will bankrupt their family, or will have to stop taking the drugs due to financial constraint. These problems prompted the National Health Security Board to find ways to provide universal access to essential medicines without any financial barrier.

The implementation of the Government Use of Patents on the four anti-cancer drugs was based on the advice of the Subcommittee on Selecting Essential Drugs with Access Problems under the National Health Insurance schemes and was confirmed by the Committee to Support the Implementation of the Government Use of Patents. The only reason for the implementation of the Government Use of Patents is to *allow universal access to essential medicines by all the beneficiaries of the National Health Security System, which are all publicly financed schemes. This is the goal of the previous as well the new Thai Constitution of 2005, and the National Health Security Act of 2002.* The details of the rationale are as follows (information before negotiation by the Negotiation Committee):

1. The drug Docetexel (trade name Taxotere) is used to combat lung and breast cancer. The price of an 80 mg. injection for this patented medicine is 25,000 Baht, while the generic equivalent costs only 4,000 Baht, representing a price differential of more than 6 times the amount for a patented medicine than its generic equivalent.

2. The drug Letrozole (trade name Femara) is used to combat breast cancer. The price of one tablet of 2.5 mg. of the patented drug is 230 Baht, while the price of the generics are 6-7 Baht, representing a price differential of 30 times the amount for a patented medicine than its generic equivalent.

3. The drug Erlotinib (trade name Tarceva) is used against lung cancer. The price of one tablet of 150 mg. of the patented drug is 2,750 Baht, while the generic costs only 735 Baht, representing a price differential of more than 4 times the amount for a patented medicine than its generic equivalent.

4. The drug Imatinib (trade name Glivec) is used to combat Chronic Myeloid Leukemia and Gastrointestinal Stromal Tumor (GIST). The price of a 100 mg. tablet of the originator brand costs 917 Baht, while the generic version costs only 50-70 Baht, representing a price differential of almost 20 times the amount for a patented medicine than its generic equivalent.

In conclusion, these four essential anti-cancer drugs can be made available at prices ranging from 4 to more than 30 times lower than the patented products. These lower prices would be affordable to the National Health Insurance Schemes, which would provide the drugs to all who need them. This will further prevent untimely death, as well as catastrophic illnesses, among Thai people.

The Subcommittee on Selecting the Essential Drugs with Access Problems under the National Health Insurance schemes thus proposed a note (annex 1) to the Public Health Minister on September 25, 2007 to implement appropriate measures to increase access to these drugs. The minister then requested the opinion of the Committee to Support the Implementation of the Government Use of Patents. The committee met on October 2, 2007 and proposed the implementation of the Government Use of Patents on the four anti-cancer drugs, requesting that the Government Pharmaceutical Organization obtain good quality generics, and also asking the Food and Drug Administration to persuade the generic drug companies to register the four anti-cancer drugs (the Thai FDA has since issued a letter in keeping with the request – annex 2). The committee chair submitted a note to the Public Health Minister in keeping with the committee resolution of October 19, 2007 (annex 3). In spite of the fact that the Minister can immediately endorse the implementation of the Government Use of Patents on the four drugs, he has requested that the Committee to Negotiate for the Price of Essential Patented Drugs move on with the negotiation. The more than twelve rounds of negotiation went on for more than two months, with limited progress, which led to the final decision to implement the Government Use of Patents on the four drugs.

Question 2: Has there been any negotiation with the patent-owners before deciding to implement the Government Use of Patents on the four anti-cancer drugs?

It should be noted that, according to Article 31(b) of the Agreement on Trade-Related Aspects of Intellectual Property Rights under the WTO, and Article 51 of the Thai Patent Act, in the case of public, non-commercial use, any ministry, bureau, or department can implement the government use of a patent without the requirement to negotiate with the patent-owner. This has been confirmed by paragraphs 5(b) and (c) of the Doha Ministerial Declaration on the TRIPS Agreement and Public Health, which gives WTO members the right to determine under which condition to implement the government use of a patent.

Nevertheless, to allow patent-owners the opportunity to offer appropriate proposals to promote universal access to these four essential anti-cancer drugs, the Public Health Minister decided to request that the Committee to Negotiate for the Price of Essential Patented Drugs enter into discussions with the patent-owners, beginning in mid-October, 2007. Some significant progress has been achieved after more than two months of more than 12 rounds of serious negotiation, including:

1. Docetexel. The patent-owner revised its offer two to three times, and the last offer might have brought the price down to around one-third of the original price. However, there were some unpractical conditions for the proposal. For example, the patent-owner proposed to pay for the fourth to sixth round of treatments, with the government paying for the first three to four rounds. This is difficult to implement for each patient, and there is no way to know how much the price can be reduced. The committee has requested that the patent-owner come up with a net reduced price of the drug. The final proposal from the company came on December 20, 2007, with a proposed donation of twice the amount purchased. However, the agreement included the conditions that the drug had to be put into the National List of Essential Drugs and there was to be a minimum amount of annual purchase. Although this proposal may have allowed a price reduction down to one-third of the original price, this is still much higher than the price of generics. The final offer from the generic company to the Government Pharmaceutical Organization of Thailand on February 5, 2007 was 4.7 percent of the original product's price.

2. Letrozole. The company provided several proposals with some donation of drugs based on amount of purchase. The last proposal came on December 17, 2007, when it was proposed that the patent-owner would donate an equal amount of drugs purchased, with the condition that purchases had to total at least 60,000 boxes per year. Nevertheless, the Committee found that the price proposed was still higher than the price that the National Cancer Institute receives, and was still much higher than generic prices.

3. Erlotinib. The company only agreed to attend negotiations once out of five invitations. However, the patent-owner proposed on December 21, 2007 to reduce the price to 30 percent, with the condition that the drug had to be put into the National

List of Essential Drugs and made reimbursable by all schemes of National Public Health Insurance**.**

4. Imatinib. The initial offer was that the patent-owner would pay for the last 9 months and the government pay for the first three months in a year. The patent-owner would also abolish the Glivec International Patient Access Program (GIPAP) in Thailand. This was not accepted by the Committee. The second proposal was that the patent-owner would allow all patients under the Universal Health Insurance Scheme (the Gold Card Scheme) to apply for assistance under the GIPAP, under the condition that the patient is uninsured and that their household annual income does not exceed a certain level. The level of household income as reported by one oncologist was three times the Gross Domestic Product per capita (or around 300,000 Baht). This condition would have put around 10 million people out of the GIPAP system, which is not acceptable.

In summary, the negotiations have not been successful to the point of fulfilling the conditions that allow National Health Insurance Schemes to provide universal access to these four anti-cancer drugs without undue financial burden. Furthermore, the administrative burdens from the conditions proposed by the patent-owners are also very problematic.

The chairman of the Committee to Support the Implementation of the Government Use of Patents further proposed that the Public Health Minister sign the four Notifications of the Government Use of Patents on the four anti-cancer drugs on December 28, 2007 (annex 4). *The Public Health Minister signed the 4 notifications (annex 5-8) on January 4, 2007. However, to allow for the last chance of negotiation, the minister has decided to defer the implementation of the notifications and request the Negotiation Committee to move forward for further negotiation. The results of this final negotiation are as follows:*

1. Novartis proposed on January 18 and confirmed on January 23, 2008, to allow all patients under the universal health insurance scheme, whose household income is less than 1.7 million Baht per year and need 400 mg. of Imatinib per day, or whose income is less than 2.2 million Baht per year and need 600 mg. of Imatinib per day, to have free access to Imatinib, if indicated by the attending physicians (annex 9). This condition essentially put all the patients under the universal health coverage scheme into the GIPAP system. So there is no further need to implement the Government Use of Patents on this drug. However, to ensure continuity and sustainability of this commitment from Novartis, a conditional Government Use of Patent was proposed. A new draft of the Ministerial Notification to implement the Government Use of Patent on Imatinib on the condition that the GIPAP fails or is terminated was proposed to the Minister.

2. The other three drugs did not propose any new offer, while the generic drug companies proposed further price reduction. Thus, the committee proposed that the minister endorse the implementation of the notifications signed on January 4, 2008.

More details appear in the note from the Chairman of the committee to the Public Health Minister on January 25, 2008 (annex 10). *The Public Health Minister endorsed the proposal to implement the previously signed notifications, except for*

Imatinib, and also signed a new notification on the conditional Government Use of Patent on Imatinib (annex 11).

It is thus very clear that, in spite of the fact that the international and Thai legal frameworks do not require prior negotiation, the Thai Ministry of Public Health has tried its best to move in the constructive direction of negotiating with patent-holders. The success in the case of Imatinib is a good example.

Furthermore, even after the notification has been signed, the Ministry still goes on to negotiate with the patent-holders. If any patent-holder can provide the drugs at a price within 5 percent of their generic competitors, the Ministry will buy from the patent-holders, in spite of the higher price. This 5 percent is meant to reward the loyalty of the patent-holders, and has been used also in the previous three Government Use of Patents. This 5 percent credit point system will be implemented only when the negotiation fails and the ministry has to sign an official notification.

Question 3: Why did the health minister make the decision during the tenure of the interim government? Could he have waited for the new minister to make the decision?

From the detailed information in questions 1 and 2 above, it is clear that the process to decide upon the Government Use of Patents on the four anti-cancer drugs started in September 2007. However, the public health minister wanted to create a constructive environment and partnership with the patent-holders, and tried to avoid the implementation on the Government Use of Patents. This is evidenced by the extensive and intensive negotiations conducted by the Ministry resulting in the success in the case of Imatinib. So this is not a new policy or movement. It is, rather, the continued implementation of the established policy of universal access to essential drugs.

The issue of Government Use of Patents is a complex one. It will take much more time for the new public health minister to understand and make the decision. The patients have been waiting since October 2007 for their access to these drugs. If the decision can only be made by the entry of the new government, the patients will have to continue to wait without the hope of access to these drugs.

Question 4: What are the reasons for the Health Minister's recent visit to India? Has there been any agreement with any Indian generic drug company on the procurement of the generic version of the patented drugs that may be considered as conflict of interest?

To ensure that generic drugs imported from India are of high quality, the Public Health Minister (Dr. Mongkol Na Songkhla) has visited the Indian drug manufacturers twice.

The first visit was December 15 to 18, 2007. This was to visit the factories of Emcure Pharmaceuticals, Hetero Drugs, Dr. Reddy Laboratories, Netco Pharma, and the Serum Institute of India.

The second trip was on January 8 to12, 2008. This was to visit the Dabur Company, which produces anti-cancer drugs.

There have been no agreements or Memoranda of Understanding (MOU) signed with any of the Indian drug firms during the two visits. The cost of travel was also paid by the Ministry's and the Government Pharmaceutical Organization's budgets, not by any of the drug companies.

The Minister and the technical team were highly impressed by the high quality standard of the Indian drug factories, and also learned that some of these companies have registered their drugs with the U.S. FDA.

The procurement of generic drugs under the Government Use of Patents is governed by the Government Pharmaceutical Organization procurement rules and regulations. It has to go through a transparent system of open bidding, in which the Public Health Minister has no role or involvement at any step, and there has not been any conflict of interest.

