



COVID-19 vaccine counterfeits set off alarms across the globe

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CAJICA, Colombia – A cooler box with 70 vials allegedly filled with counterfeit COVID-19 vaccines seized from a Chinese couple in Colombia’s El Dorado International Airport on Feb. 17 underscored the growing challenges facing pharmaceutical companies, law enforcement authorities and health care regulators around the world. Patient safety, company liability and the security of distribution channels have all been areas of growing concern.

In early February, Latin American regulators Invima (Colombia), Cofepris (Mexico) and Digimed (Peru) issued alerts almost simultaneously to warn the public of the risk of counterfeit vaccines in local markets.

“Cybercriminals have popped up through social networks or by different electronic means to advertise coronavirus vaccines,” Invima director Julio Aldana said in a video (<https://twitter.com/invimacolombia/status/1357083676287320065?s=20>) posted to Twitter Feb. 3.

For its part, Cofepris issued a health warning (<https://www.gob.mx/cofepris/articulos/cofepris-informa-sobre-la-comercializacion-ilegal-de-la-vacuna-contra-covid-19-de-la-empresa-astrazeneca-s-a-de-c-v?idiom=es>) about the illegal marketing of vaccines supposedly manufactured by Astrazeneca S.A. de C.V. of Mexico City, the local arm of Astrazeneca plc.

“In Mexico, the sale of the vaccine to the private sector is not authorized and, moreover, Astrazeneca S.A. de C.V. does not recognize any distributor to that end,” said the regulator.

That was Cofepris' second warning. In early February, Mexican authorities took down a website using Pfizer Inc.'s brand and claiming to have doses of the company's BNT162b2 vaccine for sale for \$150. Mexican police said vaccines of doubtful origin pose a significant threat to the public.

The challenges are not limited to a single region.

On Feb. 1, China's Ministry of Public Security said via the state-controlled news agency Xinhua that it had arrested 80 people across three provinces whom it claimed were involved in the production of more than 3,000 doses of fake vaccines.

In the U.S., law enforcement agencies have warned (<https://www.bioworld.com/articles/501514-dea-beware-vaccine-fraud>) of the increased risk of counterfeit vaccines and fraud and have launched multiple operations, arrests and seizures.

"As a number of COVID-19 vaccines come closer to approval and global distribution, ensuring the safety of the supply chain and identifying illicit websites selling fake products will be essential," said (<https://www.interpol.int/News-and-Events/News/2020/INTERPOL-warns-of-organized-crime-threat-to-COVID-19-vaccines>) Interpol on Dec. 2, 2020, when it issued an orange notice to warn of the threat that fake vaccines pose to public safety. "The need for coordination between law enforcement and health regulatory bodies will also play a vital role to ensure the safety of individuals and wellbeing of communities are protected," it said.

For the general public, counterfeit and fake vaccines pose significant health risks. For vaccine makers, typically large multinationals, the issue poses liability and reputational issues. In the context of the COVID-19 pandemic, a third growing issue has been the tracking of vaccines, some of which may have been stolen from government vaccination programs and distributed directly or through increasingly common e-commerce sales.

Patients at risk

"This type of behavior puts the integrity and life of consumers and the people around them at risk, making them believe that they are being vaccinated with a product that has met all health safety and transport standards, while that is not the case," Enrique Martinez, partner and director at the Colombian consultancy of Martinez Escallon & Asociados, which focuses on issues related to counterfeiting and smuggling in the pharmaceutical industry, told *BioWorld*.

"The role of e-commerce platforms that serve as trade centers must be proactive and responsible, to prevent fake drugs and biologics from entering the market and preventing themselves from becoming part of the chain that helps counterfeiters to promote and deliver those products to the detriment of society and consumers," said Martinez.

"Many of the largest platforms in the region already work hand in hand with the owners of the brands, and with the authorities, but in general we believe that they could be even more diligent when allowing their platforms to be used to sell medicines, which additionally, in many countries, their sale or promotion by these means is prohibited," he explained.

In Peru, criminals have promoted online sales of vaccines allegedly manufactured by the China National Pharmaceutical Group Corp. (Sinopharm) at \$2,734 for two doses. Peru has already received a batch of 300,000 doses of Sinopharm's vaccine and it is unknown if the illegal sales were for fake products or shots

stolen from the government.

“The Ministry of Health reiterates to the population that vaccines against COVID-19 are free and will be applied only in nationally authorized public health establishments,” the government said in a message posted to Twitter (https://twitter.com/Minsa_Peru/status/1358934014288162819?s=20).

In neighboring Ecuador, police raided a clinic in which authorities estimate that about 70,000 doses of a fake vaccine of an undisclosed brand were administered.

Growing liability for companies

Whether counterfeit or stolen from chains of custody, the concern around fake vaccines is on the rise. In parts of Asia, particularly China, the concern is especially acute.

“Any counterfeit of their drugs represents both a health threat and a threat to the company's reputation,” Kent Kedl, a Shanghai-based partner and head of greater China at risk consultancy Control Risks, told *BioWorld*. Kedl said that counterfeits are a significant issue for multinational pharmaceutical companies and that his company deals with the issue several times a year.

“If and when something happens, authorities will often go after the company whose name is on the drug, even if they are not the ones that manufactured or distributed it,” Kedl said.

David Swain, partner and head of intellectual property at law firm Lewis Silkin's Hong Kong office, shares similar concerns regarding the exposure for companies whose brands are being forged.

“Depending on the manner of counterfeiting in question, a number of problems may arise for pharmaceutical companies, including potential legal action by patients, and detrimental effects on their brands and reputation,” Swain said.

Like Martinez in Colombia, Swain is also concerned about the risk to public safety that this type of crime represents, particularly at this point in time.

“The biggest issue with trafficking fake vaccines and other medicines is the effect on the public, as these are very likely not to generate immunity or cure, and can harm or in extreme cases even kill,” he said.

The Chinese couple arrested in Colombia had vials branded as vaccines manufactured by the Chinese Academy of Medical Sciences, from Kunming, China, which is moving forward with a phase III trial for its Vero cell vaccine candidate. The couple were released and fined for trying to import a product without a sanitary registration and it has not been established whether the vials were originals or counterfeits.

“Traceability of vaccines that are administered is important and therefore to have control over the destination and application of each dose has become more relevant than ever,” said Martínez. “With traceability, there can be controls in case any doses are stolen from custody, and investigations can be carried out to bring criminals to justice.”

Warnings in the U.S.

Last year U.S. Immigration and Customs Enforcement's Homeland Security Investigations (HSI) launched a dedicated Operation Stolen Promise 2.0 to fight counterfeit products, including vaccines, related to the COVID-19 pandemic. Under this [operation](https://www.ice.gov/topics/operation-stolen-promise), 235

criminal arrests have been made and more than \$33.5 million in illicit proceeds seized along with almost \$20 million in disrupted transactions and recovered funds.

On Feb. 12, HSI said it had dismantled a fraud scheme purporting to sell COVID-19 vaccines in Baltimore.

“As the public seeks vaccines to protect themselves and their families from COVID-19, fraudsters are waiting to take advantage of their desperation,” said Baltimore Special Agent in Charge James Mancuso.

According to Swain, from Lewis Silkin, a coordinated strategy between law enforcement agencies and pharmaceutical companies is key in identifying counterfeits. Martinez, in Colombia, agrees.

“In the case of Colombia, authorities are very proactive on the issue, and they work hand in hand with the pharmaceutical companies, channeling the information they may have, while effectively deploying the entire force of the state to combat counterfeiters,” Martinez said.