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Access to drugs: the case of Abbott in Thailand

In March, 2007, Abbott Laboratories announced that it was withholding all new medicines from Thailand. The company's position was put crudely: "Thailand has chosen to break patents on numerous medicines, ignoring the patent system. As such, we've elected not to introduce new medicines there."[1]

Abbott was reacting to the Thai Ministry of Public Health's announcement in January that it would issue compulsory licences for non-commercial use on a number of medicines. This move followed repeated attempts to negotiate affordable prices with several manufacturers,[2] including for Abbott's lopinavir-ritonavir, an important antiretroviral medicine recommended as a second-line treatment for developing country settings.[3]

Since late 2005, Médecins Sans Frontières and other groups have raised concern that Abbott has not prioritised the registration of the new version of lopinavir-ritonavir in less developed countries, and lacked clear plans for making the drug affordable. This new version, which was registered in the USA in October, 2005, and in Europe in July, 2006, has several important advantages for tropical countries: it does not need to be refrigerated, has no food restrictions, and has a lower pill requirement.

In March, 2006, physicians and patient groups from 24 countries wrote to Abbott requesting that the company immediately file for registration of the new lopinavir-ritonavir formulation in all countries where the old formulation was registered or pending (at the time this represented some 68 countries), as well as in all other developing countries.[4]

Abbott responded that to be able to register in developing countries, they first needed to obtain a Certificate of Pharmaceutical Product (CPP) by registering in Europe. In fact, Abbott could have used the CPP that was provided upon approval in the USA in 2005. We have queried this issue several times but Abbott has simply reiterated their incorrect claim that a European CPP was required.

Abbott claimed that they would be registering their new tablet formulation of lopinavir-ritonavir "very soon" in Thailand, China, and Guatemala.[5] 6 months after this promise was made, and more than a year since US Food and Drug Administration (FDA) approval was granted and the registration process could have begun, Abbott had still not submitted registration dossiers in China or Guatemala.

In Thailand, registration was applied for in early September, 2006, but Abbott failed to include the CPP. On Sept 14, 2006, the Thai FDA informed Abbott of the missing documentation and proposed a meeting with Abbott in mid-December to facilitate registration. The company requested a postponement and the Thai FDA agreed to delay until Jan 4, 2007, but Abbott again failed to send a complete dossier within this deadline. Finally, the Thai FDA took the unprecedented step of proceeding with registration anyway, given the pressing need for this drug in Thailand.

Why did Abbott stall the registration process for its new drug? One industry analyst has suggested that "it may be legitimate for Abbott to want to build up the more profitable US market before expanding globally".[6] In 2006, sales exceeded US$1·1 billion, of which 45% came from the USA[7] (a country with only 3% of the global HIV burden). One has to question how big a western market Abbott requires before the needs of the less developed world are considered.

A second issue affecting access is price. Abbott has set an annual price of $2200 per patient for lopinavir-ritonavir in Thailand—more than six times the current

cost of first-line antiretroviral therapy, and too expensive for a country where the average annual wage is $1600 a year. By contrast, production costs of lopinavir-ritonavir have been estimated by WHO to be as low as $338 per patient per year.[8] On April 10, 2007, Abbott announced a new lopinavir-ritonavir price of $1000 per patient per year for governments of more than 40 low and low-middle income countries. However, the company has yet to specify which countries are able to benefit from this price.[9]

As a consequence of the much higher price that Thailand is obliged to pay, the drug is rationed. Currently around 90 000 people are receiving antiretroviral therapy in Thailand and an increasing number need to switch to second-line regimens. It is estimated that around 8000 people would currently benefit from lopinavir-ritonavir, but in 2006 the Thai Ministry of Public Health was only able to afford the drug for around 600 people, leaving more than 90% of people currently in need of lopinavir-ritonavir without access.

To provide the best possible care for people with HIV/AIDS, the Thai government—and those of other developing countries—needs to be able to take action if a drug company refuses to make an essential drug available at an affordable price. The patent for lopinavir-ritonavir will not expire in Thailand until 2016. Patients failing first-line antiretroviral therapy in Thailand cannot wait 10 years to be able to access a generic version of a drug that has been in common use in the USA since 1996.

Abbott claims that by issuing a compulsory licence Thailand is "ignoring the patent system" but compulsory licensing is an integral part of national and international (World Trade Organization) intellectual property law;[10] its use in Thailand has been advocated by the World Bank[11] and various UN agencies[12] as a way to respond to rising antiretroviral drug costs. WHO has confirmed that Thailand's actions fully comply with international law,[2] and this has been reiterated by statements from other governments;[13] even the US government—which traditionally takes a strong stance in favour of intellectual property rights—respects the legal right of Thailand to issue compulsory licences.[2]

By ignoring repeated requests to make its drug available and affordable in Thailand, Abbott left the Thai government with little other choice than to seek alternative sources of this medicine. The fact that Abbott is now withholding all other new medicines from Thailand demonstrates a total disregard for both public health in developing countries and the spirit and intent of the patent system it pretends to uphold.

Paul Cawthorne, Nathan Ford, David Wilson, Kannikar Kijtiwatchakul, Virat Purahong, Nimit Tianudom, Supatra Nacapew

Médecins Sans Frontières, 533 Mooban Nakorn Thai 14, Ladprao Soi 101/1, Bangkapi, Bangkok, Thailand (PC, NF, DW, KK); Thai Network of People living with HIV/AIDS, Bangkok (VP); AIDS Access Foundation, Bangkok (NT); and Centre for AIDS Rights, Bangkok (SN)

msfb-bangkok@brussels.msf.org

We declare that we have no conflicts of interest.

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