CHAIR’S NOTE

COVID-19 VACCINE AND THE THREAT OF ILLICIT TRADE

While communities and economies around the world confront the lethal effects of COVID-19, the threat of illicit trade keeps wreaking havoc on people’s safety and the security of nations. Before the coronavirus pandemic, global illicit trade was already booming from an array of trafficking and smuggling crimes. COVID-19 has accelerated illicit trade across the Internet on social media, e-commerce platforms, and online marketplaces, alarming law enforcement and broader communities in many parts of the world.

On April 23, 2020, the OECD Task Force on Countering Illicit Trade organized a webinar to explore the main impacts that the COVID-19 pandemic is having on illicit trade. One of the main findings of the webinar was that several sectors might be particularly at risk for fraud and illicit activity. These include pharmaceuticals and other industries that criminals frequently targeted before the pandemic.

Building on the conclusions of the April 23 webinar, the OECD Task Force on Countering Illicit Trade organized a webinar on June 10 that focused on illicit trade in fake medicines. The webinar concluded that the pharmaceutical sector is particularly at risk. During the pandemic, there has been a pronounced spike in demand for pharmaceuticals that often is not met. Criminals are targeting this niche, seeing an opportunity for easy profits.

The recent introduction of vaccines for COVID-19 offers a promise of a change in the landscape. For societies, it brings hope. For criminals, it brings prospects of profits, as the mechanisms that facilitate illicit trade in fake pharmaceuticals will also work for the COVID-19 vaccine. To address these issues, the OECD Task Force on Countering Illicit Trade organized a fourth webinar on December 21, 2020. The webinar focused on mapping different types of illicit trade risks related to the COVID-19 vaccine and gauging governance responses.

The meeting gathered about 150 participants from the TF-CIT public and private stakeholder networks. Mr. Chris Martin, Senior Counsellor at the UK HM Revenue and Customs and Chair of the TF-CIT, chaired the webinar. Speakers at the webinar represented both the public and private sectors.

**Key messages to consumers (US HSI)**

- Always consult with a licensed medical professional to obtain a COVID-19 vaccine or treatment.
- Do not purchase COVID-19 vaccines and treatments over the Internet.
- Do not purchase COVID-19 vaccines and treatments through an online pharmacy.
- Ignore unsolicited offers for vaccinations and miracle treatments or cures.
- Don’t respond to texts, emails, or robocalls about vaccines and treatments.
- Be wary of ads for vaccines and treatments on social media.
Effective distribution of the vaccine is an unprecedented challenge

To best secure the process, vaccine distribution is being controlled by national governments. Private companies carry out production, but all the output has been commissioned by the governments that manage the distribution and vaccination process. There is no vaccine that an individual could freely purchase on the market.

For example, the EU vaccine supply chain relies on advanced purchase agreements concluded by EU authorities on behalf of the Member States with six pharmaceutical companies. So far, the European Commission has secured about two billion doses. Most of the production is taking place within the EU. Each EU Member State receives doses based on its population. Shipping is done across each Member State under the supervision of National Health Agencies. Shipments are secured with a track-and-trace system to manage eventual product recalls.

The number of people to be vaccinated is unprecedented. In this context, it is essential to highlight that, given limited production capacities, it will be impossible to satisfy demand within a short time. Furthermore, logistical complexities and risks (discussed below) can make the situation even more
difficult. The vaccination process will be spread over many months, and it seems unavoidable that there will be some unmet demand on the market.

**Governments and industries prepare for all kinds of unexpected threats**

National authorities are aware of the unprecedented scale of this challenge. Still, there is a significant degree of uncertainty behind the process, and the types of risks that might arise are mainly unknown. There are no lessons learned from the past that would give a sense of risks related to the COVID-19 vaccine. Authorities and industry must prepare for the unexpected.

In preparation for potential illicit trade-related risks, national authorities, together with the industry, are working on a palette of likely scenarios, preparing to monitor distribution processes, while looking for bottlenecks and screening delays. Specific measures are being applied to every part of the distribution process to enhance transparency and minimize risks. For example, track-and-trace technologies are being used to check the distribution process effectively, and vials are being destroyed after vaccinations to prevent their re-use for illicit purposes.

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Criminals actively capitalize on the COVID-19 crisis

Existing evidence shows that for criminals, the COVID-19 crisis has been an excellent opportunity for profits. Changing enforcement priorities, closures of stores, unsatisfied demand, distorted supply chains, and the spiking demand for some products (e.g. pharmaceuticals) has created conditions in which criminal networks thrive.

For example, in the United States, the Department for Homeland Security carried out operation Stolen Promise that focused on the illegal import and sale of counterfeit and substandard products. It detected and deterred financial fraud scams, and prevented the exploitation of relief and stimulus programmes. The results of this operation demonstrated the activity of criminals. More than 1 600 COVID-19-related seizures of fake and substandard goods and almost 71 000 COVID-19-related domains were seized on the Internet.

