No. 0100.3/

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Your Excellency,

Please kindly refer to your letter No. TRA-JJB-D(2007)1334 dated 18 July 2007, sending a copy of the letter from Commissioner Peter Mandelson concerning compulsory licensing of pharmaceutical patents in Thailand.

On behalf of the Ministry of Public Health (MOPH), I would like to clarify and provide following information regarding your concerns related to the issue of compulsory licensing (CL) or Government Use of Drug Patents in Thailand.

1. The Government Use of Patents for the three medicines in Thailand are all aimed for public non-commercial use, which means generic version of the three medicines will be used for patients under the three National Health Insurance Schemes mainly at the public facilities, and paid fully by the public budget. The generic products will not be sold for any patients who prefer to receive private treatments and pay out of their own pockets. These patients who pay out of pocket for their medical care plus additional 2 millions foreign patients in Thailand, will continue to pay for the high price patented drugs and will not have access to the drugs acquired through the CL processes. They are the only payers for the Research and Development cost of the patented drugs before CL. Those publicly paid patients had extremely limited access to these patented drugs, and thus contribute very little or not at all to the Research and Development cost.

Therefore, Thailand CL is opening a new market for these patented medicines for those who cannot afford them and never have access. The current markets of those out of pocket patients and the foreign patients on the patented medicines are still there and remained untouched. Furthermore, apart from the designated Government Pharmaceutical Organization, the patent holders still possess their sole rights to produce, import and sell their patented products. They still have sole rights to grant voluntary licenses to anybody if they would like to.

2. With the limitation of the generics and the limited indications to implement the CL, the Government Use of Patents can only be implemented on some essential medicines that are complied with the criteria as listed in our white paper. We do believe that it is possible to use the CL as a routine measures. For example, lifestyle medicines, such as those used to prevent hair loss or to treat erectile dysfunction syndrome, as well as those used for cosmetic purposes will not meet the criteria for CL or Government Use of Patent.

3. Although under the Thai Patent Act and the TRIPs agreement, there is no need for prior negotiation and discussion to implement CL for public non-commercial purpose, the MOPH had tried (both officially and unofficially as stated in the White Paper) through several means and mechanisms to discuss and negotiate with the patent holders. Due to lack of interest and cooperation from the patent holders, our negotiations failed and we needed to announce the Government Use of Patents on the three medicines,

which was the best choice for Thailand at that time to achieve the universal access of patients in the country.

However, after the announcements, MOPH's door is always open for every pharmaceutical company for constructive discussions and negotiations, and currently all three patent holders, as well as other companies, are in the processes of negotiation with the committee set up by the MOPH. Definitely, if the conditions offered by the patent holder companies are reasonable and agreeable, MOPH will purchase medicines from the patent holders. It is thus the patent holders that will help us not to have to resort to the use of CL.

4. I would like to reiterate to Your Excellency that the European Parliament (EP) resolution adopted on 12th July 2007 has clearly stated that the EP asked the Council to support the developing countries which used the flexibilities enshrined in the TRIPS Agreement. In addition, the EP asked the Commission and the Member States to provide financial support for local production of pharmaceuticals in developing countries. The resolution did also show an intention of the EP to encourage developing countries to use all means available to them under the TRIPS Agreement, such as compulsory licensing and the mechanism provided by Article 30 thereof, to increase the access to essential medicines. Further, regarding the said resolution, the Council was asked to mandate the Commission to refrain from taking action to interfere with these proceedings. I would like to request for Your Excellency's kind advice on how the commission is going to react to the EP resolution and how Your Excellency's letter support the said EP resolution. I also take the liberty to copy this letter as well as Your Excellency's letter to the Chairperson of the EP for his information and proper actions.

Furthermore, public use of CL is not new, many European countries had implemented it before as shown in the examples in our white paper. I hope that Your Excellency will be able to advise me, with clear evidences, on their processes of prior negotiations and negotiations after the implementation of CL.

5. In implementing the CL, we intend to pay a 0.5 % loyalty to the patent holders. This figure was set up based on the past experiences of other countries as well as on the volume of drugs used. This figure is negotiable, but so far no company has paid any interest in negotiating on it. The 5 % credit points that the MoPH allows for the patented products over the generics is equivalent to paying 5 % loyalty, as compared to 0.5% as described above. This means that if the patent holders agree to sell their products to the government at the price not more than 5% above the lowest generics, we will buy from the patent holders and there is thus no necessity to implement the CL. This increase from 0.5 to 5% loyalty is to show our gratitude to the patent holders when they show their commitment to serve the public at large.

I would like to reiterate, to Your Excellency, that this 5% credit points only apply to drug procured under the CL negotiation, to be used by those low income patient under the public schemes. The patent holders still can sell their drugs to those out of pocket patients and the 2 million foreign patients at their market price. So far it only applies to three drugs under the CL. All other drugs not under the CL procurement will not be subject to this proposed 5% credit points.

Your Excellency, I hope the above information is clear and could make you understand Thailand's goodwill towards the achievement of the universal access to essential medicines for Thai people through the implementation of Government Use of Patents on the three medicines. I do really hope that our clarification message will be conveyed to the EU Commissioners and EU member countries also. I also hope that Your Excellency will encourage the European drug companies to come to the negotiation table with more generous proposal for the benefit of the public at large.

If there are any more questions to be clarified or any further discussions needed, you are very welcome to directly contact us.

Please accept, Your Excellency, the assurances of my highest esteem and consideration.

Sincerely yours,

(Dr. Mongkol Na Songkhla)
Minister of Public Health

His Excellency
Mr. Friedrich Hamburger
Ambassador and Head of the Delegation of the European Commission to Thailand.
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