



RESEARCH BRIEF

COVID-19-related Trafficking of Medical Products as a Threat to Public Health



UNITED NATIONS OFFICE ON DRUGS AND CRIME Vienna

REPORT ON COVID-19-RELATED TRAFFICKING OF MEDICAL PRODUCTS AS A THREAT TO PUBLIC HEALTH

UNITED NATIONS OFFICE ON DRUGS AND CRIME (UNODC) RESEARCH BRIEF PREPARED BY THE RESEARCH AND TREND ANALYSIS BRANCH AND THE UNODC GLOBAL RESERACH NETWORK





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EXECUTIVE SUMMARY

Restrictions on movement imposed by governments across the world due to the COVID-19 pandemic have had an impact on the trafficking of substandard and falsified medical products. Interpol and the World Customs Organization (WCO) reported that seizures of substandard and falsified medical products, including personal protective equipment (PPE), increased for the first time in March 2020.

The emergence of trafficking in PPE signals a significant shift in organized criminal group behaviour that is directly attributable to the COVID-19 pandemic, which has brought huge demand for medical products such as PPE over a relatively short period of time. It is foreseeable that, with the evolution of COVID-19 and developments in medicinal treatments and/or the repurposing of existing medicines, criminal behaviour will shift from trafficking in PPE to the development and delivery of a COVID-19 vaccine. Furthermore, cyberattacks on critical infrastructure involved in addressing the pandemic are likely to continue in the form of online scams aimed at health procurement authorities.

Challenges in pandemic preparedness, ranging from weak regulatory and legal frameworks to the prevention of the manufacturing and trafficking of substandard and falsified products and cyber security shortcomings, were evident before COVID-19, but the pandemic has exacerbated them and it will be difficult to make significant improvements in the immediate short term.

The report concludes that crime targeting COVID-19 medical products will become more focused with significantly greater risks to public health as the containment phase of the pandemic passes to the treatment and prevention stages.

CRIME & COVID-19

An increase in cyberattacks and online scams correlate with the spread of COVID-19

CYBERATTACKS AND ONLINE SCAMS TARGETING HOSPITALS AND CRITICAL PUBLIC INFRASTRUCTURE ENGAGED IN COMBATING COVID-19, HAVE BEEN ON THE RISE SINCE Q1 OF 2020 – AND ARE EXPECTED TO CONTINUE

MOST COMMON

COVID-RELATED CYBERCRIMES



PRODUCT IS PAID FOR BUT NEVER DELIVERED

DATA IS STOLEN AND SOLD IN THE DARK WEB



KEY MESSAGES

COVID-19 has been the catalyst for a hitherto unseen global market for the trafficking of PPE. There is also some evidence of the trafficking of other forms of substandard and falsified medical products, but not to the same extent as PPE. Research will be required to determine the reasons for this. It can be expected that as a treatment becomes available and a vaccine to prevent contracting COVID-19 is identified, the focus will move away from PPE scams towards vaccine and treatment scams, including cyber scams.

The shift in cyberattacks towards medical product supplies and health infrastructure correlates with the spread of COVID-19. As the pandemic further develops to the stabilisation phase, it is anticipated that any suspension of ransomware attacks on critical health facilities and the medical product supply chain will resume.

In the context of COVID-19, the absence of an effective and comprehensive regulatory framework in some countries, including weak technical capacity, constrained access and ineffective oversight to address substandard and falsified medical products, is not only life-threatening for those countries, it is also a challenge for the global community. The global challenge to countries and international organizations to respond to the immediate effects of COVID-19 has been impacted by the trafficking of substandard and falsified medical products, which undermined their preparedness for the pandemic and their capacity to prevent the spread of the disease.

Strengthening legal frameworks and penalties with a view to achieving a more harmonized global approach to the criminalization of the manufacturing and trafficking of falsified medical products will enable better national, regional and international responses to this type of crime, which impacts individual and public health on a global basis.

Building governance improvements by addressing good practices in the procurement of medical products and the elimination of opportunities for corruption is an essential development to prevent substandard and falsified medical products from entering the health system.

Preventing, detecting and responding to medical product-related crime will require new or additional cross-skill training in the medical product sector and enhanced national coordination mechanisms by all relevant actors to address current and future challenges.

SUBSTANDARD & FALSIFIED (SF) MEDICAL PRODUCTS

MOST COMMONLY CIRCULATED IN THE MARKET



PURPOSE AND SCOPE

This report covers the COVID-19-related trafficking of substandard and falsified medical products, including personal protective equipment intended for medical purposes, as a threat to public health.

Substandard and falsified medical products exclude intellectual property infringements or violations.

LIMITATIONS OF THIS RESEARCH BRIEF

The aim of this research brief is to present a condensed assessment of the impact of the COVID-19 pandemic on the trafficking of substandard and falsified medical products. It builds on information UNODC has collected from:

- Responses submitted by Member States to UNODC following a call for information on the impact of COVID-19 on drugs and crime;
- Information provided by UNODC field offices;
- Systematic analysis of open sources, official evidence, media and institutional reports.

The analysis presented here should be viewed as a preliminary assessment of the impact of COVID-19 on activities related to trafficking of substandard and falsified medical products, including illicit events such as cybercrime, fraud, and scams associated with this phenomenon. Some of the content of this Brief may be based on anecdotal information with the aim to alert the international community of the possible threat posed by organized crime in relation to the trafficking and supply of substandard and falsified medical products over the short and long term, in the context of the COVID-19 pandemic.

USE OF TERMS IN THIS REPORT

Substandard medical products¹: also called "out of specification", these are authorized medical products that fail to meet either their quality standards or specifications, or both.

Unregistered medical products: medical products that have not undergone evaluation and/or approval by the national or regional regulatory authority for the market in which they are marketed/ distributed or used, subject to permitted conditions under national or regional regulation and legislation.

Falsified medical products: medical products that deliberately/fraudulently misrepresent their

identity, composition or source. A falsified medical product in this report includes an intentionally manufactured substandard medical product.

Medical products: medicines, including vaccines, excipients and active substances, as well as medical devices, their parts and materials, and accessories used in conjunction with medical devices.²

Organized criminal group: a structured group of three or more persons, existing for a period of time and acting in concert with the aim of committing one or more serious crimes to obtain, directly or indirectly, a financial or other material benefit.³

Serious crime: conduct constituting an offence punishable by a maximum deprivation of liberty of at least four years or a more serious penalty.⁴

INTRODUCTION

Organised criminal groups have adjusted to the opportunities arising from the COVID-19 pandemic to exploit the vulnerabilities and gaps existing in health and criminal justice systems.⁵ They exploit fears and uncertainties among populations and authorities to generate a demand for scarce medical products. The falsification of medical products at the manufacturing stage raises significant risks for public health, as such products may not properly treat disease or illness and may facilitate the development of drug resistance. The evidence to date indicates that such criminality involving manufacturing and trafficking has closely followed the spread of COVID-19.⁶

At the onset of the pandemic, demand for medical products, including PPE to help prevent the spread of COVID-19, suddenly outstripped supply. Criminal groups quickly adapted by providing substandard and falsified medical products, including PPE, and offering non-existent supplies of products to defraud individuals and procurement agencies. Public pressure on health systems to acquire sufficient PPE for a country's needs created an opportunity for criminals to take advantage of the situation and supply substandard and falsified PPE with lower good governance checks.