Question 5: Is it true that Thailand plans to implement the Government Use of Patents systematically on all patented drugs?

Since 1992, when Thailand revised its Patent Act to include product patents due to the pressures from the USTR, it is estimated that there have been more than 200 patented drugs registered with the Department of Intellectual Property in the Ministry of Commerce. It is very difficult to know exactly how many patented drugs exist, as the patents are approved in the Thai language and the search is next to impossible. Nevertheless, only seven drugs have been considered for the implementation of Government Use of Patents. This is less than five percent of the total patented drugs. This is clear evidence that the Thai Public Health Ministry implements the Government Use of patents only when truly necessary, not on a routine basis. The decision has to go through the three participatory mechanisms, or committee/subcommittee. This is the strategy to create a transparent and participatory process, and also to allow for negotiation with the patent-holders based on a constructive approach. This may retard the access to essential drugs of the Thai people to a certain extent, but it allows for peaceful solutions.

The three mechanisms that are established to consider each step of the implementation of Government Use of Patents are to ensure transparency, participation, and to generate systematic and constructive approaches. This is to avoid criticism that over processes being 'unilateral', 'non-participatory', and 'non-transparent', 'non-prudent', and 'overused'.

Furthermore, the Ministry of Public Health has also appointed a joint committee between the Ministry and the industries, i.e. PReMA, to provide recommendations for the sustainable development of the healthcare system (annex 12). This is meant to be a prospective and constructive forum for participatory discussion. The committee has agreed on the three objectives (annex 13):

1) Improvement of the access to essential medicines for low-income people.
2) Reduction of the country's neglected health problems.
3) Strengthening the national health system's development capacity.

Further decisions on which other drugs are in the pipeline for possible implementation of the Government Use of Patents depends on the consideration of the Subcommittee, and will be further dealt with by the other two committees. There are two main criteria for their consideration, i.e.:

1. Drugs and medical supplies within the National List of Essential Drugs, or that are necessary to solve public health problems, or necessary to use in emergencies or epidemics, or to save lives.

2. There are problems in access to those drugs and medical supplies, as well as creating a high financial burden that the National Health Insurance Systems cannot afford.

Question 6: How does Thailand intend to improve the decision-making processes to implement the Government Use of Patents in order to make it more transparent?

We have formally and informally requested advice from our trade partners who had concerns on the transparency of implementation. We would like to learn which steps are not transparent, and are ready to improve. However, so far we have not received any advice, verbally or officially. The only critique that we have heard is that we enter into discussion with the patent-holders, which we have already done, since before the first batch of the Government Use of Patents between 2004 and 2006. The result in the case of Imatinib is a good example of our attempts in this area.

We have also requested that the Director General of WHO, based on the World Health Assembly resolution WHA 60.30, send a team of technical experts from WHO, together with relevant organizations like WTO, UNCTAD, and UNDP, to analyze our implementation processes and provide technical guidance for better and more transparent processes. This group of experts worked in Thailand from February 4 to 6, 2008 and met with all relevant stakeholders. The expert group has presented a very good report, which provides systematic approaches toward implementing TRIPS flexibilities for increased access to essential medicines, as well as other possible non-TRIPS-related strategies. *The group has not described any non-transparency of the processes that Thailand has implemented with the Government Use of Patents. Thailand has actually implemented all the necessary steps suggested in the report. Some actions, like the prior negotiation, were more than what suggested in the report.* The report also advises Thailand to apply TRIPS flexibilities both before and after granting the patent.

The implementation of the TRIPS flexibilities may be a normal practice in developed countries, but they are quite new for developing countries like Thailand. So we should regard this movement as a social innovation to achieve better access to essential medicines, and as a learning experience to strengthen social understanding of the issue. It should be used as a mechanism to engage constructively all stakeholders, including the patient groups, the drug industry, the other public sectors, and relevant IGOs, to solve the problem of inadequate access to essential medicines under the universal health care policy.

Question 7: Will this decision be a reason for the USTR to consider moving Thailand from the Priority Watch List to the Priority Foreign Country list, and if so, how is this going to affect Thai exports to the U.S.?

The rationale behind moving Thailand from the status of Watch List (WL) to Priority Watch List (PWL) last July was mainly due not to the implementation of the Government Use of Patents, but was based more on inadequate enforcement for the protection of other forms of intellectual property, such as the illegal production and distribution of optical disc media, books, and entertainment and business software. For the implementation of the Government Use of Patents on drugs, the concern was on transparency and due process, which had never been clarified on any specific point, so far, except to request that Thailand negotiate with the patent-holders. The discussions with the patent-holders have been carried out intensively, as described in questions 1 and 2. The success in the case of Imatinib shows that it is possible to achieve a good and constructive solution, if the patent holder has a real commitment to support the Thai people's right to universal access to essential drugs under the universal health care scheme.

The U.S. Trade Act, Article 301, provides conditions for listing trade partners as Priority Foreign Countries when it shows *the most onerous and egregious acts, policies, and practices which have the greatest adverse impact (actual or potential) on the relevant U.S. products.*

The implementation of the Government Use of Patents on seven essential drugs complied completely with the international and national legal framework. Furthermore, the four anti-cancer drugs for which Thailand decided to implement the Government Use of Patent are all non-U.S. products. Thus, the USTR does not have any basis for putting Thailand on the Priority Watch List as regards the issue of Thailand's decision to implement the Government Use of Patents.

If there is still concern over the lack of transparency and due processes, then Thailand will need to be advised clearly and specifically on how to improve in these areas.

The data from the Ministry of Commerce shows that the value of export of those goods whose GSP were abolished in last July continue to increase, not decrease. All evidence indicates that the significance of the GSP in supporting Thai exports to the U.S. is constantly declining, and will gradually be totally abolished or minimized in the near future. On the contrary, the negative implications on the access to essential medicines from the market exclusivity of the patented products are increasing, and will generate more and more obstacles to the access of essential medicines in the near future.

Question 8: The Prime Minister instructed the Ministry of Public Health to hold further discussion with the Ministry of Commerce and the Ministry of Foreign Affairs regarding Thailand's position on the implementation of compulsory licensing for government use. Has this happened, and what was the outcome?

The Ministry of Public Health (MoPH) on August 24, 2007, held a discussion with the Ministry of Commerce and the Ministry of Foreign Affairs regarding Thailand's position on this issue. Participants were from the Ministry of Commerce, the Ministry of Foreign Affairs, the National Health Security Office, the Ministry of Labour, the Ministry of Science and Technology, the AIDS Access Foundation, the Thai Network of People Living with HIV/AIDS, the Cancer Care Network and Oxfam, Great Britain. The meeting reached a consensus as follows (annex 14):

1) Thailand honors its obligation under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and the Doha Declaration on the TRIPS Agreement and Public Health. *However, it is stated in the Agreement and the Declaration that in the circumstances of public health crises, or where the public interest arises, public health interest shall be given priority and put before trade interest, and that the WTO members have the right to use TRIPS flexibilities and the freedom to determine the grounds upon which such flexibilities are used;*

2) The Thai government has an obligation under the Constitution of Thailand B.E. 2550 and the National Health Security Act B.E. 2545 to ensure that all Thais have access to medicines listed on the National List of Essential Medicines. This is achievable through various measures such as budget raises and the promotion of the rational use of drugs, including the use of flexibilities granted under the TRIPS Agreement, the Doha Declaration and the Thai Patent Act B.E. 2522 as amended by the Patent Act (No.2) B.E. 2535 and the Patent Act (No.3) B.E. 2542;

3) Thailand has a policy of using TRIPS flexibilities embodied in the TRIPS Agreement, the Doha Declaration and the Thai Patent Act *only when necessary*. This is to achieve our ultimate goal of availability of essential medicines for our people, according to the right conferred under the National Health Security Act. However, the measures will be *implemented with due consideration and not in an indiscriminate manner or for frivolous reasons.* Furthermore, negotiations with pharmaceutical companies will be built on respect for our mutual interest in bringing improvements to Thailand's public health services.

4) Section 51 of the Thai Patent Act defines the right of the Minister, Permanent Secretary and Director-General of any ministry, bureau or department of the Government to issue a compulsory license in order to carry out services for public consumption, and in case of urgency, e.g., to increase access to essential medicines for the Thai people. Therefore, *it is not possible for anyone to announce or commit to any person or country that Thailand will not implement the Government Use of Patents on pharmaceutical patents in any circumstances.* Doing so is deemed to be a neglect of

duty or failure to exercise the rights established by the law to safeguard public interest and public health, and can incur a criminal charge.

5) There is no country or government in the world that would renounce its rights to implement a Government Use of Patents on any drug patent. On the contrary, developed countries grant more compulsory licenses than developing countries.

In addition, in late December 2007, the Ministry of Commerce advised the Deputy Prime Minister and Industry Minister, H.E. Kosit Panpiemras, to hold discussion between three ministries - the Ministry of Public Health, the Ministry of Commerce and the Ministry of Foreign Affairs - about the implementation of the Government Use of Patents by the Thai government. The meeting was scheduled on January 3, 2008. The Ministry of Public Health's officials, led by Dr. Vichai Chokewiwat, Advisor to the Public Health Minister, Chair of the Government Pharmaceutical Organization (GPO) Board and Chair of the Committee to Support the Implementation of the Government Use of Patents, and Dr. Siriwat Tiptaradol, Secretary General of the Thai Food and Drug Administration (FDA), and their team, who were vested **with full powers and duties**, had planned and held several meetings in preparation for the discussion. Unfortunately, however, the discussion was postponed without a new date set.

Question 9: How can we be sure that the drugs obtained under the Government Use provision will not slip through the system into the market, or how will we prevent the practice of diversion, i.e. patients selling the drugs to pharmacies or private hospitals?

The four compulsory licensed drugs are anti-cancer drugs, of which over-the-counter sale is strictly prohibited. They are available by medical prescription only and must be prescribed by specialist doctors. Moreover, they are live-saving drugs for cancer patients. Some of them are intravenous medications which must be administered by doctors or specialist nurses. So, there should be no worry that patients who will receive these licensed drugs under the national health security system will sell the drugs to pharmacies. Doing so will only do harm to their lives, for they will have traded their live-saving medications. Furthermore, no pharmacy will buy them because it is illegal; they are prescription-only medicines, and hence are not available for sale or distribution as mentioned above.

For hospitals, these drugs will be supplied to contracted hospitals under the national health security system only. Non-contracted private hospitals will not be able to buy these licensed drugs from the Government Pharmaceutical Organization (GPO). In addition, these drugs are dispensed under strict control, and every prescription is recorded to ensure transparency and accountability. This is to prevent the drugs from slipping through the system. It is quite certain that the drugs obtained under the Government Use provision for public consumption under the national health security scheme will not be used for commercial purposes, which is inconsistent with the Thai patent law and international agreement on intellectual property rights.

