

Open Letter to Merck Sharp and Dohme Corporation “No molnupiravir Patent in Thailand, What Right Would Merck Exercise to Block the Importation”

- *Molnupiravir is a medicine that was researched and developed by one of the universities in the United States with a certain amount of budget sponsored by the US government, which such budget came from taxes of American citizens. The research right has been sold to a multinational drug company for the purpose of further development in COVID-19 treatment.*
- *After completion of drug registration in the United States, the corporation succeeded in making a deal with the US government to sell molnupiravir at the price of USD 700 per treatment (approx. THB 20,000), while the total cost of production including profits and taxes should not exceed USD 20 per treatment (approx. THB 600).*
- *Thailand has ordered this drug from the multinational drug company at the price of USD 300 per treatment (approx. THB 10,000), while the generic-drug companies in India manufacture and sell at the price not exceeding USD 16 per treatment (approx. THB 500).*
- *There is no patent application of molnupiravir filed in Thailand. So, it means that Thailand can import generic drugs at a lower price. However, there is duress to block the importation of the generic drugs.*

Why Do We Need Access to Molnupiravir?

During the past two years, countries around the world have been facing the pandemic of COVID-19. Until today, the global COVID-19 infection rate has exceeded 457 million people and there are more than 6 million deaths. In Thailand, more than 3.1 million people have been infected and over 24,000 died. In fact, the actual infection rate is much higher than that. Although Thailand has provided 2 shots of vaccination, until 11 March 2022, to 71.4% of the population in Thailand, but there is only 30% in Thailand who received a booster shot.

Providing COVID-19 vaccine seems to be insufficient to cope with the pandemic situation, vaccines provided has a limited efficacy on stopping the spreading of the coronavirus. Even though the vaccines are able to decrease rates of the severe illnesses, there are still a lot of people who have not been vaccinated due to medical reasons. New strains of COVID-19 continue emerging and it has a chance that the vaccines currently available may have limited efficacy in preventing from the new variants' infection

Therefore, the drugs that can treat COVID-19 patients who have mild and moderate symptoms are crucially needed, as they can assist decrease in the bed occupancy rate in the hospital and the burden of the hospital staff who are currently burning out in providing healthcare services.

One of the drugs mentioned which have been used globally to treat COVID-19 is molnupiravir, which WHO has recommended to be used as a treatment for non-severe COVID-19 patients with the highest risk of hospitalization. It is the drug that public health agencies in many countries also recommended to be used.

Who Invests in the Research and Development of Molnupiravir?

Molnupiravir was the drug that Emory University has been researched and developed in 2013 - 2020 with the funding support of USD 35 million sponsored by the US government which were from the US citizens' taxes. The result of the R&D has shown that molnupiravir is able to treat influenza. The research of Emory University has been sold and transferred until it landed in hands of the multinational drug company, Merck Sharp & Dome, known as Merck or MSD. Merck had conducted further clinical trial adapting it for the COVID-19 treatment in 2021.

In June 2021, the US government made a purchase deal of molnupiravir with Merck at approximately 1.7 million doses at the price of USD 1.2 billion (THB 36,000 million), which means that the average cost of treatment per patient is approximately USD 712 (THB 21,360).

How Much Does It Cost to Produce Molnupiravir?

In October 2021, Harvard University in the US with King's College Hospital in the UK has published the report on the cost of production of molnupiravir. From the study, the result shows that the cost of producing one 200 mg. tablet is USD 0.44 (THB 13) and the cost of treatments per patient for the duration of 5 days are USD 17.74 (THB 532). When including profits and taxes, molnupiravir should not be priced over USD 20 US dollars (THB 600) per treatment.

Therefore, it is obvious that Merck has sold molnupiravir to the US government 35 times higher price than it should be, in spite of the research and development of molnupiravir being funded by the US government from the US citizens' taxes.

Making an Image or Promoting Access?

In October 2020, Merck has issued the voluntary licensing measure through the international organization, "Medicine Patent Pool" (MPP). With this measure, Merck allowed 8 generic pharmaceutical companies in India to produce and market the generic versions of molnupiravir at lower price to the 105 low- and middle-income countries without being deemed as patent infringement. However, it does not include Thailand and many other developing countries that are encountering the critical crisis of no or insufficient COVID-19 medicines.