While no medicine has been shown to prevent or cure COVID-19, this has not hindered the offering of treatments and in vitro diagnostic (IVD) test kits by those exploiting uncertainty and fear for illicit gains. As media and other public commentary reports on clinical trials of potential medicinal substances that may prevent or treat COVID-19,⁷ it is anticipated that those substances and existing medicines will be diverted from their legitimate markets and that substandard and falsified versions will emerge.

THE IMPACT OF COVID-19 ON CRIME RE-LATED TO SUBSTANDARD AND FALSI-FIED MEDICAL PRODUCTS

Exploitation of an opportunity provided by COVID-19

COVID-19 has been the catalyst for a hitherto unseen global market for trafficking⁸ by organized criminal groups of substandard and falsified medical products including PPE.⁹ The quantities of substandard and falsified medical products and PPE seized worldwide (see Maps) indicate that criminal groups have taken advantage of the emerging opportunities. Criminal groups involved in drug trafficking have in the past shown their adaptability in taking advantage of crises to get their products to the market and it is likely that they will do so again with regards to substandard and falsified medical products in the COVID-19 crisis.¹⁰ The production capacity needed to resource materials and manufacture significant quantities indicates an ability to shift illicit production activities to PPE manufacturing at short notice. This is indicative of organised crime involvement with a level of organization and agility to adapt to an emerging opportunity which is matched by the ability to access customers and effect the supply of substandard and falsified products on a global basis.¹¹

COVID-19 has created a fertile crisis environment for an effective fraud scheme to flourish leading to the betraval of medical product procurement bodies and individuals. The emergence of the pandemic has seen data-compromise frauds, including phishing, scamming and business email compromise, through the manipulation of corporate websites, to convince purchasers that firms are genuine. In many data-compromise frauds, there is no intention to supply medical products; it is simply a scheme to deprive the buyer of the purchase price. During COVID-19, high profile instances of fraud have been uncovered¹² along with ransomware attacks on hospitals,¹³ other organizations and critical infrastructure engaged in combating COVID-19, all of which require significant planning and resources on the part of the perpetrators. The trend of illicit events related to COVID-19 substandard and falsified products over time correlates with the spread of the pandemic.14

THE STAGES OF A HEALTH CRISIS & CRIMINALITY

OPPORTUNISTIC CRIMINAL ACTIVITIES DURING HEALTH CRISES HAVE A DETRIMENTAL EFFECT ON PUBLIC HEALTH & THE ECONOMY

CONTAINMENT PHASE

TO PREVENT THE SPREAD OF THE VIRUS, ACCESS TO LARGE QUANTITIES OF PPE & TESTING KITS IS ESSENTIAL CRIMINAL ACTIVITIES SUCH AS FRAUD & THE SALE OF SF MEDICAL PRODUCTS, TAKE ADVANTAGE OF A SITUATION WHERE DEMAND OUTSTRIPS SUPPLY



THREATS ONLINE



FRAUDULENT WEBSITES

The manipulation of a corporate website to make the purchaser believe that the firm is genuine



PHISHING & SCAMMING

A type of data-compromise fraud via email that steals the user's personal information



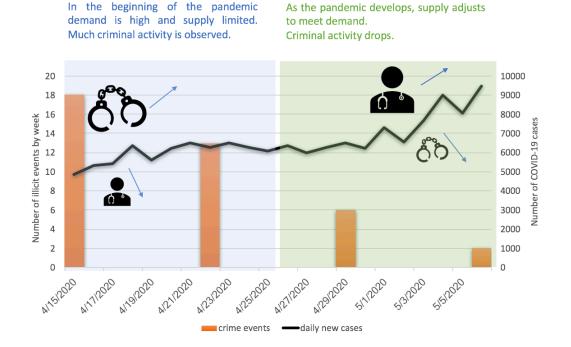
RANSOMWARE ATTACKS

A malware attack that threatens to publish the victim's data or perpetually block access to it unless a ransom is paid



Did you know? The most frequent type of COVID-related cybercrime is **fraud**, where the purchaser pays for the supply of a medical product that is never delivered

Figure 1: Trends in the number of illicit events¹⁵ related to COVID-19 involving medical products recorded in selected countries in Asia¹⁶:



Source: Elaborated by UNODC from European Commission Joint Research Centre, Infectious Diseases Data Observatory Medicine Quality Monitoring Globe Index and UNODC field offices and Worldometer (for data on new COVID-19 cases recorded daily).

NOTABLE CASES WORLDWIDE DURING THE COVID-19 PANDEMIC



AN INTERPOL OPERATION UNVEILED LARGE-SCALE TRANSNATIONAL FRAUD INVOLVING PROCUREMENT OF FACE MASKS WORTH €15 MILLION

IN MARCH 2020, GERMAN HEALTH AUTHORITIES CONTRACTED 2 SALES COMPANIES IN SWITZERLAND AND GERMANY TO PROCURE €15 MILLION WORTH OF FACE MASKS THROUGH A CLONED WEBSITE OF AN APPARENTLY LEGITIMATE COMPANY IN SPAIN

IN NIGERIA, NATIONAL AUTHORITIES CONFIRMED A HIGH PROLIFERATION OF **CHLOROQUINE** IN-COUNTRY, INDICATING THAT THE PRODUCTION OF SF PHARMACEUTICALS COULD BE ON THE RISE.

IN ARGENTINA, LAW ENFORCEMENT PLACED UNDER INVESTIGATION AN ORGANIZATION MANUFACTURING **HAND** SANITISER GEL, FACE MASKS AND OTHER PPE THAT WAS NOT AUTHORISED FOR DISTRIBUTION BY GOVERNMENT INSTITUTIONS. IN APRIL 2020, THE GOVERNMENT OF SLOVENIA PLACED AN ORDER OF 3 MILLION MEDICAL MASKS TO A COMPANY IN BOSNIA & HERZEGOVINA, PAYING A €300,000 ADVANCE. THE MASKS WERE NEVER DELIVERED, FRAUD & MONEY LAUNDERING IS SUSPECTED

Note: For further information see Endnotes.17

CONTRIBUTING AND EXPLOITED WEAKNESSES

Regulatory and legal frameworks

Organized criminal groups exploit gaps and discrepancies in national legislation and criminal justice systems.¹⁸ Weak and/or inconsistent regulatory and legal frameworks for preventing, deterring and punishing offenders who manufacture or traffic in falsified medical products has become more evident in the rapidly evolving circumstances of the pandemic.