All the drugs licensed under the Government Use provision for use in the National Health Security Office's universal health scheme are procured by the Government Pharmaceutical Organization (GPO) under its aggregate drug procurement plan (bulk purchasing) and dispensed under the **Vendor Managed Inventory (VMI)** system. GPO will procure the drugs and supply them according to the demand of each hospital, to make sure that all the licensed drugs will not slip through the system.

Question 10: As anti-cancer drugs are live-saving drugs, how can we be certain that the generic copies of these drugs will be equivalent in quality to the patented products?

The World Health Organization (WHO) has a system of prequalification only for anti-retrovirals, anti-TB and anti-Malaria drugs. The system does not cover other drugs, including anti-cancer drugs. As a result, the drug quality assurance of these generic copies, whether derived from the Government Use provision or not, is subject to Thailand's drug qualification standards as well as the quality control of the companies and the competent officials of the exporting countries. The Thai drug qualification standards are follows:

1) Drug registration system: the Department of Medical Science and the Food and Drug Administration (FDA) are responsible for drug registration. They also have established a specific drug approval process for generic copies derived from the Government Use provision to ensure fast and rigorous implementation. They expedite the approval process and carry out rigorous examination of applications and drug samples, even by visiting generic drug manufacturing facilities in India to evaluate their manufacturing standards and quality;

2) Post-import surveillance system: the Government Pharmaceutical Organization (GPO) conducts quality surveillance of randomized samples of imported drugs to ensure drug quality before distributing them to hospitals. It also regularly performs quality surveillance of randomized samples of drug products stored in hospitals' warehouses;

3) Drug quality reporting system: medical professionals who prescribe these drugs can report any quality problems with the imported drugs to the Food and Drug Administration (FDA) immediately, and the FDA will take immediate action to investigate the problems and collect the drug samples for further analysis.

Through these rigorous and ongoing quality control systems, we are confident that the drugs imported under the Government Use provision are equivalent in quality to the patented products.

Annex 1

Unofficial Translation

No. NHSO 05/013521

25 September 2007

Subject: Increased access to medicines
Attachments: 1) Comparison table of anti-cancer drugs whose access should be increased
2) Justification for the selected list of anti-cancer drugs whose access should be increased

Dear Honorable Minister of Public Health,

The Subcommittee on Selecting the Essential Drugs with Access Problems under the National Health Insurance schemes organized its meeting on 20 September 2007. The meeting examined a list of anti-cancer drugs with difficulties in access. More details of these drugs are shown in Attachment 1).

The Subcommittee would like to inform Your Excellency that according to the examination of the list of anti-cancer drugs, access to four items of them should be improved on the grounds described in Attachment 2, as follows:

1) Imatinib (under the trade name Glivec™), for the treatment of chronic myeloid leukemia and GIST;
2) Docetaxel (under the trade name Taxotere™), for the treatment of lung and breast cancers;
3) Erlotinib (under the trade name Tarceva™), for the treatment of lung cancer; and
4) Letrozole (under the trade name Femara™), for the treatment of breast cancer.

Please kindly be informed and consider appropriate decisions for further operation.

Yours truly,

(Mr Sanguan Nitayarumphong)
Chair of the Subcommittee on Selecting the Essential Drugs with Access Problems
under the National Health Insurance schemes

Bureau of Policy and Plan
Tel: 02 8314000 Ext. 8601, Fax: 02 831 4004
Responsible person: Mrs Narisa Muntangoon

(*Translation from the handwritten texts)*
"Assign Mr. Vichai and Mr. Siriwat (Chairman of the Committee to Support Implementation of Government Use of Patent and Committee on Price negotiation of patented essential drugs, respectively), please take appropriate actions".

Mr. Mongkol Na Songkhla, Minister of Public Health, signed on 25 September 2007.

Comparison table of anti-cancer drugs whose access should be increased

Name	Original name/ owner	Indication	ED/ NED	2005 Sale		2006 Sale		Presentation	Price (Baht/unit)		Distributor (in India)
				Total sale (mB)	Sale rank	Total sale (mB)	Sale rank		Original	Generic	
1. Rituximab inj.	Mabthera®/ Roche	Lymphomas	NED	226.6	29	172.3	62	10 ml vial	15,631	Around 50% of original price	Dr.Reddy's
2. Imatinib tab.	Glivec®/ Novartis	Leukemia, GIST	NED	204.9	40	255.5	32	100 mg tab	917	50.2 58.6 70.0	Abil Natco Dabur
3. Capecitabine tab.	Xeloda®/ Roche	Colorectal cancer	ED	153.5	56	206.2	48	150 mg tab 500 mg tab	- 158.72	- 105	- Dabur
4. Gemcitabine HCl inj.	Gemzar®/ Eli Lilly & Co.	Pancreatic cancer	ED	144.1	66	159.6	70	200 mg vial 1 g vial	2,171.03 10,356.50	900 3,200	Dabur Dabur
5. Docetaxel inj.	Taxotere®/ Sanofi Aventis	Breast & Lung cancer	NED	144.0	67	164.5	67	20mg/0.5ml vial 80mg/2ml vial	7,030 25,000	1,800 4,000	Dabur Dabur
6. Gefitinib tab.	Iressa®/ Astrazeneca	Lung cancer	NED	130.2	85	31.7	149	250 mg tab	2,183	227.5 256.13	Abil Natco
7. Erlotinib tab.	Tarceva®/ Roche	Lung cancer	NED	na	na	na	na	50 mg tab 100 mb tab 150 mg tab	- - 2,750	260.75 485.33 735.58	Abil Abil Abil
8. Letrozole tab.	Femara®/ Novartis	Breast cancer	ED	na	na	56.4	138	2.5 mg tab	230	6.71 6-7	Abil Cipla

Justification for the Selected List of Anti-cancer Drugs Whose Access Should Be Improved

Cancer is now Thailand's number one killer, with the highest mortality rate. Although the knowledge of its prevention has been widely disseminated, cancer incidence rate still cannot be put under control. While many effective anti-cancer drugs have been invented covering a variety of cancers, but access to these drugs are very difficult due to their exorbitant prices. Therefore, the Ministry of Public Health should pay special attention to find ways to improve the access to this group of medicines.

Lung and breast cancers have the highest incidence among the Thai men and women, respectively. Effective anti-cancer drugs are available for the treatment of these two types of cancer. The drug for treatment of breast cancer, in particular, is recommended as the first line drug on the National List of Essential Drugs. As for Chronic Myeloid Leukemia and Gastrointestinal Stromal Tumors (GIST), although not at the top priority, effective specific drug is available and cannot be replaced by other medicines.

Imatinib (under the trade name Glivec™) is used for the treatment of Chronic Myeloid Leukemia and GIST. Docetaxel (under the trade name Taxotere™) is used for the treatment of lung and breast cancers. Erlotinib (under the trade name Tarceva™) is used for the treatment of lung cancer and Letrozole (under the trade name Femara™) is used for the treatment of breast cancer.

These four medicines are patented and thus so highly priced that they are difficult to obtain. A 100-mg tablet of Glivec™ costs 917 baht whereas an 80-mg injection of Taxotere™costs 25,000 baht. A tablet of 150-mg of Tarceva™ is priced at 2,750 baht and a 2.5-mg tablet of Femara™ sells at 230 baht. It was found that the patients under the national health security system could hardly get access to these four drugs. At the same time, the generic versions of these medicines are produced in some countries at much lower prices. A 100-mg tablet of the generic Imatinib (equivalent to Glivec™) sells for only 50.2 baht while an injection of the 80-mg generic Docetaxel (equivalent to Taxotere™) costs just 4,000 baht. A tablet of 150 mg of the generic Erlotinib (equivalent to Tarceva™) is priced at only 735.58 baht, and a 2.5-mg tablet of the generic Letrozole (equivalent to Femara™) sells at 6-7 baht.

Under the medical welfare system of civil servants and government employees, the Controller General's Department designates two of the four cancer drugs-- Imatinib (Glivec™) and Erlotinib (Tarceva™) as drugs that require pre-authorization because of their high expenses. Therefore, the Subcommittee on Selecting the Essential Drugs with Access Problems under the National Health Insurance schemes recommends that the Ministry of Public Health find an effective way to enable the people to get increased access to these four medicines.

Annex 2

Unofficial Translation

Notification of the Thai Food and Drug Administration
Re: Registration of Four New Generic Drugs

To increase accessibility of anticancer drugs to patients suffered from cancer, which is a significant public health concern in Thailand, followings anticancer drugs that meet standard of quality and have reasonable prices are needed: 1) Imatinib; 2) Docetaxel; 3) Erlotinib; and 4) Letrozole.

Therefore, the Thai Food and Drug Administration (FDA) invites all pharmaceutical companies, which are interested in either manufacturing or importing the 4 aforesaid generic drugs, to submit their registration dossiers or documents as requested by the Thai FDA to the Drug Control Division through the Accelerated or Priority Review Process for New Generic Drug Registration as stated in the Notification of the Thai Food and Drug Administration Re: Registration of New Drugs and New Generic Drugs dated August 3, 2004.

It is hereby announced.

Given on the 12th Day of December B.E. 2550 (2007)

(Singed) Siriwat Tiptaradol
(Mr. Siriwat Tiptaradol)
Secretary-General
Thai Food and Drug Administration

Annex 3

Memorandum

Office: Technical Support Team **Tel:** 0-2590-2040 **Fax:** 0-2591-8496
No. SorTor 0100/TST/Special **Date:** 19 October 2007
Subject: Increased access to medicines

H.E. Dr. Mongkol Na Songkhla
Minister of Public Health
Ministry of Public Health
Muang District, Tiwanont Road
Nonthaburi 11000
Thailand

Your Excellency,

The Subcommittee on Selecting the Essential Drugs with Access Problems under the National Health Insurance schemes proposed to the Minister of Public Health, via the letter from the National Health Security Office (NHSO) no.NHSO 05/013521 dated 25 September 2007, to find effective ways to improve the accessibility of 4 anticancer drugs. The proposed list includes 1) Imatinib for the treatment of Chronic Myeloid Leukemia and Gastro-Intestinal Stromal Tumours (GIST); 2) Docetaxel for the treatment of lung and breast cancers; 3) Erlotinib for the treatment of lung cancer; and 4) Letrozole for the treatment of breast cancer.

In this regards, the Committee to Support the Implementation of the Government Use of Patents would like to report to Your Excellency that the NHSO's proposed list and its related information were considered in the Committee Meeting (7/2550) on 2 October 2007. The Committee resolved and would like to propose to Your Excellency that the accessibility to the 4 proposed drug items should be improved using Government Use of Patent as a tool. In addition, the Committee has suggested that the Government Pharmaceutical Organization (GPO) searches for the sources of the 4 aforesaid generic drugs that meet quality standard with reasonable prices; whereas the Thai Food and Drug Administration (FDA) invites all interested pharmaceutical companies to submit their registration dossiers of the 4 drugs to the FDA for market authorization in order to establish a competitive market for these drugs.

Your Excellency, please be kindly informed of the committee's resolution and proposal, and kindly consider appropriate assignments for further actions. Please accept, Your Excellency, the assurances of my highest esteem.