While many of the generic-drug companies in India, regardless of inclusion in the Merck-MPP voluntary licensing agreement, are able to produce and supply molnupiravir at the same quality as Merck produces at the price of only USD 12 – 14 per treatment (approx. THB

400 – 460). Molnupiravir was opposed on the ground that it should not be granted the patent from many companies and NGOs in India and there is no patent granted in India yet.

No patent...So How Can It Be Infringed?

Although Thailand is not on the Merck-MPP voluntary licensing's eligible country list, the civil society organizations in Thailand that are working to promote access to medicines have researched the patent status and found that Merck did not file for patents for molnupiravir in Thailand.

Later, the civil society organizations sent an enquiry letter to the Department of Intellectual Property, Ministry of Commerce on 14th September 2021 about patent applications filed for molnupiravir, and the Department of Intellectual Property had a reply on 16th December 2021 that there was no patent application filed monupiravir in Thailand as well.

Furthermore, on 12th December 2021, the civil society organizations sent a letter to the Minister of Public Health to inform that molnupiravir does not have any patent application filed in Thailand. Thailand can import or manufacture molnupiravir without being considered an infringement of the patent. They also asked the government to have price negotiation with Merck for the purchase of originator molnupiravir to get the lower price for the emergency use during the period there is no generic drug available in Thailand yet.

From the news published in the media in November 2021, Thai government approved the procurement of 2 million tablets of molnupiravir with the budget of THB 500 million from Merck. By this deal, the treatment price can be averaged to THB 10,000 per patient (approx. USD 300). However, the study of Harvard University has shown that treatment should not cost over THB 600 per patient (USD 20), and generic molnupiravir produced in India are sold at the prices lower than THB 500 per patient (USD 16). Until now, Merck has not delivered molnupiravir to Thailand.

Profiting from People's Lives Regardless of Morality

From aforementioned incidents, it shows that Merck has taken advantage of the global COVID-19 crisis in making huge profit while countless people are getting sick and dying because of inhumanly high pricing of the medicine. Merck revealed to the international media that they have gained profit from selling molnupiravir in the last quarter of the year 2021 around USD 952 million and they expected to have income of USD 5-6 billion from selling the medicine.

In addition, Thai civil society organizations received information on 10th March 2022 that there was a person who claimed to be working for Merck, calling a local pharmaceutical manufacturer and threatening to file a lawsuit against them if they produced or imported generic molnupiravir by claiming that it infringed Merck's intellectual property rights of molnupiravir.

However, that person failed to provide details of how it infringed the intellectual property rights.

Petition

The civil society organizations in Thailand working to promote access to medicines write up and share this open letter to the public for the purpose of:

1. Inquiring of Merck Sharp & Dohme if they had assigned anyone to call and threaten any pharmaceutical manufacturer in Thailand to prevent the production and/or the importation of generic molnupiravir, and
2. Requesting MSD to reveal all the patent application numbers, related to molnupiravir, which has been filed or will be field for patents in Thailand.

We believe that the local pharmaceutical industry has no intention to infringe any intellectual property rights (IP) related to molnupiravir and has been complying with international and domestic IP laws. Local pharmaceutical industry has an important role in being responsible for the country's medicine security and promotion of access to essential medicines. Especially amid the COVID-19 crisis, they are required to produce and/or import quality and affordable molnupiravir to be an alternative to save lives of people wherein the country doesn't need to rely on Merck's exorbitant-price molnupiravir that the patients cannot access and the national health insurance schemes are unable to procure for all the patients who need it.

Only taking an enormous amount of profit regardless of people's lives in a health crisis alone is such an inhumane act. Using legal threat without any ground or vague ground in order for it to be a hindrance in accessing affordable medicines to save people's lives has truly reiterated an inhumane of the doer.

16th March 2022

AIDS Access Foundation
Thai Network of People Living with HIV/AIDS (TNP+)
FTA Watch
Drug System Monitoring and Development Center
The Rural Pharmacist Society
Drug Study Group