

# Thailand to crack down on illegal online pharmacies

Regulatory intervention by government authorities to stem the illegal sale of drugs and counterfeit medicines online has resulted in millions of dollars worth of fines being imposed on the perpetrators, and has brought online pharmacies into the regulatory spotlight, especially in Thailand. A draft bill to replace the current Drug Act in Thailand is now being discussed. Dr. Atthachai Homhuan, Manager of Regulatory Affairs at Tilleke & Gibbins, discusses recent US regulatory enforcement action against an online pharmacy hosted in Thailand and how illegal online pharmacies are being combated.

International headlines recently focused on a dramatic case of regulatory enforcement against an online pharmacy. The Pittsburgh Post-Gazette reported that a 33-year-old Thai woman was running a company with the website www.eDrugnet.com, along with at least 30 other affiliated websites. These sites sold drugs without prescriptions, despite the fact that prescriptions were required in the purchasers' country. These e-pharmacy websites were hosted in Thailand and shipped drugs to the US. After receiving emails with drug orders from foreign customers, the company would send drugs overseas in boxes labeled as samples and gifts, via express mail.

After a lengthy investigation by the US FDA, FBI, and Department of Homeland Security, the woman confessed to the scheme. She pleaded guilty in a US district court, and her websites have since been taken offline. On 31 January 2013, she was sentenced for wire fraud, money laundering, and

introducing misbranded drugs into the United States. She has already agreed to pay the US government US\$2.1 million, reflecting her company's sales, and the US District Judge added a further US\$5,000 fine to her sentence.

## Online pharmacies and counterfeit medicines

Given the millions of dollars involved in this case, it was bound to capture attention. This case highlights the lengths that government authorities are going to in order to rein in the rapid growth of online pharmacies. The authorities recognise that the sale of drugs online may offer certain advantages, but these are accompanied by potential dangers for consumer health and safety.

Online pharmacies can be beneficial in helping consumers find the specific drug products they need, and they often offer special discounts. Online pharmacies are also easy to access - a simple web search reveals a seemingly endless list of drugs that can be purchased on the web. Furthermore, if a customer feels embarrassed about purchasing a certain product (for example, erectile-dysfunction medication) from an actual pharmacy, using a virtual pharmacy can save the customer from an uncomfortable experience.

This is where problems begin to arise. Online pharmacies often trade in counterfeit medicines that contain incorrect or inactive ingredients, thus creating potentially fatal risks for patients. The trade in counterfeit drugs has grown into a global industry worth billions of dollars, and these illegal activities have flourished online.

Many online pharmacies focus their trade on specific product ranges that can be sold in a high volume online, with erectile-dysfunction (ED) drugs at the top

of the list. A recent analysis and review of unregistered ED drugs seized by police and health authorities in Eastern Thailand found that most samples (88%) contained an amount of Active Pharmaceutical Ingredients (API) below the labeled claim, while some samples contained the wrong API altogether (e.g. chloramphenicol, an antibiotic). Apart from ED drugs, counterfeit abortifacient drugs, anti-obesity drugs, antimalarial drugs, and psycholeptic drugs have a high tendency to be sold illegally via e-commerce channels.

In Thailand, almost all of these counterfeit drugs are manufactured abroad and then smuggled into the country. These products are usually labeled 'Made in Thailand' or show a Thai address. In general, the name and address are fake, and the manufacturers cannot be found in the records of the Thai FDA's pharmaceutical manufacturing database.

## Combating the problem through regulation

Despite the boom in online sales of drugs, Thailand does not yet have separate legislation governing the online sale of pharmaceutical products through e-pharmacies hosted in the Kingdom. Currently, the online sales of these products are governed by the Drug Act B.E. 2510 (1967), which broadly covers physical sales of medicinal and pharmaceutical products.

According to Section 14 of the Drug Act, the Thai FDA, as the licensing authority, will approve a 'licence to sell drugs' for business operators if they comply with certain requirements. One of the requirements is that business operators resident in Thailand must have the appropriate premises to sell or store drugs, with the appropriate equipment for use

in the sale or storage of drugs, and control over the maintenance of drug quality and quantity, as prescribed in the Ministerial Regulations. In addition, Section 21 of the Drug Act states that a business operator that has been permitted to sell modern drugs must have a pharmacist on duty during business hours.