National or regional regulatory authorities involved in protecting public health evaluate the quality, safety and efficacy of medicines, and standards authorities evaluate medical devices. However, WHO reports that 30 per cent of national regulatory authorities do not have full effective capacity to perform their functions.¹⁹ To fulfil their roles effectively, such authorities require rigorous regulatory standards and access to the latest technologies and information systems. In some countries, under-resourcing is a significant challenge for regulatory authorities and weak or ineffective regulatory frameworks, including for the classification of medical products, may contribute to a lack of detecting and reporting the trafficking of substandard and falsified medical products. Many developing countries do not have well-functioning regulatory bodies and have weak capacity to enforce regulations.20

Some countries in Africa, for example, do not have a medical device legislative or regulatory frame-

work. COVID-19 challenges this situation even further where fear and uncertainty promoted by organized criminal groups ensure that people deprived of essential medical products will not question the substandard and falsified products that they are offered.²¹

In weak regulatory systems, the supply of substandard and falsified products, for example face masks or IVD test kits, may at best constitute an infringement relating to non-compliance with standards without addressing the seriousness of the risk to the public and public health or the degree of criminality.

Due to a failure to recognise that many substandard and falsified medical product-related crimes have serious implications for society, crimes have often been relegated to administrative infringements.²² The gap in recognizing the seriousness of such crimes has provided an additional opportunity for organized criminal groups during COVID-19, as evidenced by the large quantities of PPE being seized or rejected by countries as substandard. Evidence of seizures is more striking in Europe, North America and Asia, although limited data on Africa also indicates the interception of PPE and COVID-19-related medicines (see Maps).

Gaps in legislative frameworks typically include inadequate medical product sector-specific laws and a lack of harmonization with other laws and international standards. Some laws lack definitions, allow for insufficient penalties or fail to designate offences as predicate offences in anti-money-laundering legislation.²³ In addition, the online and distance selling of medical products is often inadequately addressed.²⁴

Substandard and falsified medical product-related crimes are sometimes treated the same as property fraud, intellectual property crimes and currency counterfeiting, notwithstanding the health impact involved with substandard and falsified medical products.



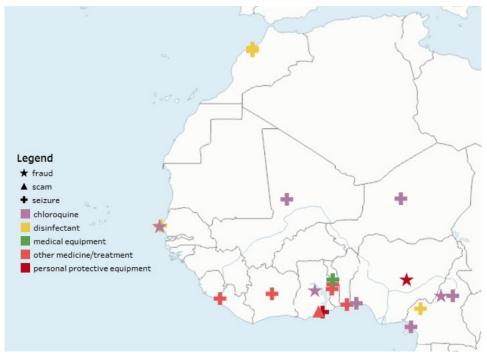
COVID-19-related Trafficking of Medical Products as a Threat to Public Health

MAP 1: ILLICIT EVENTS INVOLVING COVID-19-RELATED SUBSTANDARD AND FALSIFIED MEDICINE AND MEDICAL EQUIPMENT IN SELECTED COUNTRIES IN ASIA



Source: Elaborated by UNODC from European Commission Joint Research Centre, Infectious Diseases Data Observatory, Medicine Quality Monitoring Globe Index, UNODC field offices and UNODC-WCO Global Container Control Programme. Notes: The boundaries and names shown and the designations used on this map do not imply official endorsement or acceptance by the United Nations. Dotted line represents approximately the Line of Control in Jammu and Kashmir agreed upon by India and Pakistan. The final status of Jammu and Kashmir has not yet been agreed upon by the parties.

MAP 2: ILLICIT EVENTS INVOLVING COVID-19-RELATED SUBSTANDARD AND FALSIFIED MEDICINE AND MEDICAL EQUIPMENT IN WESTERN AFRICA



Source: Elaborated by UNODC from European Commission Joint Research Centre, Infectious Diseases Data Observatory, Medicine Quality Monitoring Globe Index, UNODC field offices, and UNODC-WCO Global Container Control Programme. Notes: The boundaries and names shown and the designations used on this map do not imply official endorsement or acceptance by the United Nations.

Enforcement capacity and resources

The COVID-19 crisis may have strengthened the capacity of law enforcement authorities in some countries and weakened it in others.²⁵ A real or perceived reduction in law enforcement capacity creates a fragility that can be exploited by criminal groups.²⁶

For an investigation to begin, a crime needs to be recognised or reported by victims or by the State. Any diminution of the capacity for preventing, detecting or responding to such reports is perceived by criminals as an exploitable weakness.

Countries lacking in knowledgeable cross-skilltrained staff, or the technical capability to detect substandard and falsified medical products, are more vulnerable to exploitation during the pandemic. Criminal groups adapt quickly to changed landscapes, often much faster than law enforcement authorities, which may lack the cross-skilltrained staff able to identify changing offending activities, the products involved and the trafficking methods.

In some countries, inadequate enforcement may have existed before the crisis, and combined with a lack of understanding of the risks posed by substandard and falsified medical products, authorities may overlook the supply of such products due to a perception that it may be better to have such products than not to have any products at all for those without the means to acquire genuine medical products.²⁷

Challenges in investigation and prosecution

The sudden emergence of a market for substandard and falsified products during the pandemic has allowed authorities little time to recognize the status of suspected substandard and falsified products and the consequent harm to citizens. This is also a hindrance to investigation, the collection of evidence and the possibility of a consequent prosecution.

Moreover, at the end of the substandard and falsified products supply chain, or the decisive crime, there may be no products remaining to analyse or test, or no chain of evidence to facilitate a prosecution and falsified documentation may be the only surviving evidence.

Furthermore, backlogs and blockages are created by a shortage of scientific analytical facilities for analysing medicines or testing medical products, often due to such facilities being diverted to COVID-19 testing, further hindering the timely (if any) results which are needed both to protect victims and to contribute to the criminal justice process.

These weaknesses impact victims as they lead to an inability to determine the cause of injury from substandard and falsified medical products and the information needed to assist them in their recovery and as well as depriving them of the possibility of obtaining justice for the harm done to them.

In addition to chain of custody, analysis and testing gaps, few prosecutors have the skills or resources to deal with the particular aspects of crime related to falsified medical products that may be transnational and complex and require expert testimony and legal assistance from other countries.

Cooperation and collaboration

Significant efforts have been made by the international community over the past 10 years to improve cooperation and collaboration among national agencies involved in medical product-related crime.²⁸ However, the lack of collaboration between various public agencies involved in combating substandard and falsified medical products is still a common challenge which becomes evident in a crisis.²⁹ Substandard and falsified medical product investigation requires a high level of collaboration among agencies nationally and internationally to trace traffickers over borders using all available resources.

This cooperation is also hampered by resource deficiencies. While digital records have become common and require digital forensic analysis to examine them, investigators do not always have access to such facilities. Cooperation between national agencies also involves budgetary and other types of competing interests, as well as legislative blockages, to the detriment of the exchange of vital information and support.³⁰

The absence of reports on substandard and falsified medical products from countries during COVID-19, for which there may be various reasons, could be an indicator of a lack of internal collaboration, which subsequently impacts international action against offenders.