In the European Union, enforcement authorities reported a massive influx of counterfeit and falsified COVID-19 products, including test kits, hand sanitizers, masks, ventilators, and gloves.

Insights into illicit trends related to the COVID-19 vaccine were demonstrated in operation STOP, which was carried out by the World Customs Organization. It showed that criminals that run illegal trade networks exploit the pandemic in several ways, including by smuggling substandard essential goods such as medicines, sanitizing gel, fraudulent medical equipment kits, etc. The scale of these operations is global, including seizures in Portugal, Niger, Argentina, etc. Significantly, to limit potential risks, criminals prefer small consignments and online orders as a means to circumvent customs checks.

Criminals have been actively capitalizing on the COVID-19 crisis since its outbreak. For them, the introduction of vaccines offers additional profit potential. There are already illicit offers of a COVID-19 vaccine on the dark web. Using these prices as a proxy, a shipment could be worth more than USD 100 million to criminals. It implies that, indeed, profits earned from illicit trade in COVID-19 vaccines might be unprecedented, well above other sectors of illicit trade.
The unmet demand for COVID-19 vaccines could boost the illicit market

The unmet demand for COVID-19 vaccines will undoubtedly lead to illicit offers from groups who have prior criminal enterprises and who will simply adapt their fraudulent operations to take advantage of the current health crisis. The illicit offers might take the form of person-to-person physical transactions in less regulated economies and Internet-based transactions in the more regulated and technology-aware societies.

Further delays in deliveries of vaccines and growing unmet demand might create additional triggers for criminals to intensify their activities. There are concerns among enforcement that the public might unknowingly buy counterfeit vaccines from illegal sources if demand remains unsatisfied. Some of them might even take the risk of looking for vaccines on illicit markets out of fear or desperation.

Critical risks areas in rolling out COVID-19 vaccines

Experts have identified three areas of particular concern for illicit trade in COVID-19 vaccines:

- Theft and diversion of vaccines
- Logistical transportation risks
- Misuse of the on-line environment

Complex distribution can lead to high risks of theft and diversion

Over time, criminals have successfully infiltrated legitimate supply chains for medicines, on numerous and increasingly frequent occasions. They will likely seek to do so with the COVID-19 vaccines as well.

Initially, criminals will likely focus on the Internet, but as more nations receive the vaccines and the supply chain is increasingly blurred, the capacity for criminals to exploit this situation by claiming that they can offer authentic vaccines will increase.

The complexity of distribution processes raises numerous risks; it is not possible to isolate a single area where theft and diversion might occur. It is likely that thefts will be observed at multiple stages of the distribution chain. These will include attempts to infiltrate legitimate supply chains with diverted and counterfeit products, and sale of counterfeit via the Internet and sale of illicit products in point of use locations.

Logistical challenges

In addition to the threats of theft and diversion, a separate category of potentially severe risks concerns logistical processes. These include potential malicious hacking attacks against logistics companies. These attacks might generate increased unsatisfied demand for the vaccine; they might also be related to disruptions of legitimate supply chains that might facilitate theft and diversion.

Another potential logistical bottleneck concerns shortages of the skilled workforce needed to administer vaccines and of personal protective equipment and medical (e.g. immunization) equipment. Arranging the just-in-time presence of personnel and management of the supply processes is a great challenge, and it can result in significant disruptions to the whole process if this is not achieved.

Although these factors directly trigger illicit trade in COVID-19 vaccines, they can also stimulate demand for illicit markets for the vaccines indirectly.

These risks can, however, be significantly reduced by effective governance actions. In many OECD countries, governments monitor the situation to secure the supply chain for COVID-19 vaccines, by monitoring the packaging, storage, and shipping of products. Economies with underdeveloped health systems and government infrastructure might become more interesting targets for criminals carrying out vaccine and treatment frauds.
There are no legal sales of the COVID-19 vaccine online. Any sales are either a scam or an illicit offer.

The online environment is one of the most challenging areas related to the illicit trade in COVID-19 vaccines. Incidences of scams and fraud related to the COVID-19 vaccines have already been observed. Criminals misuse all potential channels, including rogue online pharmacies, e-platforms, and social networks; in most cases, they use logos of genuine producers to legitimize their illicit offers. Experts also expect that criminals will begin to seek to misuse text messages, emails, or automatized calls about vaccines and treatments.

The scale of COVID-19-related online threats has been increasing since the outbreak of the pandemic. In the US alone, some 70,000 websites related to COVID scams have already been closed. Based on previous experience with other medicines and treatments, experts expect that these scams will be directed not only towards the general public but also towards health agencies and governments, in the form of fake tenders.

There are also spam and phishing emails that are made to appear as legitimate invitations to obtain a vaccine or treatment from pharmaceutical companies, online pharmacies, and the medical community. These emails often link to a spoofed website, which mirrors an actual site to lend legitimacy to the scam. So far, this type of fraud appears to focus on stealing personal identifying information, but enforcement remains vigilant for any changes to this trend.