These two sections of the Drug Act forbid the distribution of drugs 'virtually,' since neither the requirement of appropriate premises nor that of an on-duty pharmacist would be satisfied by an online operation.

### Restrictions on drug advertising

Despite the fact that it is illegal under Thai law to market drug products online, many online pharmacies are using social media marketing as a promotional channel to attract customers and sell illicit medicines and psychotropic substances. Many pharmacies are creating fan pages via social media as part of 'their direct-to-consumer advertising' strategies. This can put many people at a greater risk of buying and using dangerous products.

With regard to online advertising, while there are no specific rules on the use of the internet or social media for drug advertisements, the Thai FDA enforces and regulates the promotion of drugs via Sections 88 to 90 of the Drug Act. Under Section 88 bis, businesses that advertise drugs via radio, television, movies, or through printed matter must receive permission from the Thai FDA for the text, sound, and/or picture(s) used in their advertisement(s).

Nevertheless, according to the Thai FDA, most online advertisements (more than 85%) are being presented without permission. Currently, the FDA has made it a priority to deal with this

**Despite the boom in online sales of drugs, Thailand does not yet have separate legislation governing the online sale of pharmaceutical products through e-pharmacies hosted in the Kingdom.**

problem. Thus, business operators must ensure that their social media marketing strategies meet Thai FDA requirements, as well as the requirements of the Drug Act. Any violation of the Drug Act's marketing provisions is subject to a fine of up to THB 100,000 (US\$3,340).

### Increasing international and local enforcement

Coupled with the increase in regulatory enforcement, government authorities are taking other aggressive actions against online pharmacies and counterfeit medicines both internationally and locally. According to a report by the World Health Organisation (WHO), over half of the medicines from illegal internet pharmacies are counterfeit. In order to fight against this phenomenon, the WHO set up the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) in 2006. IMPACT has led international actions, offering guidance on how to strengthen legislative and regulatory frameworks. Through IMPACT, the WHO has worked with regulatory agencies such as Interpol to uncover counterfeit operations.

In 2010, Operation Pangea III, co-ordinated by Interpol and IMPACT, collated data from 45 participating countries and uncovered a vast network of counterfeit drug sales on the internet. The operation revealed 694 websites engaged in illegal activities, 290 of which have now been shut down. One of the first co-ordinated operations, Storm II, successfully targeted eight countries across Southeast Asia, including Thailand. The operation led to the seizure of 20 million fake medicines, including antibiotics, antimalarial and birth control tablets, tetanus serums, aspirin,

and ED drugs.

Building on this international co-operation, the Thai FDA has established the Center for Combating Counterfeit Drugs. This centre engages consumers in the broader enforcement effort by encouraging tipsters to provide information about counterfeit medicines to government authorities<sup>1</sup>.

### Looking ahead

Thailand's current drug laws were established more than 40 years ago and are therefore ill suited to deal with e-commerce. A draft bill to replace the current Drug Act is now being discussed, but like its predecessor, the current draft remains silent on the issue of online pharmacies or the online trade of drugs. The new draft law does mention the imposition of civil liability, which could apply to e-commerce Drug Act violators. Through additional civil liability, legislators have sought to increase compensation for victims of drugs sold in violation of the Drug Act.

Will civil liability be enough to quell the perpetration of online trading or e-commerce in medicines? Given how difficult it is to identify the operators of online pharmacies, there are doubts about whether the enactment of the new draft law will do much to alleviate the damage resulting from online drug purchases. As an alternative, Thai law may prioritise preventing these adverse results by imposing regulations directly on online pharmacies and distributors of pharmaceutical products, as such regulations could be much more effective than merely compensating victims in retrospect.

**Dr. Atthachai Homhuan** Manager,  
Regulatory Affairs  
Tilleke & Gibbins  
atthachai.h@tilleke.com

1. Via [complain@fda.moph.go.th](mailto:complain@fda.moph.go.th)