FRAUD & SEIZURES



ONGOING THREATS

Criminals exploit corruption, the relaxation of due diligence checks and systemic weaknesses exacerbated by COVID-19³¹ to the detriment of the health budget. This particularly applies to authorities vulnerable to succumbing to scamming operations where money is paid and nothing is received in return, as has been evident during the COVID-19 crisis.³²

Public health contracts for medical products, including PPE, are lucrative, and are therefore susceptible to corruption.³³ Corruption in public health systems is a global problem³⁴ that together with the challenges of COVID-19, creates optimal conditions for the illicit diversion of publicly owned and funded medical products. This extends to theft from supply chains and hospitals,³⁵ as well as procurement corruption.³⁶ While a rapid emergency response is imperative, governments must also remain accountable for how resources are spent. An effective way to increase accountability is to identify and manage corruption risks within authorities mandated with procuring and distributing medicine and medical supplies.

The illicit diversion of legitimate medical products to sell to other markets as COVID-19-related products reduces the stock available for the intended market. This results in shortages, referred to by the World Health Organization (WHO) as stockouts, of products which in many cases have already been paid for by the national public health budget. This occurs in both developing and developed countries.³⁷ Shortages of medical products create opportunities for medical product traffickers.

Organized criminal groups in the Western Balkans are believed to be involved in money laundering and investing their illicit gains in the production and trafficking of falsified medical products and PPE.³⁸ The high demand for scarce medical products, combined with curtailment in the supply of

Pangea Operation XIII, 3-10 March 2020

In March 2020, Interpol coordinated Operation Pangea XIII to target illegal online sales of medicines and medical products. Law enforcement and health regulatory authorities from 90 countries participated in the joint action which led to 121 arrests worldwide and the seizure³⁹ of substandard and falsified face masks as well as over US\$14 million worth of potentially dangerous pharmaceutical products.⁴⁰ Compared to an earlier operation in 2018, Interpol reported an increase of about 18 per cent in seizures of unauthorized antiviral medication and a more than 100 per cent increase in seizures of unauthorized chloroquine (an antimalarial), indicating a surge in substandard and falsified medical products and unauthorized medication circulating in the market that may be connected to the COVID-19 pandemic.



legitimate products due to movement restrictions, has created a significant sales and supply opportunity for criminals, resulting in a manifold increase in advertisements⁴¹ and supply directly connected to the COVID-19 pandemic.⁴² There is every reason to expect this trend to continue, especially in regions where the illicit drug trade is under pressure from movement controls⁴³ and law enforcement. Interpol reported that Operation Pangea XIII in March 2020 saw significantly increased seizures of COVID-19-related medical products.⁴⁴

While it remains to be seen if this trend is specific to COVID-19 or includes other contributory causes, any further continuation will increase the threat to individual and public health and to criminal justice systems as criminal groups bring their product acquisition skills and trafficking networks to subvert legitimate medical product supply chains.

Dark Web

The darknet remains a small but growing trafficking space for the illicit marketing of substandard and falsified medical products which does not seem to have been significantly altered by the COVID-19 crisis. However, this may change in the future, particularly when a COVID-19 treatment or vaccine is developed.

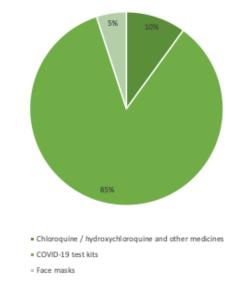
Monopoly Market, a Dark Web marketplace, banned its vendors from supplying medical products that are in short supply because of the pandemic, as well as the use of COVID-19 as a marketing tool. While this may be a welcome message, the risks continue as such declarations do not exclude the legitimate health care supply chain, or the pharmaceutical, medical device or medical PPE industry from attack. Other cybercriminals have not made any such declaration to exempt critical COVID-19-related targets and are expected to continue with cyberattacks.⁴⁵ The opportunities for gain during COVID-19 will continue to be exploited as long as the pandemic continues to cause disruption and chaos.

A study of some of the largest English-language online marketplaces on the Dark Web was conducted in April 2020 to identify transactions involving medicines and medical equipment related to COVID-19 and to determine the quantity and type of products being listed and sold.⁴⁶ The marketplaces surveyed included: Empire Market, Dark Market, Versus, White House Market, Tor Market and Monopoly.

The analysis did not produce significant convincing evidence of major sales involving COVID-19-related medicine and medical equipment. Although a small number of listings of relevant products was observed, these appear to generate very little revenue. Notably, on Monopoly market, which is smaller than the other marketplaces covered by the survey, only one COVID-19-related product was listed - hydroxychloroquine sulphate. Market administrators posted a warning to potential buyers that the drug is not to be considered a reliable cure for COVID-19 and that self-diagnosis is not advisable.

A breakdown of sales of COVID-19-related products on Empire Market in April 2020 shows that the overwhelming majority of transactions involved COVID-19 test kits, including antibody tests. Sales of face masks, hydroxychloroquine and other COVID-19-related medicines such as remdesivir accounted for approximately 15 per cent of such sales.

Figure 2: Breakdown of sales of COVID-19related-medical products on Empire Market recorded in April 2020



For further information see Annex.

Unknown threats

It is likely that new threats will emerge during and following the treatment and prevention phases of COVID-19. Seizures of small quantities of substandard and falsified COVID-19-related medical products may indicate the emergence of new illicit markets. A seizure of 3,300 thermometers was reported in Thailand following their trafficking through three other countries⁴⁷ and a report of thermometers which do not conform with EU regulations was also noted in Italy.⁴⁸

Further reports of similar seizures in other countries may emerge over time with serious public health implications for COVID-19 infection temperature indicators if they are not detected. There have been reports of substandard and falsified ventilators^{49 50} in Russia, where a fraud enquiry has begun, as well as in the UK, where ventilators supplied were substandard and potentially dangerous.⁵¹ The supply of substandard ventilators was also reported in Bosnia and Herzegovina.⁵²

Medical oxygen is also an essential component for the treatment of COVID-19 patients in critical care, even for those that do not require a mechanical ventilator. However, no seizures of substandard and falsified medical oxygen have been reported to date. Pulse oximeters, used by patients with chronic respiratory illnesses to monitor their blood oxygen levels, are reported to be in demand by healthy individuals concerned about COVID-19.⁵³ This risks creating a shortage of pulse oximeters to the detriment of ill patients which would be exacerbated if that shortage were to be filled by substandard and falsified pulse oximeters.

The products mentioned above have been in high demand and short supply, but contrary to PPE, seizures of trafficked substandard and falsified products have not been reported. This could be because they are not considered a priority and consequently, they are not intercepted by law enforcement authorities, or because of a lack of capacity. The most opportune falsified medical products for criminals to produce are those that no one knows are falsified. Were this to occur, they may go undetected but could have tragic consequences.

Demand-led supply during COVID-19 and the future criminal threat involving vaccines

The demand-supply gap in COVID-19-related products that naturally arose in the early containment phase of the pandemic is gradually being reduced for some products. Producers and suppliers of non-pharmaceutical medical products, including medical grade face masks and surgical gowns, are responding more rapidly by increasing manufacturing capacity thereby reducing opportunities for scams and trafficking in substandard and falsified products.

Since the production of such products does not require highly technical infrastructure or sophisticated know-how, the supply chain can be quickly adapted to larger demand. However, when it comes to pharmaceutical medicines to prevent and treat the virus, no such products have yet been found, and building a supply chain to satisfy global demand will require a much longer time scale.