Sincerely yours,

(Mr.Vichai Chokevivat)
Advisor to the Minister of Public Health
Chairman, Committee to Support the Implementation of
the Government Use of Patents

(Translation from the hand-written text)
"Assign the Chairman of the Price Negotiation Committee (Secretary General of the Thai FDA) to act according to the appropriate processes".

Mr.Mongkol Na Songkhla, Minister of Public Health, signed on 20 October 2007.

Annex 4

Memorandum

Office: Technical Support Working Group **Tel:** 0-2590-2040 **Fax:** 0-2591-8496
No. SorTor 0100/TST/Special **Date:** 28 December 2007
Subject: Signing in the notification on the Government Use of Patent on Four Anti-cancer Drugs

Honorable Minister of Public Health,

According to the letter, dated 25 September 2007, the National Health Security Office has proposed to the Minister of Public Health to find effective ways to improve the access to 4 essential anti-cancer drugs, and Your Excellency has entrusted the Committee to Support the Implementation of the Government Use of Patents to consider the matter. After due consideration, the Committee proposed to Your Excellency according to its letter numbered SorTor 0100/TST/Special and dated 19 October 2007, that the government use of patent be implemented on all four items. Your Excellency gave instructions on 20 October 2007 assigning the Committee on Price Negotiation of the Patented Essential Drugs to take further appropriate actions.

So far, the Committee on Price Negotiation of the Patented Essential Drugs has already negotiated with Sanofi Aventis, Novartis and Roche for a total of 12 times over the period of three months, as follows:

1) On Imatinib, Novartis did not offer to lower its price, but offered to give the drug free of charge to the patients under the Universal Coverage (Gold Card) health insurance scheme. The offer was in line with the condition of the Glivec International Patient Assistance Program (GIPAP), operated by Max Foundation. Such conditions were based on the following two principles.

1.1 The patients' expenses are not funded by any health insurance scheme; and

1.2 The patients' household income must not be higher than the set limit, which was three times the per capita GDP (information from a chemotherapist from a medical school who is familiar with this program).

Such offer is a status quo proposal. Furthermore, as the National Drug List Committee is considering including Imatinib in the list, which will become part of the benefit package of the Gold Card scheme. In effect, this will disqualify the Gold Card holders to the GIPAP, as regards condition 1.1. Even though condition 1.1 is waived by the company (which is practically difficult because of the international nature of the program), still there are about 10 million Thais that will not meet the requirement of condition 1.2. The case in point was a middle class engineer suffering from GIST, who could not afford to pay for the medicine and had to stop taking it which resulted in worsening of his illness, as previously informed.

A generic drug, produced by Dabur Company in India, and is applying for registration with the Food and Drug Administration, costs only 170 baht per one tablet of 400 mg, compared with the price of 3,427 baht of a tablet of similar dose of the original drug.

It is therefore deemed reasonable to exercise Government Use of Patent on Imatinib, as initially proposed by the Committee.

2) On Docetaxel, Sanofi Aventis proposed many conditions. Among them were an annual number of patients must be at least 1,500; the medicine must be included in the National List of Essential Drugs. The price of the 80-mg drug will then be reduced from 25,000 baht to around 3,750 baht (inclusive of premiums), which will be difficult to manage. This offer is based on an annual contract basis, which can be changed anytime. The net price of a generic drug from India is not more than 2,500 baht, which can be further lowered without any conditions attached.

If the Ministry of Public Health accepts Sanofi Aventis's conditions, it will not be able to buy the generic drug that costs almost 50% lower and in the following years, the company could ask for a higher price or reduce the premiums, as the contract is signed on a yearly basis and there is no competition. In addition, it is difficult to manage because the price of the medicine is inclusive of premiums.

So it is considered appropriate to exercise Government Use of Patent on Docetaxel, as initially proposed by the Committee.

3) On Letrozole, Novartis offered to reduce the price from 230 baht per tablet to 150 baht on condition that an annual purchase of the drug must be at least 60,000 boxes. Meanwhile, a generic version of the medicine, produced by Dabur Company and is applying for registration with the FDA, is priced at 21 baht per one tablet, seven times cheaper.

It is thus deemed appropriate to exercise Government Use of Patent on Letrozole, as initially proposed by the Committee.

4) On Erlotinib, Roche proposed to lower the price of its 150-mg tablet from 2,750 baht to 1,925 baht while India's generic version sells at 700 baht (not yet negotiated) per tablet, nearly three times cheaper.

So it is considered reasonable to exercise Government Use of Patent on Erlotinib, as initially proposed by the Committee.

Please be informed and kindly approve and sign the four ministerial notifications as attached.

(Dr Vichai Chokevivat)
Advisor to the Minister of Public Health
Chair of the Committee to Support the Implementation of the Government Use of Patents

(Translation from the hand-written text by the minister)

- Approved;
- Signed; and
- Please defer the implementation of these notifications to allow the Committee on Price Negotiation of the Patented Essential Drugs to have another chance of final negotiation.

(Mr Mongkol Na Songkhla)
Minister of Public Health
Signed on 4 January 2008

Annex 5

Unofficial Translation

Notification of the Ministry of Public Health
Re: Exercising of Right on Pharmaceuticals Products Patent for Docetaxel

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By virtue of section 51 of the Patent Act, B.E. 2522 (1979) as amended by the Patent Act (No. 2), B.E. 2535 (1992) and the Patent Act (No. 3), B.E. 2542 (1999), any ministry, bureau or department of the Government may, by themselves or through others, exercise any right under section 36 by paying a royalty to the patentee or his exclusive licensee under paragraph 2 of section 48 and shall notify the patentee in writing without delay, notwithstanding the provisions of section 46, section 47, and section 47 bis.

The objective of this provision is explicitly expressed that all public non-commercial activities, such as public health services, may lawfully exercise such right without the need for prior negotiation with the patent holder and without the requirement to follow the processes as specified in section 46, section 47, and section 47 bis.

Cancers have been continuously ranked among the top leading causes of death in Thailand for many years. Patients face both suffering from seriousness of the diseases and treatment as well as the high cost of treatment, including operation, radiation, and especially chemotherapy. These are serious burden, in particular economic burden, to patients and their families. Many low and middle-income families face serious financial catastrophe or even bankruptcy.

Lung and breast cancer are the top cancers among Thai male and female, respectively. At present, Docetaxel or the trade name Taxotere® in Thailand has clearly been reported effective for treatments of the 2 cancers.

In addition, Docetaxel is also used effectively to treat gastric cancer, and head and neck cancers. Therefore, the drug is very important for many cancer patients. However, it is very expensive because of its patent protection which enables the patent holder to have market exclusivity without competition. Either Government Pharmaceutical Organization or other pharmaceutical manufacturers cannot domestically produce or import the drug to be distributed and used in Thailand.

Although the Ministry of Public Health could immediately exercise the right under any patent by virtue of section 51 of the Patent Act, the Ministry of Public Health did try with all means to negotiate with the patent holder for several months. The negotiation, however, could not reach an agreeable solution. Although price reduction was offered, they are still much higher than prices of the generic companies, and conditions offered by the patent holders would also post many hurdles to the drug management system. The Ministry of Public Health, hence could not let cancer patients under the 3 health insurance schemes wait for a cheaper- or reasonable-priced drug without time limitation.

Therefore, the Ministry of Public Health, hereby notifies, by virtue of section 51 of the Patent Act, B.E. 2522 (1979) as amended by the Patent Act (No. 2), B.E. 2535 (1992) and the Patent Act (No. 3), B.E. 2542 (1999), that it is now exercising the right under drug patent of drugs contain Docetaxel in all formulations, including its derivatives patented in Thailand. In this regard, the Ministry of Public Health entrusts the Government Pharmaceutical Organization to exercise the right in its name in accordance with section 36 paragraph 1 of the Patent Act, B.E. 2522 (1979) as amended by the Patent Act (No. 2), B.E. 2535 (1992) and the Patent Act (No. 3), B.E. 2542 (1999) subject to the following conditions:

(1) the right shall be exercised from now on **until the patent expired or no essential need** on the drug;

(2) the exercise of the right is limited to provision of drugs having the aforesaid generic name to unlimited number of patients who are entitled persons under the National Health Security System Act, B.E. 2545 (2002), insured persons under the Social Security Act, B.E. 2533 (1990) and persons entitled to medical benefits for civil servants and government employees scheme;

(3) a royalty fee of 3 per cent of the total sale value of drug having the aforesaid generic name by the Government Pharmaceutical Organization shall be paid to the patent holder.

The Ministry of Public Health, shall notify the patent holder and the Department of Intellectual Property for information without delay.

It is hereby announced.

Given on the 4th Day of January B.E. 2551 (2008).

(singed) Mongkol Na Songkhla
(Mr. Mongkol Na Songkhla)
Minister of Public Health

Annex 6

Unofficial Translation

Notification of the Ministry of Public Health
Re: Exercising of Right on Pharmaceuticals Products Patent for Letrozole

By virtue of section 51 of the Patent Act, B.E. 2522 (1979) as amended by the Patent Act (No. 2), B.E. 2535 (1992) and the Patent Act (No. 3), B.E. 2542 (1999), any ministry, bureau or department of the Government may, by themselves or through others, exercise any right under section 36 by paying a royalty to the patentee or his exclusive licensee under paragraph 2 of section 48 and shall notify the patentee in writing without delay, notwithstanding the provisions of section 46, section 47, and section 47 bis.

The objective of this provision is explicitly expressed that all public non-commercial activities, such as public health services, may lawfully exercise such right without the need for prior negotiation with the patent holder and without the requirement to follow the processes as specified in section 46, section 47, and section 47 bis.

Cancers have been continuously ranked among the top leading causes of death in Thailand for many years. Patients face both suffering from seriousness of the diseases and treatment as well as the high cost of treatment, including operation, radiation, and especially chemotherapy. These are serious burden, in particular economic burden, to patients and their families. Many low and middle-income families face serious financial catastrophe or even bankruptcy.

Breast cancer has the highest incidence among Thai female. At present, Letrozole has clearly been reported effective and important for treatment of breast cancer. However, it is very expensive because of its patent protection which enables the patent holder to have market exclusivity without competition. Either Government Pharmaceutical Organization or other pharmaceutical manufacturers cannot domestically produce or import the drug to be distributed and used in Thailand. Although the Ministry of Public Health could immediately exercise the right under any patent by virtue of section 51 of the Patent Act, the Ministry of Public Health did try with all means to negotiate with the patent holder for several months. The negotiation, however, could not reach an agreeable solution. Although price reduction was offered, they are still much higher than prices of the generic companies, and conditions offered by the patent holders would also post many hurdles to the drug management system. The Ministry of Public Health, hence could not let cancer patients under the 3 health insurance schemes wait for a cheaper- or reasonable-priced drug without time limitation.