There are also instances of vaccines and treatments being offered for sale in bulk on the dark web. It is yet to be determined if counterfeit or unapproved products actually exist or if these offers are simply a way to steal by never delivering what is offered.

For criminals, the online environment is becoming the main channel for promoting counterfeit medicines, including illicit COVID-19 vaccines that will be directly shipped to customers or via dealers. Illicit vaccines can fit easily in small parcel boxes or bubble-wrap letter packets that can be sent to end consumers. It also offers an effective way to avoid detection by the customs and enforcement authorities, and consequently lowers potential losses for counterfeiters.

Importantly, it must be highlighted it is virtually impossible to purchase an authentic, effective vaccine online. Even if fraudsters could obtain the legitimate product, it is unlikely that they would maintain the product at the required temperatures for storage or delivery. If an offer is not a classical scam and criminals do ship a product, it will be most likely counterfeit or unapproved.

The potential damaging effects for public health are massive.

The useful and timely distribution of vaccines must meet high standards of storage and transportation. Criminals do not bother to meet these criteria, consequently posing significant health threats to consumers. If illicit trade in the COVID-19 vaccine is not countered effectively, its damaging health effects might become far-reaching. Therefore, the trade might also undermine national vaccine programmes and sabotage co-ordinated global efforts to combat the pandemic.

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Good governance and co-operation with the pharmaceutical industry is paramount

Governments prepare for unknown challenges – there will be no second chance

For governments, preparing governance frameworks to counter illicit trade related to COVID-19 vaccines is a challenge. Unlike for illicit trade in other goods, there are no illustrative lessons from the past. Governments must prepare for unknown threats.

Enforcement gets ready on both sides of the Atlantic

Enforcement agencies in many OECD countries are preparing for threats.

For example, as mentioned above, the US Homeland Security Investigations (HSI) unit launched Operation Stolen Promise in April 2020 to counter the increasing and evolving threat posed by COVID-19-related fraud and criminal activity. Since the Operation’s inception, HSI has capitalized upon its unique, expansive federal criminal investigative authorities, its strong intelligence analysis capabilities and resources, its broad domestic and international footprint, and its robust law enforcement and private sector partnerships to lead the government’s investigative response to pandemic-related crime.

In the coming months, HSI anticipates that high public demand for access to vaccines and treatments will lead to illegal attempts to introduce counterfeit versions of these items into US and global marketplaces. In response, HSI has initiated Operation Stolen Promise 2.0 that is built around four central pillars:

1. partnership
2. investigation
3. disruptions
4. education

These represent a core element of the HSI approach to address all forms of COVID-19 fraud, including counterfeit vaccines and treatments.

In the European Union, co-operation is intensifying among key agencies, including Europol, DG OLAF, DG Taxud and national enforcement agencies. The agencies meet regularly with the overall goal of ensuring effective distribution of the vaccine, while minimizing risks. As enforcement techniques in the EU rely on risk analysis and profiling, quick and effective information sharing becomes essential for swift responses from enforcement authorities.
Good governance and co-operation, working hand-in-hand with the pharmaceutical industry, is the key to ensuring adequate distribution of COVID-19 vaccines.

Effective co-operation between the pharmaceutical industry that develops COVID-19 vaccines and enforcement is essential to secure supply chains. This includes securing and tracking shipments, identifying fraudulent vaccines, destroying used vials, etc. So far, the successful co-operation between Pfizer and US enforcement has made diversion of vaccines and treatments unlikely and allowed investigators to concentrate on fraud operations as they are detected. With the potential new suppliers of vaccines, enforcement must continue this close co-operation to minimize distribution risks. At the same time, enforcement must remain vigilant to any changes in types of fraud, and they must be on the lookout for counterfeit and unapproved vaccines and treatments.

The criminal situation is dynamic. Good international co-operation is needed to monitor trends and to detect bottlenecks as early as possible.

The distinctive character of this situation means that little is known about potential future scenarios. Consequently, distribution of COVID-19 vaccines and all illicit trade-related incidents should be closely monitored, and reporting should be co-ordinated. Close and detailed monitoring should include all information about potential risks, and include evidence about seizures and analysis of samples of illicit vaccines. Such a level of detail will allow authorities to spot bottlenecks in systems and to identify possible weak and risky elements in the distributions chain.

Co-ordination of reporting will allow stakeholders to keep up to date with problems and let them respond more effectively to evolving challenges. In this context, the OECD TF-CIT can provide an effective platform for i) discussing and exchanging experiences, ii) considering ways to close governance gaps and iii ) identifying best practices.

Awareness is crucial

The unprecedented challenges posed by COVID-19 put a high degree of responsibility on law enforcement agencies. To avoid scaremongering and causing undue panic, it is vital to ensure transparency and information management consistency.

Government agencies should clearly and transparently communicate to the general public on actual risks. As it is impossible to satisfy the demand for vaccines at once, awareness campaigns should reassure people that everyone will get vaccinated according to the priorities established by national vaccination plans.