This time gap, in the absence of a scientific solu-

tion, is an opportunity for criminal groups to sell substandard and falsified medical products. For legitimate vaccine products, the global manufacturing capacity is limited by many technical and regulatory factors as well as the fact that there are only a relatively small number of such manufacturers in existence, and they may not readily cope with rapid change.⁵⁴

It is to be expected that criminal actors will seize new opportunities to market substandard and falsified vaccines as soon as a legitimate vaccine candidate is announced and before the genuine product can be legitimately produced and supplied.⁵⁵

Again, as demand is likely to be greater than the ability to supply legitimate vaccines, the illicit market space will continue to expand whenever there are anecdotal reports of unproven remedies.⁵⁶

Some illegal activities surrounding falsified vaccines have already emerged, even though a vaccine has not yet been discovered. A website advertising a fraudulent coronavirus vaccine was detected in the United States of America. The US Department of Justice has subsequently issued a public warning against criminals seeking to exploit the state of emergency and uncertainly surrounding COVID-19 by advertising illegitimate vaccines.⁵⁷

SOLUTIONS AND POLICY IMPLICATIONS

Enhancing regulatory and legislative measures

Medical product-related crime involves the trafficking of products from source production countries, through transit countries, to the destination countries where they will be used. The challenge is thus an international responsibility to be addressed by all affected countries and regions.

Putting in place strong legislative and regulatory frameworks to combat substandard and falsified medical product-related crime requires a focus on criminalising behaviour and protecting the integrity of medical products and legitimate supply chains in order to protect public health and deter offenders.

This would be best achieved through a common international approach to building systems for combating substandard and falsified medical products. However, in the absence of such an approach, the implementation of good legislative practices to develop national laws would bring a commonality throughout regions and globally. This would nevertheless still require significant cooperation through an integrated approach among neighbouring countries and others involved in pursuing the traffickers of substandard and falsified medical products and should include the application of preventive measures.

Victims

The manufacture and trafficking of falsified medical products are crimes of deception. However, in contrast to other types of fraud, human health, welfare and lives are impacted by substandard and falsified medical products. This distinction is not often noted by criminal justice systems, or by criminal elements.

The impact distinction is left to aggravating factors and victim impact statements in the event of a conviction by the courts. International organizations and countries have increasingly begun to recognise the need to focus on victims, the impact on public health system protection and the criminalisation of offending behaviours.⁵⁸ COVID-19 may provide the impetus to criminal justice systems to move this opportunity to fruition.

Victims, whether individuals or public procurement authorities, need to be encouraged to report crimes, however embarrassing they may be, despite the risk of inviting political scrutiny in the case of public authorities. Openness and transparency in public service are crucial to stopping criminal exploitation, preventing harm to patients and recovering lost funds. Denial of the situation only enables such frauds to continue and others to become victims, to the detriment of vital public health funds. Poor governance in the public sector allows organised crime to prosper.⁵⁹

Staffing resources

The diversion of relevant staff at this time, including law enforcement, regulatory and analytical laboratory personnel, away from addressing medical product crime, further risks weakening national and international responses. Lessons learned from this crisis should be incorporated into new or additional training.

Inter-agency cooperation

There is general agreement that cooperation at the national level between medical product regulatory authorities, police, customs and judicial authorities, and other stakeholders, is the most effective means of addressing the impact of the trafficking of substandard and falsified medical

products on individual and public health.

This is evidenced by many publications, including legal instruments, guides on drafting legislation, reports and studies, some of which are mentioned in this report. Obvious areas for cooperation include the investigation of substandard and falsified medical products, which is no longer seen as the preserve of policing alone, but as also requiring the active involvement of medical product regulators, customs authorities and industry. Challenges remain in many countries while others are improving in this respect.⁶⁰

In order to reduce criminality, there is a need to address weaknesses in legitimate medical product supply chains and improve the cooperation infrastructure between the authorities responsible for preventing, detecting, investigating and responding to cases of substandard and falsified medical products. It is imperative that national authorities establish or strengthen investigative and cooperative agreements between agencies to facilitate the exchange of information and intelligence and the processing of evidence for judicial examination.

Risk communication and awareness-raising

Public awareness campaigns on the identification of substandard and falsified medical products are required and such messages need to be effectively communicated. WHO is working on risk communication and awareness raising and has produced materials to address deficiencies and provide support to Member States in this area.⁶¹

UNODC has also released an awareness campaign on COVID-19-related issues, including the risk of purchasing substandard and falsified medical products. The use of risk communication and awareness campaigns can increase the public's confidence to discriminate between reliable factbased sources of information and suspect information and services.⁶²

Good governance

Several international organizations have raised questions about fraud and a lack of governance in public health procurement processes and provided guidance to reduce the threat of corruption. Good governance and the building of resilient and pandemic-ready health procurement processes should be part of a coordinated effort to consolidate guidance from all relevant bodies into a single response document. Ensuring that candidate medicines and existing finished dosage forms of medicines are reported responsibly as potential treatments for COVID-19 would help reduce the irrational demand for existing medicines which risks diverting them away from their indicated use.

Irrational advertising on social media and technology platforms could be addressed through enhanced vigilance by service providers to prevent the promotion of false claims and remedies. While some social media⁶³ and e-business platforms⁶⁴ are tacking misinformation and the offering of unfounded medical products related to COVID-19, much more could be achieved through international agreements with those providers.

ACTIONS AND POLICY IMPLICATIONS

UNODC and WHO, working in partnership with other stakeholders, including Interpol and WCO, will need to build a cohesive approach to supporting international efforts to determine results-driven objectives and then work collaboratively towards achieving them.

Developing countries and those in need should be supported with confidence-building measures to correct identified deficiencies and weaknesses. This action needs to take place in the near future to significantly impact the anticipated shift in COVID-19-related medical product crime over the next 12 months when a vaccine may be developed, but not yet available to the global population. Much uncertainty exists regarding when such a vaccine might become readily available.⁶⁵

COVID-19 has impacted the normal approaches of UNODC and WHO under their specific mandates on substandard and falsified medical products from the Commission on Crime Prevention and Criminal Justice (CCPCJ)⁶⁶ and the World Health Assembly (WHA)⁶⁷ respectively. UNODC focuses on criminal offences relating to substandard and falsified medical products from the criminal law perspective, while WHO focuses on the health impact of substandard and falsified medical products, strengthening regulatory systems and addressing regulatory prevention, detection and responses.

Both involve separate confidence-building initiatives with Member States and developing the separate frameworks within which Member States' different agencies operate. COVID-19 introduced the imperative to collaborate and possibly conduct joint developments to address the trafficking of medical product-related offences impacting on public health as a single focused issue.