Therefore, the Ministry of Public Health, hereby notifies, by virtue of section 51 of the Patent Act, B.E. 2522 (1979) as amended by the Patent Act (No. 2), B.E. 2535 (1992) and the Patent Act (No. 3), B.E. 2542 (1999), that it is now exercising the right under drug patent of drugs contain Letrozole in all formulations, including its derivatives patented in Thailand. In this regard, the Ministry of Public Health entrusts the Government Pharmaceutical Organization to exercise the right in its name in accordance

with section 36 paragraph 1 of the Patent Act, B.E. 2522 (1979) as amended by the Patent Act (No. 2), B.E. 2535 (1992) and the Patent Act (No. 3), B.E. 2542 (1999) subject to the following conditions:

(1) the right shall be exercised from now on **until the patent expired or no essential need**;

(2) the exercise of the right is limited to provision of drugs having the aforesaid generic name to unlimited number of patients who are entitled persons under the National Health Security System Act, B.E. 2545 (2002), insured persons under the Social Security Act, B.E. 2533 (1990) and persons entitled to medical benefits for civil servants and government employees scheme;

(3) a royalty fee of 3 per cent of the total sale value of drug having the aforesaid generic name by the Government Pharmaceutical Organization shall be paid to the patent holder.

The Ministry of Public Health, shall notify the patent holder and the Department of Intellectual Property for information without delay.

It is hereby announced.

Given on the 4th Day of January B.E. 2551 (2008).

(singed) Mongkol Na Songkhla
(Mr. Mongkol Na Songkhla)
Minister of Public Health

Annex 7

Unofficial Translation

Notification of the Ministry of Public Health
Re: Exercising of Right on Pharmaceuticals Products Patent for Erlotinib

By virtue of section 51 of the Patent Act, B.E. 2522 (1979) as amended by the Patent Act (No. 2), B.E. 2535 (1992) and the Patent Act (No. 3), B.E. 2542 (1999), any ministry, bureau or department of the Government may, by themselves or through others, exercise any right under section 36 by paying a royalty to the patentee or his exclusive licensee under paragraph 2 of section 48 and shall notify the patentee in writing without delay, notwithstanding the provisions of section 46, section 47, section 47 bis.

The objective of this provision is explicitly expressed that all public non-commercial activities, such as public health services, may lawfully exercise such right without the need for prior negotiation with the patent holder and without the requirement to follow the processes as specified in section 46, section 47, and section 47 bis.

Cancers have been continuously ranked among the top leading causes of death in Thailand for many years. Patients face both suffering from seriousness of the diseases and treatment as well as the high cost of treatment, including operation, radiation, and especially chemotherapy. These are serious burden, in particular economic burden, to patients and their families. Many low and middle-income families face serious financial catastrophe or even bankruptcy.

Lung cancer has the highest incidence among Thai male. At present, Erlotinib or the trade name Tarceva® in Thailand has clearly been reported effective and important for treatments of lung cancer. However, it is very expensive because of its patent protection which enables the patent holder to have market exclusivity without competition. Either Government Pharmaceutical Organization or other pharmaceutical manufacturers cannot domestically produce or import the drug to be distributed and used in Thailand. Although the Ministry of Public Health could immediately exercise the right under any patent by virtue of section 51 of the Patent Act, the Ministry of Public Health did try with all means to negotiate with the patent holder for several months. The negotiation, however, could not reach an agreeable solution. Although price reduction was offered, they are still much higher than prices of the generic companies, and conditions offered by the patent holders would also post many hurdles to the drug management system. The Ministry of Public Health, hence could not let cancer patients under the 3 health insurance schemes wait for a cheaper- or reasonable-priced drug without time limitation.

Therefore, the Ministry of Public Health, hereby notifies, by virtue of section 51 of the Patent Act, B.E. 2522 (1979) as amended by the Patent Act (No. 2), B.E. 2535 (1992) and the Patent Act (No. 3), B.E. 2542 (1999), that it is now exercising the right under drug patent of drugs contain Erlotinib in all formulations, including its derivatives patented in Thailand. In this regard, the Ministry of Public Health entrusts the Government Pharmaceutical Organization to exercise the right in its name in accordance with section 36 paragraph 1 of the Patent Act, B.E. 2522 (1979) as amended by the Patent Act (No. 2), B.E. 2535 (1992) and the Patent Act (No. 3), B.E. 2542 (1999) subject to the following conditions:

(1) the right shall be exercised from now on **until the patent expired or no essential need**;

(2) the exercise of the right is limited to provision of drugs having the aforesaid generic name to unlimited number of patients who are entitled persons under the National Health Security System Act, B.E. 2545 (2002), insured persons under the Social Security Act, B.E. 2533 (1990) and persons entitled to medical benefits for civil servants and government employees scheme;

(3) a royalty fee of 3 per cent of the total sale value of drug having the aforesaid generic name by the Government Pharmaceutical Organization shall be paid to the patent holder.

The Ministry of Public Health, shall notify the patent holder and the Department of Intellectual Property for information without delay.

It is hereby announced.

Given on the 4th Day of January B.E. 2551 (2008).

(singed) Mongkol Na Songkhla
(Mr. Mongkol Na Songkhla)
Minister of Public Health

Annex 8

Unofficial Translation

Notification of the Ministry of Public Health
Re: Exercising of Right under Drugs and Pharmaceuticals Products Patent for Imatinib

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By virtue of section 51 of the Patent Act, B.E. 2522 (1979) as amended by the Patent Act (No. 2), B.E. 2535 (1992) and the Patent Act (No. 3), B.E. 2542 (1999), any ministry, bureau or department of the Government may, by themselves or through others, exercise any right under section 36 by paying a royalty to the patentee or his exclusive licensee under paragraph 2 of section 48 and shall notify the patentee in writing without delay, notwithstanding the provisions of section 46, section 47, section 47 bis.

The objective of this provision is explicitly expressed that all public non-commercial activities, such as public health services, may lawfully exercise such right without the need for prior negotiation with the patent holder and without the requirement to follow the processes as specified in section 46, section 47, and section 47 bis.

Cancers have been continuously ranked among the top leading causes of death in Thailand for many years. Patients face both suffering from seriousness of the diseases and treatment as well as the high cost of treatment, including operation, radiation, and especially chemotherapy. These are serious burden, in particular economic burden, to patients and their families. Many low and middle-income families face serious financial catastrophe or even bankruptcy.

Chronic Myeloid Leukemia and Gastro-Intestinal Stromal Tumours are cancers that have very few drugs of choice for their chemotherapy treatments. At present, Imatinib or the trade name Glivec® in Thailand has clearly been reported effective for treatments of the 2 cancers. However, the drug is very expensive because of its patent protection which enables the patent holder to have market exclusivity without competition. Other pharmaceutical manufacturers cannot domestically produce or import the drug to be distributed and used in Thailand. It costs more than a million baht per patient per year for chemotherapy using Glivec® as a drug of choice, hence low- and middle-income patients cannot definitely get an access to the treatment. Although the patent holder has offered a program called GIPAP to help low-income patients getting access to the drug, there are still more than 10 million of low and middle-income people under the 3 health insurance schemes in Thailand being excluded by the program. Since all public health insurance schemes in Thailand cannot afford to pay for such high priced drug, market competition by importation or domestic production of generic products can bring the price down to tens of thousands baht per year. This reduced price could provide access for all patients under the 3 public health insurance schemes. This competitive market could lead to the real universal coverage in the country and to the prevention of financial catastrophe among patients' families.

Although the Ministry of Public Health could immediately exercise the right under any patent by virtue of section 51 of the Patent Act, the Ministry of Public Health did try to negotiate with the patent holder for several months by asking for either price reduction or an increase in accessibility among patients under Universal Coverage and Social Security Health Insurance schemes by GIPAP with no condition on income level or any other conditions. The negotiation, however, could not reach an agreeable solution that could provide true benefits for patients. The patent holder has insisted on its condition for GIPAP patients, which is a condition that will exclude more than 10 million of low and middle-income people from the program. The Ministry of Public Health, hence could not let all cancer patients under the 3 health insurance schemes wait for a cheaper- or reasonable-priced drug without time limitation.

Therefore, the Ministry of Public Health, hereby notifies, by virtue of section 51 of the Patent Act, B.E. 2522 (1979) as amended by the Patent Act (No. 2), B.E. 2535 (1992) and the Patent Act (No. 3), B.E. 2542 (1999), that it is now exercising the right under drug patent of drugs contain Imatinib in all formulas, including its derivatives patented in Thailand. In this regard, the Ministry of Public Health entrusts the Government Pharmaceutical Organization to exercise the right in its name in accordance with section 36 paragraph 1 of the Patent Act, B.E. 2522 (1979) as amended by the Patent Act (No. 2), B.E. 2535 (1992) and the Patent Act (No. 3), B.E. 2542 (1999) subject to the following conditions:

(1) the right shall be exercised from now on **until the patent expired or no essential need**;

(2) the exercise of the right is limited to provision of drugs having the aforesaid generic name to unlimited number of patients who are entitled persons under the National Health Security System Act, B.E. 2545 (2002), insured persons under the Social Security Act, B.E. 2533 (1990) and persons entitled to medical benefits for civil servants and government employees scheme;

(3) a royalty fee of 5 per cent of the total sale value of drug having the aforesaid generic name by the Government Pharmaceutical Organization shall be paid to the patent holder.

The Ministry of Public Health, shall notify the patent holder and the Department of Intellectual Property for information without delay.

It is hereby announced.

Given on the 4th Day of January B.E. 2551 (2008).

(singed) Mongkol Na Songkhla
(Mr. Mongkol Na Songkhla)
Minister of Public Health

Annex 9

John B Ketchum
Region Head

Novartis Asia Pacific
Pharmaceuticals Pte Ltd
Pharma Regional Office
10 Hoe Chiang Road
#15-02 Keppel Towers
Singapore 089315
Tel 65 6722 6038
Fax 65 6722 6006
Email
john.ketchum@novartis.com
www.novartis.com

Company Registration
Number: 200707750D

NOVARTIS
ONCOLOGY

23 January 2008

H.E. Dr. Mongkol Na Songkhla
Minister of Public Health
Ministry of Public Health
Tiwanon Road
Nonthaburi 11000
Thailand

RE: CML AND GIST PATIENT ACCESS TO GLIVEC

Dear H.E. Dr. Mongkol Na Songkhla,

GIPAP is one of the most comprehensive direct-to-patient access programs created for a life-saving medicine. Since its launch in 2002, GIPAP has helped more than 26,000 patients in over 80 countries including Thailand. Novartis will continue to work with the governments, payors, charities and others to further enhance access to Glivec through public-private partnerships that respond to changes in local economies and healthcare infrastructures.

Referring to our letter of 25 September 2007 and to ensure correct understanding, we have the pleasure to reaffirm patient access to Glivec as follows:

1. Novartis is committed to supporting access to Glivec through GIPAP, the Glivec International Patient Assistance Program. Patients currently enrolled in GIPAP will continue to receive Glivec free of charge as long as they continue to receive clinical benefit from the medicine determined by their physicians.
2. Patients receiving care under the National Health Security Office (NHSO) can apply to the GIPAP program and will be enrolled and receive Glivec at no cost when they fulfil GIPAP entry criteria as follows:

   a) Patients need to be diagnosed by specialists or experts in CML/ GIST, and the confirmation of the Glivec treatment for the patients.

   b) Patients who have income per household lower than socio-economic criteria which vary according to the amount of the dosages per day; in case of patients under the treatment of Glivec 400 mg. per day, the patients must have household income less than 1.7 million baht per year. In case of patients under the treatment of Glivec 600 mg. per day, the patient must have household income less than 2.2 million baht per year. Regarding to the socio-economic criteria, the household income is also flexible based on number people in the household.

