



<< Left
Kittiya Nopparatrunroj
 Consultant
kittiya.n@tilleke.com

<< Right
Tayagorn Warathornthnakul
 Consultant
tayagorn.w@tilleke.com

Thailand Takes Steps to Ensure Availability of High-Demand Medical Supplies

Dealing with the COVID-19 pandemic has taken top priority for almost every country in the world. In Thailand, even though the strength of the country's health security measures has been ranked sixth-best globally, COVID-19 hit hard, and the country has only just begun to detail with the effects of the outbreak.

In the early stages of the outbreak in January 2020, only passengers who had visited mainland China were subject to close monitoring by communicable disease control officers. By late February, South Korea had become another epicenter of the outbreak, and many Thai nationals who had been working there chose to return home to Thailand to avoid COVID-19 infection. Thailand's Ministry of Public Health (MOPH) was concerned that the local outbreak would become more widespread as a result of these returnees infecting others (if indeed they were infected). While this risk now seems to have been successfully handled, the virus continues to rage in various countries in Asia and around the world.

These circumstances preceded the MOPH designating COVID-19 as a "dangerous communicable disease" under the Communicable Disease Act B.E. 2558 (2015). While incoming international travel was effectively sealed off relatively early on, the few remaining incoming travelers have been subject to certain conditions such as quarantine and special monitoring.

Communicable disease control officers are empowered to require suspected persons to be diagnosed and quarantined. Under the current rules, all COVID-19 patients and suspected COVID-19 patients—defined as having a fever higher than 37.5 degrees Celsius and any other symptom associated with COVID-19, such as coughing, a runny nose, a sore throat, or shortness of breath—are brought to a medical facility specified by the MOPH for diagnosis, treatment, isolation, and quarantine, as necessary. People returning from high-risk areas but not showing any symptoms have been subject to a mandatory 14-day quarantine and have had to adhere to strict health-related follow-up exams.

Apart from the quarantine measures, people have been advised to strictly practice good personal hygiene throughout the course of the outbreak. Unsurprisingly, alcohol-based hand sanitizers and face masks have faced severe shortages in Thailand. The MOPH has been involved in the supply of these high-demand items by relaxing some regulations on their importation and production. However, these moves alone are not considered sufficient. The Department of Internal Trade of the Ministry of Commerce has also stepped in to control the supply and set up the maximum allowable purchase price of face masks. Other regulations related to these products have been modified to counteract shortages—examples include reclassification of alcohol-based hand sanitizers, implementation of fast-track pathways for the domestic production of alcohol-based hand sanitizers, declaration of alcohol-based hand sanitizers and disposable medical masks as controlled goods, and so on. Regulations

such as these will likely continue to change periodically, so healthcare entrepreneurs should check frequently that they are compliant with the latest updates.

Thailand's Updated Regulations on Alcohol-Based Hand Sanitizers and Disposable Medical Masks

The Cosmetics Act B.E. 2558 (2015) and the Medical Device Act B.E. 2551 (2008), as amended, provide the regulatory framework for the trading and post-marketing surveillance of both alcohol-based hand sanitizers and face masks in Thailand. In 2019, the MOPH reclassified alcohol-based hand sanitizers as medical devices (instead of their previous categorization as cosmetics), with the reclassification to enter into force on March 11, 2020. However, the COVID-19 outbreak intervened, causing a shortage of alcohol-based sanitizers. The MOPH acted to ease this shortage by canceling the reclassification of alcohol-based hand sanitizers because the more stringent controls applied to medical devices would cause unnecessary delays. Alcohol-based hand sanitizers will therefore continue to be classified as cosmetics for the foreseeable future.

For new registrations of alcohol-based hand sanitizers, it was announced that only products containing alcohol concentrations greater than 65% w/w would be allowed to be registered (through notification and approval) as controlled cosmetics. The notification certificate is valid for three years and is renewable. The Thai Food and Drug Administration (FDA) has also relaxed regulations to allow pharmaceutical manufacturers, traditional drug manufacturers, and medical device manufacturers located in Thailand to produce and sell alcohol-based hand sanitizer without having to first obtain a cosmetics manufacturing license. In other words, after registering its product with the FDA, the manufacturer can bring it to market.

The shortage of disposable masks is much more acute. Hospitals have run out of their supply due to high public demand, low production scale, and hoarding. Some people have seen this as an opportunity to earn extra income by making and selling homemade masks as an alternative to commercial face masks. These reusable homemade masks are not classified as medical devices and cannot be claimed to be personal protective equipment against the coronavirus. Only disposable medical masks are regulated; they are classified as low-risk medical devices. Imported masks require product registration with the Thai FDA. For domestically manufactured masks, although product registration is not required, the domestic manufacturer is still required to register the establishment as a medical device manufacturer with the FDA. Due to the COVID-19 outbreak, the Medical Device Control Division has agreed to facilitate all registration processes for establishments producing disposable medical masks.

Price Controls

As both alcohol-based hand sanitizer and disposable medical masks are currently in high demand, the Thai Central Committee on Prices of Goods and Services (CCP) has published a notification announcing price controls. For alcohol-based hand sanitizer, the manufacturer, importer, and distributor of the product must notify the CCP of the pricing details. In addition, the price may not be increased without receiving permission from the CCP. For domestically manufactured disposable medical masks, the retail price must not exceed THB 2.50 (approx. USD 0.08). However, the price of imported masks has not yet been fixed. The CCP has only required that the importer,

Continued on page 15

Thailand Secures Medical Supplies (from page 14)

distributor, and retailer not mark up the price more than 10%, 10%, or 23%, respectively. As for exports, the CCP has banned all unauthorized exportation of medical masks. Though they had previously directed exporters to seek permission only for shipments of 500 masks or more, this led some exporters to divide their shipments to circumvent the requirement. Therefore, according to the latest CPP notification, all exporters must first obtain approval from the CPP before exporting mask products, regardless of the amount to be exported. Meanwhile, the price of these products in the Thai market continues to rise as the fixed-price policy only applies to domestically manufactured disposable medical masks and because some traders do not obey the law when faced with high demand.

In summary, the widespread concern about the COVID-19 pandemic has spurred the Thai government to ensure an adequate supply of masks and alcohol-based hand sanitizer for the public. Their regulatory moves and relaxation of certain requirements have indeed eased supply problems; on the other hand, vendors acting in bad faith have exploited legal loopholes, increasing the already substantial chaos and turmoil gripping society. For instance, there were reports of individuals hoarding large quantities of masks for resale in the black market and for illegal exportation. Moreover, some unscrupulous vendors recycled used masks and resold them as new ones. As a result, the government has ordered severe punishment for anyone who violates the law during this trying situation. It is thus imperative at this time that healthcare entrepreneurs understand and comply with the law governing the supply of products in need during the COVID-19 pandemic. 🙏