While there has been significant progress towards developing frameworks to focus specifically on substandard and falsified medical products in the last 10 years, few countries have an adequate legal and regulatory system in place to address substandard and falsified medical product-related crimes associated with COVID-19. As highlighted by the CCPCJ, the United Nations Convention against Transnational Organized Crime can be used as an instrument to address the trafficking of substandard and falsified medical products⁶⁸ and UNODC has developed a Guide to Good Legislative Practices related to substandard and falsified medical product crime.⁶⁹

The only dedicated international criminal law instrument in the field of substandard and falsified medical products, the Medicrime Convention, focuses on the primary aim of criminalising offending behaviour to protect public health.⁷⁰ Regulations relating to falsified medicinal products focus primarily on protecting the integrity of products in order to protect public health.⁷¹

Awareness-raising

Awareness-raising among the public, regulators, law enforcement and healthcare professionals is a necessary component of preventing, detecting and responding to medical product-related crime involving **substandard and/or falsified** medical products. For the public, awareness-raising programmes are important "to support consumer protection, understanding and involvement in ensuring their safety and preventing the consumption of falsified medical products".⁷²

To achieve these aims, appropriate communications tools (social media, internet platforms, television, online and physical newspapers etc.) can be used to reach the target audience taking into account the demographics of existing and potential victims, product types and distribution channels. Support from the media and civil society organizations should be sought to provide training to relevant stakeholders and support awareness-raising campaigns.

Risk awareness is supported by risk communication which should be underpinned by reporting mechanisms to ensure the targeted collection of quality data in the desired quantities. COVID-19 highlights the challenges to ensure that people and communities receive reliable and evidence-based information. During the pandemic, actions by some social media and e-commerce platforms⁷³ indicate an awareness of the weaknesses exposed by the onset of COVID-19 and an understanding that their users require adequate and fact-based information. However, other information providers may have not yet recognised the actions that are now needed to protect the public.

INTERPRETATION OF SEIZURE DATA

This report is limited by the statistical data available on seizures that would enable the deduction of trends across regions and globally. The recorded quantities of substandard and falsified medical and PPE products seized provide a global picture of trends building since the start of 2020.

Regional trends indicate that significant seizures of protective equipment, mostly substandard and falsified face masks and IVD test kits for COVID-19, have occurred in the regions where the highest number of deaths and infections were first recorded: Asia, Europe and the Americas. Substandard and falsified medicines were identified in several regions, including Africa, where several seizures of chloroquine tablets have been reported.

The extrapolation of the statistics on seizures is limited to the disclosures by certain countries, as not all countries have supplied data or disclosed that they have not made any such seizures.

Furthermore, the collection of data is dependent on the understanding within a given country of which products can be legally seized, how they might be classified and having the resources to seize and report on them. It is not necessarily indicative that the African region, which is known to already be impacted by COVID-19, is still in the pre-containment phase when there is the opportunity to acquire appropriate PPE before contamination escalates.

While this conclusion could be drawn from the identified trends, it is acknowledged that the medical product regulatory framework, especially for medical devices, is not strong in parts of Africa and this could account for the statistical deficit. There are numerous examples throughout the world of intentionally supplied substandard medical products⁷⁴ and PPE⁷⁵ during COVID-19. However, it should be noted that some countries may have viewed the products simply as substandard and not recorded them as falsified. More research is needed when statistical data becomes available on a wider basis to encompass all regions and as many countries as possible.

CONCLUSIONS & RECOMMENDATIONS

Data collected by UNODC on the extent of substandard and falsified medical products seized globally indicates that initial trends focused on the containment phase of the pandemic while efforts to find a treatment and a vaccine to prevent the disease are ongoing.

This confirms trends observed by other organizations. It is anticipated that, if or when a viable medical treatment is identified, it will be subjected to falsification, theft or diversion by organised criminal groups.

It is also likely that the approval of a viable vaccine will lead to similar targeting. Both expected trends will be accompanied by greater planning and execution by organised criminal groups bringing significantly greater risk to individual and public health due to the type of medical products involved.

The following key outcomes have been identified:

- COVID-19 has been the catalyst for a global market for the trafficking of PPE not seen before. Other forms of substandard and falsified medical product supplies do not appear to have altered to any significant extent at this point.
- It can be expected that a viable treatment and a preventive vaccine will be the subject of falsification, theft and diversion by organised criminal groups.
- An increase in cyberattacks correlates with the spread of COVID-19. Such attacks are expected to continue despite declarations by some cybercriminals that they will not attack the public health infrastructure.
- The absence of an effective, comprehensive and enforceable regulatory framework in many countries to address substandard and falsified medical products, in particular medical devices, has life-threatening consequences and is a challenge for the global community.
- The absence of international coordination in addressing the manufacturing and trafficking of falsified medical products hinders a cohesive approach to responding to this type of crime which impacts individual and public health both locally and on a global basis. The international community needs to bring order to the individual efforts of relevant stakehold-

ers to develop effective systems acceptable to all.

- Building governance improvements by implementing good practices in the procurement of medical products and the elimination of the opportunity for corruption is an essential development to prevent substandard and falsified medical products and associated PPE from entering the health system. Relevant international bodies can support countries to implement such improvements by developing a single set of governance recommendations for good practices.
- Preventing, detecting and responding to substandard and falsified medical product crime will require new or additional cross-skill training in the medical product sector to address cur-

rent and future challenges. This may be best achieved through a coordinated effort by relevant international bodies including UNODC, WHO, Interpol, World Customs Organization and other stakeholders.⁷⁶

 The international community has a responsibility to foster and facilitate shared approaches to developing global solutions for combating the trafficking of substandard and falsified medical products affecting individual and public health both nationally and internationally.⁷⁷

ANNEX

Advertising and selling COVID-19-related medicines and medical equipment on the Dark Web

A growing body of evidence shows that COVID-19-related scams are taking place on the 'surface web',⁷⁸ which refers to the Internet pages indexed by search engines. Less is known about the scope of illicit activity on the Dark Web involving COVID-19-related products, including medicines and medical equipment.⁷⁹ A study of several Dark Web anonymous marketplaces conducted in April 2020 sought to address this gap and identify a range of transactions involving medicines and medical equipment related to COVID-19.⁸⁰

The marketplaces included in the study were: Empire Market, Dark Market, Versus, White House Market Monopoly and Tor Market, which are among the largest English-language darknet markets. Empire Market was identified as the largest active online anonymous marketplace, with over 33,500 drug listings. Two of the marketplaces covered by the survey, Monopoly (466 listings) and Tor Market (322 listings), are socalled boutique markets which are much smaller than the other four. Monopoly specializes in drugs such as narcotics and prescriptions medicines whereas Tor Market is only active in New Zealand. Previous studies suggest that a positive correlation should not be made directly between the number of listings on a marketplace and purchases of the advertised commodities, as the former is not considered to be a reliable indicator of actual economic activity.81

The marketplaces were surveyed by applying three categories of queries to item titles and descriptions: 1. Miracle cures, including keywords/ tags such as 'hydroxychloroquine', 'chloroquine' and 'azithromycin'; 2. General terms, using keywords such as 'corona' and 'covid'; and 3. Testing and protection, which included keywords such as 'N95', 'mask' and 'test kit.' The queries were entered into the search boxes of all six marketplaces; results were manually inspected and classified. The clusters of key words included in the queries yielded different results in each of the marketplaces.