NOVARTIS
ONCOLOGY

3. With the strong commitment to patient assistance, the company promises that GIPAP program will continue to help patients whether or not Glivec is listed into NLED

4. If you have any enquiries regarding GIPAP, please contact Mr Pramon Viwattanakulvanid, GIPAP coordinator at 02-685-0768 or 081-804-9182 or Mr Wirat Saekuai, Max Foundation Representative in Thailand at 02-224-9888 or 081-207-5155. For more information, please also visit GIPAP website at www.gipapthailand.org

Yours sincerely,

John B Ketchum
Region Head, Oncology Asia Pacific

Copy Dr. Siriwat Thiptharadon

Annex 10

Memorandum

Office: Technical Support Team **Tel:** 0-2590-2040 **Fax:** 0-2591-8496
No. SorTor 0100/TST/Special **Date:** 25 January 2008
Subject: Request for an approval to implement the Ministerial Notifications on Exercising of Right on Pharmaceutical Products Patent

Dear Honorable Minister of Public Health,

The Minister of Public Health signed, on 4 January 2008, four Ministerial Notifications on Exercising of Right on Pharmaceutical Products Patent, as proposed by the Committee to Support the Implementation of the Government Use of Patents, on 28 December 2007. The Minister also decided that the implementation be deferred until the Committee on Price Negotiation of the Patented Essential Drugs had the final negotiation.

So far, the Committee on Price Negotiation of the Patented Essential Drugs has already followed such instructions, with the following conclusions:

1. Novartis provided new detailed conditions on the access to Imatinib under the GIPAP project. The company's condition on household income levels were increased to 1.7 million baht (for the patients having to take 400-mg drug per day) and 2.2 million baht (for the patients having to take 600-mg drug per day), which would cover all the patients under the Universal Coverage (Gold Card) scheme. In case that any specific problems arise, Novartis (Thailand) is willing to shoulder the additional costs. With such offer, the implementation of government use of patent on Imatinib is thus no longer necessary. But the GIPAP could end anytime in the future. So to ensure that the patients will receive the medicine continuously, it is deemed appropriate to implement a conditional government use of patent on Imatinib. It is proposed to implement the government use of patent when the GIPAP ends, or when the project's operation cannot enable all the patients under the Universal Coverage (Gold Card) scheme to have access to Imatinib, as detailed in the attached new ministerial notification.
2. As for the other three anti-cancer drugs, the three original drug-producing companies maintained their initial offers.
3. The generic drug-producing company (Dabur of India) has reduced the drug prices, as follows:
   3.1 Imatinib: proposed to reduce the price from 170 baht per one 400-mg tablet to 135 baht, or around 4 per cent of the price of original medicine ;
   3.2 Docetaxel: proposed to reduce the price from 2,500 baht to 1,875 baht, or 50% of the reduced price of original medicine.
   3.3 Letrozole: proposed to reduce the price from 21 baht to 15 baht, or 10% of the reduced price of the original medicine.; and
   3.4 Erlotinib: The price information is unchanged.

With such outcomes of the final round of negotiation, it is considered reasonable to propose to Your Excellency to decide on the implementation of the three ministerial notifications already signed, except the one on Imatinib, and to sign the notification on exercising of patent right on Imatinib with the provision prescribed in the attached ministerial notification. The Minister's Office shall be obliged to further inform the Government Pharmaceutical Organization, patent-holding companies and Department of Intellectual Property.

Please be informed and kindly approved the implementation of the three ministerial notifications on exercising patent right on Docetaxel, Letrozole and Erlotinib; and consider signing the new ministerial notification specifically regarding Imatinib.

(Dr Vichai Chokevivat)
Advisor to the Minister of Public Health
Chair of the Committee to Support the Implementation of the Government Use of Patents

(Translation from the hand-written text)
- Approved and signed, cancel the 4-January 08 notification on Imatinib;
- Minister's Office, please take action.

(Mr Mongkol Na Songkhla)
Minister of Public Health
Signed on 25 January 2008

Annex 11

Unofficial Translation

Notification of the Ministry of Public Health
Re: Exercising of Right on Pharmaceuticals Products Patent for Imatinib

By virtue of section 51 of the Patent Act, B.E. 2522 (1979) as amended by the Patent Act (No. 2), B.E. 2535 (1992) and the Patent Act (No. 3), B.E. 2542 (1999), any ministry, bureau or department of the Government may, by themselves or through others, exercise any right under section 36 by paying a royalty to the patentee or his exclusive licensee under paragraph 2 of section 48 and shall notify the patentee in writing without delay, notwithstanding the provisions of section 46, section 47, and section 47 bis.

The objective of this provision is explicitly expressed that all public non-commercial activities, such as public health services, may lawfully exercise such right without the need for prior negotiation with the patent holder and without the requirement to follow the processes as specified in section 46, section 47, and section 47 bis.

Cancers have been continuously ranked among the top leading causes of death in Thailand for many years. Patients face both suffering from seriousness of the diseases and treatment as well as the high cost of treatment, including operation, radiation, and especially chemotherapy. These are serious burden, in particular economic burden, to patients and their families. Many low and middle-income families face serious financial catastrophe or even bankruptcy.

Chronic Myeloid Leukemia and Gastro-Intestinal Stromal Tumours are cancers that have very few drugs of choice for their chemotherapy treatments. At present, Imatinib or the trade name Glivec® in Thailand has clearly been reported effective for treatments of the 2 cancers. However, the drug is very expensive because of its patent protection which enables the patent holder to have market exclusivity without competition. Other pharmaceutical manufacturers cannot domestically produce or import the drug to be distributed and used in Thailand. It costs more than a million baht per patient per year for chemotherapy using Glivec® as a drug of choice, hence low- and middle-income patients cannot definitely get an access to the treatment. Although the patent holder has offered a program called GIPAP to help low-income patients getting access to the drug, there are still more than 10 million low and middle-income people under the 3 health insurance schemes in Thailand being excluded by the program. Since all public health insurance schemes in Thailand cannot afford to pay for such high priced drug, market competition by importation or domestic production of generic products can bring the price down to tens of thousands baht per year. This reduced price could provide access for all patients under the 3 public health insurance schemes. This competitive market could lead to the real universal coverage in the country and to the prevention of financial catastrophe among patients' families.

Although the Ministry of Public Health could immediately exercise the right under any patent by virtue of section 51 of the Patent Act, the Ministry of Public Health did try to negotiate with the patent holder for several months by asking for either price reduction or an increase in accessibility among patients, especially those under the Universal Coverage scheme (golden card patients), by GIPAP with no condition on income level or any other conditions.

Finally, it is very please that the patent owner, Novartis, has offered to the Ministry of Public Health a new condition for patients to enter GIPAP as stated in the letter from Novartis (Thailand) Ltd. signed by its Country President, Ms. Sirilak Suteekul, on 18th January 2008. This last offer could provide an access for all to patients under the Universal Coverage (Gold Card) scheme. Therefore, there is no further need to implement the government use of patent on this drug.

However, to ensure continuous and sustainable access to Imatinib of patients registered under the new condition of GIPAP, the Ministry of Public Health, hereby notifies, by virtue of section 51 of the Patent Act, B.E. 2522 (1979) as amended by the Patent Act (No. 2), B.E. 2535 (1992) and the Patent Act (No. 3), B.E. 2542 (1999), that it is exercising the right under drug patent of drugs contain Imatinib in all formulations, including its derivatives patented in Thailand. In this regard, the Ministry of Public Health entrusts the Government Pharmaceutical Organization to exercise the right in its name in accordance with section 36 paragraph 1 of the Patent Act, B.E. 2522 (1979) as amended by the Patent Act (No. 2), B.E. 2535 (1992) and the Patent Act (No. 3), B.E. 2542 (1999) subject to the following conditions:

(1) the right shall be only exercised when the GIPAP is terminated or if the program offered does not follow the new condition of GIPAP stated in the company's letter as previously mentioned or if the program cannot provide access to every patient under the Universal Coverage scheme (golden card scheme);

(2) the right shall be only exercised under the condition (1) as stated above, and it shall be exercised until the patent expired or no essential need;

(3) under the right exercised, unlimited number of patients who are entitled persons under the Universal Coverage scheme (golden card scheme) can be prescribed drug having the aforesaid generic name, depending on doctors' judgment;

(4) under the right exercised, a royalty fee of 5 per cent of the total sale value of drug having the aforesaid generic name by the Government Pharmaceutical Organization shall be paid to the patent holder.

The Ministry of Public Health, shall notify the patent holder and the Department of Intellectual Property for information without delay.

It is hereby announced.

Given on the 25th Day of January B.E. 2551 (2008).

(singed) Mongkol Na Songkhla
(Mr. Mongkol Na Songkhla)
Minister of Public Health

Annex 12

Unofficial Translation

Announcement

No. 1/2550

Re: Appointment of the Joint Committee between Representatives of Ministry of Public Health and Representatives of Pharmaceutical Research and Manufacturers Association for Development of a Sustainable Quality Healthcare Service System

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With great concerns on public health problems in the country and with its aim at the development of a sustainable quality Thai healthcare service system, the Ministry of Public Health Thailand has continuously played a critical role on providing access to treatments, disease prevention, health promotion and rehabilitation. However, at present, it is evidenced that Thailand is still facing many obstacles on its road towards an efficient and effective healthcare management system.

To achieve the equitable access to quality healthcare services among the Thai population, the Advisor to the Minister of Public Health hereby:

1. Appoints the Joint Committee between Representatives of Ministry of Public Health and Representatives of Pharmaceutical Research and Manufacturers Association for Development of a Sustainable Quality Healthcare Service System whose component is as follow:

1.1 Mr.Vichai Chokevivat	Chair
1.2 Mr. Teera Chakajnarodom	Member
1.3 Representative of the National Health Security Office	Member
1.4 Ms. Bussakorn Anuchartworakul	Member
1.5 Ms. Jiraporn Limpananont	Member
1.6 Mr. Pairoj Kaewmanee	Member
1.7 Mr. Suchart Chongprasert	Member
1.8 Mr. Manu Sawangjaeng	Member
1.9 Mr. Somkiat Mahapan	Member
1.10 Mr. Douglas Cheung	Member
1.11 Mr. Jose Nemencio Lim	Member
1.12 Mr. Graham Almond	Member
1.13 Mr. Karl Fredrik Oscar Swenson Andersh	Member
1.14 Mr. Nipit Piravej	Member and secretary
1.15 Mr. Sorachai Jamniandamrongkarn	Member and joint secretary
1.16 Ms. Tipicha Posayanonda	Member and assistant secretary

2. Announces that the Committee appointed in 1. has following authorities and responsibilities:

2.1 Moves to establish a mechanism towards the development of a sustainable quality healthcare service system under the principle of equity, quality, and efficiency of healthcare services for all;

2.2 Supports and promotes people under different health insurance schemes to be able to get access to quality essential drugs with no delay;

2.3 Supports and promotes pharmaceutical research and development capacity of Thailand;

2.4 Appoints multi-sector Subcommittee and/or Working Group, to specifically consider any important issues on a case by case basis as appropriate.

