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TAGS: ECON, ETRD, KIPR, TH

SUBJECT: ABBOTT LABS HALTS NEW DRUG REGISTRATIONS

- 1. Abbott Labs, the recent target of a compulsory license on their patented antiretroviral Kaletra, confirmed to Embassy that the company had withdrawn applications for registration of seven new pharmaceutical products in Thailand, and had no plans to introduce new products until its intellectual property was properly respected. The seven drugs include Aluvia, a new heat-stable version of Kaletra. Although the two drugs are identical in effect, the new version is considered ideal for tropical environments such as Thailand. Other drug applications pulled include treatments for hypertension, kidney disease, auto-immune disease and congestive heart failure. The applications had been on file with the Thai FDA for up to ten months awaiting approval.
- 2. Abbott said they had notified the FDA's Drug Control Division (DCD), but RTG officials interviewed by press said they were unaware of Abbott's actions (Embassy's calls to FDA officials were not returned today). The DCD's Senior Pharmacist Dr. Suchart Chongprasert told a Wall Street Journal reporter that he was

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surprised that Abbott would choose to unilaterally restrict its sales in Thailand and was waiting to see the actual documentation withdrawing the applications. Asked if the RTG would respond with further CLs, Dr. Suchart said the process of identifying drugs to license was lengthy and no more CLs were in the pipeline.

- 3. Matichon newspaper quoted Dr. Siriwat Tiptaradol, Secretary General of the Thai FDA, that the Ministry of Public Health planned to invite relevant parties, especially the three companies whose patents were broken, to meet on March 26 to negotiate. However, none of the three had yet to receive an invitation.
- 4. Comment: Abbott's actions will certainly be controversial. However, the action may strengthen the hand of Abbott and the rest of industry in future dealings with the RTG. Abbott's move puts the RTG on notice that there are visible consequences for its actions, rather than solely a vague weakening of the investment environment. Whether this focuses the minds of RTG officials at upcoming negotiations remains to be seen. End Comment. BOYCE

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