On White House Market, searches for 'hydroxychloroquine' or 'chloroquine' produced no results. 'Azithromycin', on the other hand, appeared in four listing, however this medicine is indicated for treating a range of diseases, from bacterial infections of the respiratory tract to venereal diseases, and is not advertised as a COVID-19 cure. Searches of the keyword 'COVID' yielded 142 results, all of which were special offers, i.e. 'discounted' prices on traditional recreational drugs such as marijuana and MDMA. Searches of keywords covering PPE (face masks) and test kits produced no results.

Searches for 'hydroxychloroquine' or 'chloroquine' conducted on Empire Market yielded 45 results, many of which were duplications and represented only seven relevant listings. This suggests that listing counts are not a reliable indicator of economic activity on marketplaces and may lead to errors. One of the vendors advertising hydroxychloroquine products at the time of the survey was subsequently banned, indicating that the product advertised could have been fraudulent. One of the medical items advertised on Empire Market was a set of twenty-five COVID-19 IgG/ IgM rapid tests with a price of US\$290. Other COVID-19-related products included antibody test kits advertised at US\$43.48 each. Limited evidence of a recorded sale of 25 test kits for US\$395 was found on Empire Market, however the proceeds are negligible in comparison to the overall volume of transactions involving narcotics on such marketplaces, which is estimated to be worth hundreds of millions of dollars every year.⁸²

Nevertheless, some vendors selling COVID-19-related medical equipment on Empire Market appeared to be established outfits, suggesting they may have good access to pharmaceutical laboratory supplies. A small number of sales of face masks was also detected on that marketplace, although at unusually high prices e.g. two N95 face masks at a price of US\$100. Only one sale of this type of face mask was documented by the survey. The high price could suggest the vendor had a limited number of items in stock and was trying to discourage buyers from purchasing the product. Furthermore, some vendors advertising face masks were subsequently banned by the marketplace, suggesting the activity was suspected to be fraudulent.

Dark Market is another major marketplace included in the survey, with approximately 34,150 listings advertised on the platform. In terms of COVID-19-related activity, searches for 'hydroxychloroquine' and 'chloroquine' yielded only one listing. Notably, 180 query results seemed to be COVID-19-related, but the vendors were in fact advertising traditional products, such as cannabis and MDMA, while using COVID terminology to capitalize on the pandemic to advertise their products.

Monopoly market, smaller than the other marketplaces covered by the survey, had only one COVID-19-related product listed – hydroxychloroquine sulphate. Market administrators posted a warning to potential buyers that the drug is not to be considered a reliable cure for COVID-19 and that self-diagnosis is not advisable. While the market did allow the product to be sold, vendors were cautioned against profiting from the pandemic and advertising hydroxychloroquine as a cure for COVID-19.

The analysis of leading online marketplaces did not produce significant convincing evidence of major sales involving COVID-19-related medicine and medical equipment. Although a small number of listings of relevant products was observed, they appear to generate very little revenue. The limited number of transactions is unsurprising, given that regular buyers on such marketplaces are well versed in purchasing drugs and have a relatively high level of technical acumen. This suggests that buyers engaging in transactions on the Dark Web are less likely to purchase medicines touted as COVID-19 miracle cures and overpriced face masks, or potentially fraudulent PPE. Notably, some COVID-19-related items listed on the marketplaces seemed to be advertised by vendors who had executed several online transactions. This may indicate that vendors were able to access a significant number of pharmaceutical products. Of the various marketplaces surveyed, the largest share of activity was observed on Empire Market. In one instance, market administrators actively sought to regulate transactions and prevent vendors from profiting from the ongoing pandemic through advertisements for hydroxychloroquine as a cure for COVID-19.

To conclude, the largest markets on the Dark Web did not exhibit significant transactions involving products directly related to COVID-19. Nevertheless, COVID-19 appeared to be used in several cases as an advertising tool for traditional narcotics. Long-term monitoring of transactions on such marketplaces is needed to assess whether the situation is evolving. Furthermore, other illicit channels, such as unlicensed Internet markets, which paradoxically may be less regulated than Dark Web markets, should also be included in future monitoring efforts, to determine the extent to which online markets contribute to the sale of COVID-19-related products.

Further in-depth analysis of vendor behaviour on Dark Web marketplaces may offer insights into the ways in which the COVID-19 pandemic is influencing illicit online sales of goods such as medical devices and equipment and licit pharmaceutical medicines. Studying the long-term impact of COVID-19 on online narcotics sales will be of equal importance, as buyers may face obstacles in meeting dealers face-to-face and as a result may turn increasingly to online sources to purchase illicit drugs. Furthermore, confinement measures and the closure of borders introduced in many countries to contain the spread of the pandemic pose significant challenges to online vendors seeking to ensure the shipping of their products is not disrupted. Disruptions or alterations to traditional procurement and shipping flows may be able to be identified through studying the longterm impact of the COVID-19 pandemic on online sales of illicit drugs. Furthermore, such a study may also identify changes in vendor and buyer behaviour and profiles triggered by COVID-19 as well as other social and economic upheavals associated with the pandemic.

Changes in the modus operandi of organized criminal groups triggered by the COVID-19 pandemic

Evidence shows that organized criminal groups are using the COVID-19 pandemic to infiltrate the legal economy and strengthen governance activities in response to emergencies triggered by the ongoing crisis.⁸³ The involvement of organized criminal groups in the provision of medicines ostensibly related to COVID-19, such as chloroquine, both in terms of infiltrating the legal supply chain and managing their illicit trade, is supported by evidence from seized shipments of illegal medical products in several countries.^{84 85} Such groups are reconsidering their strategies and increasingly switching to other types of crime involving falsified goods such as PPE and medicines.⁸⁶ Various types of cybercrime involving fraudulent medical products have been linked to new modus operandi of organized criminal groups resulting from the COVID-19 pandemic, as illustrated by the following examples:

- The UK's National Cyber Security Centre (NCSC) said it took down more than 2,000 online coronavirus scams in March 2020 which included 471 fake online shops selling fraudulent COVID-19-related items.⁸⁷
- Police in France removed 70 fraudulent websites claiming to sell chloroquine in April 2020.⁸⁸
- COVID-19-related scams in the USA amounted to approximately US\$13.4 million from the beginning of January to mid-April 2020 and have affected more than 18,000 citizens.⁸⁹

 In the first four months of 2020, 1,541 cyberattacks related to COVID-19 were detected in the United Arab Emirates including 775 malware threats, 621 email spam attacks and 145 URL attacks.⁹⁰

A considerable number of cyberattacks and scams related to the COVID-19 pandemic was recorded worldwide during the first four months of 2020. Such scams include social media advertisements and websites for the purchase of PPE, test kits, sanitizer and falsified medicines.

Qualitative assessments of the situation in North Macedonia indicate that organised criminal groups are moving away from drug trafficking to other types of crime involving falsified medical products such as protective equipment and pharmaceutical products.⁹¹ Cybercrime using various malware and ransomware packages themed around COVID-19 are also predicted to be part of the new modus operandi.

In Mexico, it has been reported that organised criminal groups, such as drug cartels, are likely to switch to cybercrime. It is expected that online fraud, including through phishing attacks, will rise during the period of emergency measures put in place to curb the spread of the pandemic.⁹²

Due to the growing demand for protective equipment, there are increased shipments of medical equipment circulating worldwide, which organized criminal groups may take advantage of to transport illicit drugs from one country to another. A case involving 14 kg of cocaine smuggled into the UK in a consignment of face masks was reported in April 2020.⁹³ Large-scale transnational fraud involving the purchase of protective equipment has also been identified as part of the new modus operandi of organised criminal groups emerging as a result of the COVID-19 pandemic.