3. The Committee appointed in 1. does not have any roles related to a decision making process of any public agencies responsible for the implementation of the government use of patent.

4. The Committee appointed in 1. shall continuously report its meeting results/its discussion outcomes or actions to the Advisor to the Minister of Public Health and the Minister of Public Health.

The Announcement shall be effective from now on.

Given on the 17th Day of December B.E. 2550 (2007).

(signed) Mayura Kusum
(Ms. Mayura Kusum)
Advisor to the Minister of Public Health

Annex 13

Unofficial Translation

Minutes of Meeting
The Joint Committee between
Representatives of Ministry of Public Health and
Representatives of Pharmaceutical Research and Manufacturers Association
For Development of a Sustainable Quality Healthcare Service System
No. 1/2008
Held on Friday 11th January 2008, at 9.30-12.00 hrs.
In the Reception Room, 5th Floor, Building 1,
Office of the Permanent-Secretary, Ministry of Public Health

Present:

1. Mr.Vichai Chokevivat	Advisor to the Minister of Public Health	Chair
2. Mr. Teera Chakajnarodom	President, PReMA	Member
3. Ms. Jiraporn Limpananont	Faculty of Pharmaceutical Sciences Chulalongkorn University	Member
4. Mr. Pairoj Kaewmanee	Legal Officer 8 Thai Food and Drug Administration	Member
5. Mr. Manu Sawangjaeng	PReMA	Member
6. Mr. Somkiat Mahapan	PReMA	Member
7. Mr. Douglas Cheung	PReMA	Member
8. Mr. Jose Nemencio Lim	PReMA	Member
9. Mr. Karl Fredrik Oscar Swenson Andersh	PReMA	Member
10. Mr. Nipit Piravej	PReMA	Member and secretary
11. Mr. Sorachai Jamniandamrongkarn	Expert Office of Policy and Plan The National Health Security Office	Member and joint secretary
12. Ms. Tipicha Posayanonda	Pharmacist 7 Thai Food and Drug Administration Technical Support Team of Secretary to the Minister of Public Health	Member and assistant secretary

Regrets:

1. Representative of the National Health Security Office	Member
2. Ms. Bussakorn Anuchartworakul	Member
3. Mr. Suchart Chongprasert	Member
4. Mr. Graham Almond	Member

Also Present:

1. Mr. Suwit Wibulpolprasert	Senior Expert in Disease Control and Prevention Ministry of Public Health

Meeting started at 9.30 hrs.

Agenda no.1 Information from Chairman

- Appointment of the Joint Committee between Representatives of Ministry of Public Health and Representatives of Pharmaceutical Research and Manufacturers Association for Development of Sustainability of the Quality Healthcare Service System

Chairman informed that the Announcement No. 1/2550 Re: Appointment of the Joint Committee between Representatives of Ministry of Public Health and Representatives of Pharmaceutical Research and Manufacturers Association for Development of Sustainability of the Quality Healthcare Service System in Thailand, dated 17 December 2007, was issued by the Advisor to the Minister of Public Health (Dr.Mayura Kusum).

Component of the Joint Committee consisted of 16 members from the Ministry of Public Health (MoPH) and PReMA (8 persons from each party), and the Committee was assigned with the following authorities and responsibilities:

1. Moves to establish a mechanism towards the development of a sustainability of the quality healthcare service system under the principle of an equality, quality, and efficiency of healthcare services for all;
2. Supports and promotes people under different health insurance schemes to be able to get access to quality drugs with no delay;
3. Supports and promotes pharmaceutical research and development capacity of Thailand;
4. Appoints multi-sector Subcommittee and/or Working Group to specifically consider any important issues on a case by case basis as appropriate.

Resolution

The meeting was informed.

Agenda no. 2 Consideration Issues

- Operation Process Guideline for the Joint Committee between Representatives of Ministry of Public Health and Representatives of Pharmaceutical Research and Manufacturers Association for Development of Sustainability of the Quality Healthcare Service System

Pharmaceutical Research & Manufacturers Association (PReMA) proposed to the meeting an operation process guideline for the Joint Committee, in which collaboration principle was stated. After consideration, following opinions were presented in the meeting:

Opinions of representatives from PReMA

- In order to solve the challenging health problems, the 3 parties including people, government, and private sector needed to work collaboratively and sincerely. Studying of any possibilities to solve problems in different dimensions and establishing of a win-win mechanism for the three parties were also suggested.

- The Joint Committee should thoroughly study the existing national healthcare system and prepare an updated database for the health budget allocation and national health insurance planning in the country.

- Since health problems were dynamic, a three-year projection of demand-supply of national healthcare needed to be studied and analyzed for further establishment of the most appropriate healthcare system in Thailand in the near future.

- Health insurance program for all that was covered by the government budget only might not be sustainable. It was likely that finally the co-payment from people, especially those with high-income, would have an important role. Therefore, MOPH should allow the private sector participating on the national co-payment planning system. Health insurance program for all in Sweden was a good case study. At the beginning, the program started with a total subsidization for healthcare expenses by Swedish government. Although it was good in a way that people did not have a burden on their healthcare cost, the over consumption of healthcare services among everybody caused too-high healthcare expenses for the government and became a problematic issue. This problem did generate negative impacts on those who really needed services, since the government did not have enough budget to pay for the essential services required for those in need patients. Therefore, Sweden had to start the co-payment system during the end of 1980. After the system was initiated, there were some problems as people were not familiar with the system that they had to pay for the services. However, after about six months, the co-payment system was well-accepted by the Swedish as it helped in decrease over consumption of healthcare services and patients in need did really get more benefits, particularly on medicines.

Opinions of representatives from MOPH

- It was very challenging to work collaboratively and sincerely for the benefits to both the public and private sectors. This was a good opportunity to prove sincerity of both parties (MOPH and PReMA).

- The 3 main objectives of the Joint Committee proposed by PReMA in the operation process guideline [***a) to improve accessibility to medicines among low-income population; b) to help decrease in health problems in the country, particularly in neglected diseases; and c) to strengthen capacity of Thailand in the public health area***] were very much agreeable. However, the 4 collaboration processes proposed in the guideline were not clear and not in line with the above 3 proposed objectives.

- At this moment, we should focus more on and take “an increase in access to essential medicines among the poor” as our first priority. At present, the gap between rich and poor countries, as well as the gap between the rich and the poor in each individual country had been continuously expanded. From Thailand’s experience for 25 years, it was found that although the copayment system was good, it was difficult to have such system effectively operated in Thailand. A study reported that copayment in Thailand did not really help the poor and considered a failure, since a lot of poor people did not even get access to the low-income patient cards and cheaper services. The cards were with many rich people, and the rich were those who got the real benefits. Therefore, it was shown that the context of situation in Thailand was different from developed countries, Thailand had a weak drug price control system, a weak monitoring system in healthcare services, and, in some cases, an

unfair taxation for the poor. It was finally concluded from our experience and study that besides copayment was strongly opposed by public sector, it could not help the poor to get more access to medicines. Therefore, it was suggested that pharmaceutical companies would rather focus more on the policy of getting more money from the rich for helping the poor. For example, differential pricing policy among different countries proposed by some companies was a good policy. However, there was no such policy proposed to be used inside each individual country.

- At present, although co-payment might not be an appropriate system for Thailand, it would be worth getting more knowledge on various co-payment systems by gathering data and information from different countries. The collected data should be presented by PReMA to the next Joint Committee meeting for a further collaboration between PReMA and the National Health Security Office (NHSO) on the development of a joint proposal on co-payment system in Thailand in the future.

Resolutions

1. The 4 collaboration processes proposed by PReMA in the operation process guideline document needed to be revised to be in line with the 3 agreed main objectives proposed.

2. Information of co-payment systems from different countries needed to be studied and presented to the next meeting by PReMA.

3. PReMA should establish a working group for studying demand-supply of healthcare services in the country by coordinating with MOPH, as appropriate, regarding information needed. In addition, a proposal for promoting or increasing an equal access to quality drugs among people under different health insurance schemes should be submitted.

Agenda no. 3 Other Issues

The next Committee meeting was agreed to be held on 5 February 2008 at 9.30 hrs.

Meeting adjourned at 12.00 hrs.

Minuted by
Mr. Sorachai Jamniandamrongkarn

Reviewed by
Mr. Vichai Chokevivat

Annex 14

Unofficial Translation

Minutes of Meeting
Discussion on Position of Thailand on the Compulsory Licensing Issue
Held on Friday 24th August 2007, at 8.30-11.30hrs.
In the Reception Room, 5th Floor, Builing 1,
Office of the Permanent-Secretary, Ministry of Public Health

Present:

Ministry of Public Health

1. Mr.Vichai Chokevivat	Senior Expert on Health Promotion
2. Mr.Siriwat Tiptaradol	Secretary-General, Thai Food and Drug Administration
3. Mr.Suchart Jongprasert	Thai Food and Drug Administration
4. Ms.Renu Srismith	National Health Security Office
5. Mr.Sorachai Jamniandumrongkarn	National Health Security Office
6. Mr.Pongsadhorn Pokpermdee	Office of the Minister

Ministry of Foreign Affairs

1. Mr.Worawut Pongprapapan	Department of American and South Pacific Affairs
2. Mr.Pirapong Pimolwichayakij	Department of American and South Pacific Affairs
3. Mr.Cherdkiat Utakorn	Department of European Affairs
4. Mr.Krai Mahasuntana	Department of European Affairs
5. Lt.Col.Bhromes Bhaholbholbhayuhasena	Department of International Economic Affairs

Ministry of Commerce

1. Ms.Kejpirun Kohsuwan	Department of Trade Negotiation
2. Ms.Duangporn Sundhurak	Department of Trade Negotiation
3. Mr.Patkamol Tattipong	Department of Trade Negotiation
4. Ms.Buddhachart Wongmongkol	Department of Trade Negotiation
5. Ms.Nusara Karnchanakul	Department of Intellectual Property
6. Mr.Suradej Aswintrangkura	Department of Intellectual Property

Ministry of Labour

1. Ms.Chitra Tanodom	Social Security Office

Ministry of Science and Technology

1. Mr.Thanit Chungtaworn	National Center for Genetic Engineering and Biotechnology

AIDS Access Foundation

1. Mr.Jon Ungphakorn
2. Mr.Nimit Tianudom

Present (Contd):
People living With HIV/AIDS In Thailand

1. Mr.Wirat Purahong

Oxfam Great Britain in Thailand

1. Mr.Chalermsak Kittitrakul

Cancer Network

1. Ms.Wacharaporn Apiwacharangkura

Meeting started at 8.30 hrs.

