

**THAILAND's Additional Comments in
The 2011 National Trade Estimate Report (NTE) for the incoming 2012 NTE Report
Submitted to the United States Trade Representatives**

23 September 2011

| No. | Claims by the U.S. | Comments from Thailand |
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| | <p>Other Barriers</p> <p>1. Pharmaceutical Sector</p> <ul style="list-style-type: none"> - In the pharmaceutical sector, the Government Pharmaceutical Organization (GPO) is not subject to registration requirements faced by the private sector. The Council of State is currently reviewing a proposed law, however, that would eliminate GPO's exemption from these requirements. GPO also is exempt from complying with the requirements of the safety monitoring period (SMP) when producing and marketing generic formulations of drugs marketed in foreign countries. Other manufacturers are subject to a mandatory two-to-four-year SMP for all new chemical entities registered and approved for marketing in Thailand. This and other Thai government requirements limiting government hospitals' procurement and dispensing of drugs not on the national list of essential drugs significantly constrain the availability of many imported products. - The U.S. pharmaceutical industry has expressed serious concern regarding the uncertain climate for its business in Thailand. The United States will continue to encourage Thailand to engage in a meaningful and transparent manner with all relevant stakeholders as it considers ways to address Thailand's public health challenges. | <ul style="list-style-type: none"> - The Government Pharmaceutical Organization (GPO) has policies to follow every requirement specified in the Drug Act, like other pharmaceutical companies. Over 90% of GPO's pharmaceutical products are either already registered with Thai FDA or under assessment by Thai FDA. GPO expects to have all of GPO pharmaceutical products registered in the near future. - Furthermore, like other drug producers, GPO's drugs are not exempted from safety monitoring program (or SMP). All GPO's new drugs are complied with all the requirements of safety monitoring period. - Regarding registration, the applicants for registration must submit formulations of drugs and experimental information to FDA for verification. Those information will be kept as secret, according to Trade Secrets Act. - Thailand's actions are entirely consistent with international law and commitments. Moreover, Thailand intends to cooperate creatively with stakeholders in order to develop an appropriate health system and enhance the general public access to essential drugs. |

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| | <p>2. Price Control</p> <p>- The Thai government retains authority to <u>control prices</u> or set <i>de facto</i> <u>price ceilings</u> for 38 goods and one service, including staple agricultural products (sugar, cooking oil, condensed milk, wheat flour, and others), liquefied petroleum gas, medicines, sound recordings, and student uniforms. Price control review mechanisms are nontransparent. In practice, the government also uses its control of major suppliers of products and services under state monopoly, such as the petroleum, aviation, and telecommunications sectors, to influence prices in the local market.</p> | <ul style="list-style-type: none"> - The controlled goods and services list (<u>not</u> “price control”) consists of 39 goods and 2 services; sugar and pork are the current commodities subject to a price control. This is done in order to maintain fairness to the producers of sugarcane and refinery sugar, middlemen and consumers. Other products under the controlled goods and services list are not subject to any price control and are subject to change or modification depending upon the necessity and appropriateness of the circumstances of each year for each commodity. - Under the Price of Goods and Services Act B.E 2542 (1999), the authorized committee has annually reviewed and determined appropriate measures for particular good and services such as declaration of stock, based on the present situation after considering the cost of living, exchange rate and other factors affecting prices of goods and services. - The notification of controlled goods and services list is annually reviewed by the Central Commission on Price of Goods and Services which composes representatives from government and related private sectors. The Commission has the power to designate the notification of any particular goods and services to be controlled goods and services. The notification shall come into force upon their publication in the Government Gazette. Thus, Thailand assures that these mechanisms are transparent. - Meanwhile, the Competition Law is being revised in order to enhance efficiency. |

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