Agenda: Discussion on Position of Thailand on the Compulsory Licensing Issue

1. Background

There was a letter from H.E. Mr. Ralph Boyce, US Ambassado to Thailand, sent to Thailand's Prime Minister, H.E. General Surayut Chulanond addressing US concerns on the issue of Compulsory Licensing implementation in Thailand, and asking for a clarification of Thailand's position on the issue mentioned.

The Prime Minister assigned the Ministry of Public Health to coordinate with Ministry of Foreign Affairs, Ministry of Commerce, and all related parties to find an official resolution for Thailand's position on the issue. The Permanent-Secretary, Ministry of Public Health (MOPH), authorized Mr.Vichai Chokevivat (Senior Expert in Health Promotion, MOPH) who was the Chair of the CL Implementation Committee as a key person to organize this multi-sector meeting.

2. Opinions presented

Ministry of Commerce

1) In addition to the letter from H.E. Mr. Ralph Boyce to the Prime Minister, Ministry of Commerce (MOC) did also receive a letter from The Rt. Hon. Peter Mandelson P.C., who was Member of the European Commission, addressing his concerns on CL in Thailand. In this regards, MOC sent a reply letter to H.E. Peter Mandelson already, informing that what Thailand had done was transparent and complied with TRIPs Agreement and Thailand's Patent Act. In addition, Thailand was willing to negotiate with pharmaceutical companies any time for the ultimate goal of access for all.

2) Information and reasons of announcing CL for other groups of medicines apart from anti-HIV/AIDS drugs should be clarified.

3) MOPH should keep the Ministry of Commerce (MOC) informed and updated about price negotiations, as well as the list of more drug items having high possibility to be announced for CL.

4) Other measures should be used to develop a sustainable and efficient healthcare in the country.

5) It should be clearly explained to both H.E. Mr. Ralph Boyce and different types of media that CL process of Thailand was legal, and Thailand would use CL only if necessary and for some drug groups only. Further, it needed to be clarified to the public that generic drugs distributed under CL announcements had to be certified on their quality and standard approval by MOPH.

Ministry of Foreign Affairs

1) Any advantages and disadvantages of the country should be studied and analyzed in all dimensions before any decision making on using the CL measure for an increase in access to medicines. The Ministry of Foreign Affairs (MFA) was being informed about concerns raised by many countries, including EU countries, about Thailand's direction and policy on CL. Many countries had concerns that Thailand might use CL for many medicines and CL might later become the systematic policy in the country.

2) Representatives from MFA believed that US was not worried about the decrease in profits of pharmaceutical companies after the CL implementation, but the US had concerns on the domino effect that other developing countries might follow Thailand on CL and this would definitely have impacts on profits of the companies.

3) US would like to see a negotiation ended with an agreeable resolution which would be beneficial to both sides (MOPH and patent holder). It was suggested that Thailand should not only consider on the price issue. For example, it was hardly possible to be agreeable on the condition offered by MOPH that the price of original drug offered should not exceed that of generic higher than 5 per cent of the generic price, since the companies were always afraid of the impact on their drug price structure worldwide.

4) To reach an agreeable negotiation that was beneficial to both sides, it was suggested that MOPH might consider other options apart from the price issue. For example, a collaboration with pharmaceutical companies to strengthen or develop healthcare services in Thailand.

5) Long-term impacts on drug prices (even there was no CL used or implemented anymore in the country), as well as other impacts should be studied.

6) Other measures could be also considered and used for the increase in accessibility, CL should be the last measure to be considered. Besides, MOPH should communicate more with other ministries on any update information regarding CL announcements.

Ministry of Science and Technology

1) The representative from Ministry of Science and Technology supported the CL measure. However, there was still a concern on the process, which was suggested to be more focused on the communication among related agencies. In addition, any leaflets or pamphlets with a short summary of CL issue could help public better understand the CL and what had been done regarding CL in the country.

2) A study on clear impacts of CL in Thailand should be conducted.

AIDS Access Foundation

1) CL was an issue that Thailand was fighting with Western countries. Therefore it was necessary that MFA had a clear position on the issue.

2) The Foundation supported MOPH for using CL as a negotiation tool, because it was an effective measure for bringing down the drug prices. In addition, the Foundation agreed with the principle used by MOPH that the price of original drug offered should not exceed that of generic higher than 5 per cent of the generic price. This would help creating a more competitive market for essential medicines. However, this principle or condition was applied to CL drugs only.

3) To be more clarified on the issue of why CL was needed for those medicines, statistics showing number of patients who really needed the medicines but could not get access should be presented.

4) Efficient communication among all related agencies, e.g. group email, was needed.

5) It should be clearly explained to both H.E. Mr. Ralph Boyce about the process and conditions Thailand had used in the drug selection and consideration processes before CL announcements. Also, it should be highlighted that Thailand was no t the only country using CL.

6) Thailand's strategy on its CL clarification presented to other countries had to be changed into a proactive way. Moreover, MOPH should consider more on other measures that might be used to increase accessibility to medicines in the future.

Ministry of Public Health

1) Process of MOPH on CL was clear and transparent. There were Sub-committee and Committee composed of members from related agencies including MOC, Office of the Council of State, and MFA responsible for CL drug consideration. Therefore, the decision was not only from MOPH. The negotiation (both official and unofficial) with patent holders was also a transparent process that had started for a long period of time, however was not successful, hence CL was announced for the most benefits to people. MOPH used the following criteria for consideration of drugs that might be announced for CL: (1) The drugs were on National Essential Drug List or (2) The drugs were needed for solving public health problems or needed for emergency cases/outbreaks or classified as lifesaving drugs; and (3) Quality generic drugs with much cheaper prices comparing to the original products had to be available. In addition, Thailand's 3 CL Announcements were publicly issued with a transparency reason. Every company was welcome to negotiate with MOPH. It did not mean that the 3 patented drugs could not be used in the country anymore. On the contrary, they still had their patented market, and MOPH could still be able to purchase the 3 patented drugs if their prices and conditions offered were reasonable and agreeable. In addition, it was emphasized that CL process was done carefully and would be used only if necessary.

2) Regarding the letter from The Rt. Hon. Peter Mandelson P.C., concerning on the issue that Thailand would implement CL on every drug whose price exceeded that of generic higher than 5 per cent of the generic price. This was a total misunderstanding, because the 5 per cent condition was specifically applied to only drugs announced for CL, not to all drug items. Moreover, this 5 per cent condition was like a 5 per cent credit points which was equivalent to paying a royalty fee of 5 per cent which was 10 times more than the announced royalty fee of 0.5 per cent. Besides, Thailand was still open for negotiations with any pharmaceutical companies. However, MOPH had sent a reply letter of clarification to H.E. Peter Mandelson already.

3) There should not be any concerns that other countries would follow Thailand on CL, because each country had its own reasons and conditions of choosing CL as a measure to increase drug access.

4) Research funding for pharmaceutical companies was mostly from the government. The company budget was mainly used for the development and marketing. Also, there would be very little impacts from Thailand's CL on income and profits of the companies because their high-priced patented drugs market providing mainly for foreigners and out of pocket patients, who never used any national health insurance schemes and services from government facilities in the country, still remained untouched. Hence, The CL drugs would be provided in a new market open for low-income patients, who were covered by national health insurance schemes but never got access to any high-priced patented drugs. Nevertheless, the patent holder companies still had an opportunity to compete with generic companies by offering reasonable prices to MOPH. For instance, if the price offered by a patent holder exceeded the lowest price offered by generic companies not more than 5 per cent of that generic price, MOPH would buy the drug from the patent holder company and would use the drug under the condition stated in the CL

announcement. It was also emphasized that CL drugs could not be distributed freely in any private hospitals, private healthcare facilities or pharmacies. (The CL drugs were able to be distributed for public non-commercial use only.)

5) In addition to the published White Paper, Thai Food and Drug Administration (FDA) had also produced 2 versions of leaflets to inform and educate public about CL.

6) According to the Price Negotiation Committee, its consideration criteria included: – (1) Offers from patent holder companies must not have any condition asking the government to repeal the CL Notifications/Announcements, because this would lead to a negligence of the government to exercise its rights according to the law; (2) If the price offered by a patent holder exceeded the lowest price offered by generic companies not more than 5 per cent of that generic price, MOPH would buy the drug from the patent holder company. (Prices that would be used for consideration should be CIF prices, not FOB, because freight and insurance varied among countries.) Also if free products were offered, the products had to be those in need, and the net price of both drug and the free offers would be used to compare with the generic drug prices; and (3) According to the price negotiation, a purchasing agreement with any company must not be the long-term one.

Resolutions

Relevant ministries were asked to consider the opinions and recommendations of the meeting and took their actions accordingly. Also the meeting agreed to respond to H.E. Ralph Boyce's comments on five aspects, as follows:

1) Thailand honors its obligation under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and the Doha Declaration on the TRIPS Agreement and Public Health. *However, it is stated in the Agreement and the Declaration that in the circumstances of public health crises, or where the public interest arises, public health interest shall be given priority and put before trade interest, and that the WTO members have the right to use TRIPS flexibilities and the freedom to determine the grounds upon which such flexibilities are used;*

2) The Thai government has an obligation under the Constitution of Thailand B.E. 2550 and the National Health Security Act B.E. 2545 to ensure that all Thais have access to medicines listed on the National List of Essential Medicines. This is achievable through various measures such as budget raises and the promotion of the rational use of drugs, including the use of flexibilities granted under the TRIPS Agreement, the Doha Declaration and the Thai Patent Act B.E. 2522 as amended by the Patent Act (No.2) B.E. 2535 and the Patent Act (No.3) B.E. 2542;

3) Thailand has a policy of using TRIPS flexibilities embodied in the TRIPS Agreement, the Doha Declaration and the Thai Patent Act *only when necessary*. This is to achieve our ultimate goal of availability of essential medicines for our people, according to the right conferred under the National Health Security Act. However, the measures will be *implemented with due consideration and not in an indiscriminate manner or for frivolous reasons*. Furthermore, negotiations with pharmaceutical companies will be built on respect for our mutual interest in bringing improvements to Thailand's public health services.

4) Section 51 of the Thai Patent Act defines the right of the Minister, Permanent Secretary and Director-General of any ministry, bureau or department of the Government to issue a compulsory license in order to carry out services for public consumption, and in case of urgency, e.g., to increase access to essential medicines

for the Thai people. Therefore, *it is not possible for anyone to announce or commit to any person or country that Thailand will not implement the Government Use of Patents on pharmaceutical patents in any circumstances.* Doing so is deemed to be a neglect of duty or failure to exercise the rights established by the law to safeguard public interest and public health, and can incur a criminal charge.

5) There is no country or government in the world that would renounce its rights to implement a Government Use of Patents on any drug patent. On the contrary, developed countries grant more compulsory licenses than developing countries.

Meeting adjourned at 11.30 hrs.

Minuted by
Mr. Pongsadhorn Pokpermdee

Reviewed by
Mr. Vichai Chokevivat