CYBERCRIME WAS DETECTED IN SEVERAL COUNTRIES During Q1, the UAE The UK's NCSC COVID-related scams in the US reported took down more 1,541 cyberattacks, than 2,000 online amounted to 13.4M including 775 COVID-19 scams; **USD** during Q1 malware threats & including 471 fake of 2020, affecting shops selling more than 18,000 621 email spam counterfeit items attacks citizens

MAP 3: ILLICIT EVENTS INVOLVING COVID-19-RELATED SUBSTANDARD AND FALSIFIED MEDICINE AND MEDICAL EQUIPMENT IN SELECTED COUNTRIES IN NORTHERN EUROPE



Source: Elaborated by UNODC from European Commission Joint Research Centre and Infectious Diseases Data Observatory, Medicine Quality Monitoring Globe Index.

Notes: The boundaries and names shown and the designations used on this map do not imply official endorsement or acceptance by the United Nations.

MAP 4: ILLICIT EVENTS INVOLVING COVID-19-RELATED SUBSTANDARD AND FALSIFIED MEDICINE AND MEDICAL EQUIPMENT IN ITALY



Source: Elaborated by UNODC from European Commission Joint Research Centre and Infectious Diseases Data Observatory, Medicine Quality Monitoring Globe Index.

Notes: The boundaries and names shown and the designations used on this map do not imply official endorsement or acceptance by the United Nations.

MAP 5: ILLICIT EVENTS INVOLVING COVID-19-RELATED SUBSTANDARD AND FALSIFIED MEDICINE AND MEDICAL EQUIPMENT IN THE UNITED STATES OF AMERICA



Source: Elaborated by UNODC from European Commission Joint Research Centre and Infectious Diseases Data Observatory, Medicine Quality Monitoring Globe Index. Notes: The boundaries and names shown and the designations used on this map do not imply official endorsement or acceptance by the United Nations.

ENDNOTES

1 **Substandard**, also called "out of specification", are authorized medical products that fail to meet either their quality standards or specifications, or both. **Unregistered medical products** that have not undergone evaluation and/ or approved by the National or Regional Regulatory Authority for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation or legislation. **Falsified medical products** that deliberately/fraudulently misrepresent their identity, composition or source. WHO, *Global Surveillance and Monitor-ing System for substandard and falsified medical products:* executive summary (Geneva, 2017). A70/23 Add. 1, annex, appendix 3. Geneva: World Health Organisation, available at https://www.who.int/medicines/regulation/ssffc/A70_23-en1.pdf; 2017 (WHO/EMP/RHT/SAV/2017.01). For further information about the WHO definition on substandard and falsified medicines/regulation/ssffc/definitions/en/.

2 UNODC, *Combating Falsified Medical Product-Related Crime: A Guide to Good Legislative Practices* (Vienna, 2019). This definition takes into account the very close relationship between medicines and medical devices, as well as the fact that criminals do not distinguish between the two types of medical products in their criminal activities and, ultimately, that both falsified medicines and falsified medical devices cause harm to members of the public.

3 United Nations, *United Nations Convention against Transnational Organized Crime* (New York, 2004), Annex 1, Article 2(a). Available at <u>https://www.unodc.org/documents/treaties/UNTOC/Publications/TOC%20Convention/TOCebook-e.pdf</u>.

4 Ibid. article 2(b). There is no requirement for countries to introduce a definition of serious crime or to follow the definition of the Convention. The definition of serious crime is included to define the scope of application in the Convention and to invoke the international cooperation provisions of the Convention. In other words, for the Organized Crime Convention to apply to the most serious falsified medical product-related offences, States should provide for maximum penalties of at least four years.

5 WHO, Global Surveillance and Monitoring System for substandard and falsified medical products: executive summary (Geneva, 2017), p.5. Available at <u>https://www.who.int/medicines/regulation/ssffc/publications/GSMS_ExecutiveSummary_EN.pdf?ua=1</u>.

6 Europol, *Viral Marketing: Counterfeit, substandard goods and intellectual property crime in the Covid-19 pandemic* (2020). Available at <u>https://www.europol.europa.eu/publications-documents/viral-marketing-counterfeits-sub-</u> <u>standard-goods-and-intellectual-property-crime-in-covid-19-pandemic</u>.

7 WHO, "Solidarity Clinical Trials for COVID-19 treatments", (2020). Available at <u>https://www.who.int/emer-gencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/solidarity-clinical-tri-al-for-covid-19-treatments</u>.

According to the UNODC publication entitled *Combating falsified medical products-related crime: A guide to good legislative practices*, **trafficking in falsified medical products** means importing, exporting, storing, transporting, donating, dispatching in transit, dispatching in free-trade zones, trans-shipping, distributing, brokering, offering, keeping for offer, selling or supplying a falsified medical product, whether on one's own behalf or for a third party. The above definition of "trafficking in falsified medical products" does not commonly cover the removal or diversion of medical products from their intended market. <u>https://www.unodc.org/documents/treaties/publications/19-00741_Guide_Falsified_Medical_Products_ebook.pdf</u>.

9 Interpol, "Preventing crime and protecting police: Interpol's COVID-19 global threat assessment", 6 April 2020. Available at <u>https://www.interpol.int/en/News-and-events/News/2020/Preventing-crime-and-protecting-police-INTER-POL-s-COVID-19-global-threat-assessment</u>.

10 UNODC, COVID-19 and the drug supply chain: from production and trafficking to use (Vienna, 2020), p. 25. Available at <u>https://www.unodc.org/documents/data-and-analysis/covid/Covid-19-and-drug-supply-chain-Mai2020.pdf</u>.

11 UNODC, *Global Study on Homicide: Understanding homicide* (Vienna, 2019), p. 41. Available at <u>https://www.unodc.org/documents/data-and-analysis/gsh/Booklet_3.pdf</u>.

12 Interpol, "Unmasked: International COVID-19 fraud exposed", 14 April 2020. Available at: <u>https://www.interpol.</u> <u>int/en/News-and-Events/News/2020/Unmasked-International-COVID-19-fraud-exposed</u>.

13 Cimpanu, C. "Czech hospital hit by cyberattack while in the midst of a COVID-19 outbreak", *ZDNet*, 13 March 2020. Available at <u>http://www.ZDNet.com/article/czech-hospital-hit-by-cyberattack-while-in-the-midst-of-a-covid-19-outbreak/</u>.

14 Cimpanu, C., "Thousands of COVID-19 scams and malware sites being created on a daily basis", *ZDNet*, 18 March 2020. Available at <u>https://www.zdnet.com/article/thousands-of-covid-19-scams-and-malware-sites-being-creat-ed-on-a-daily-basis/</u>.

15 Illicit events include fraud, scams, theft and seizures.

16 Countries included: Bangladesh, Cambodia, China, Cyprus, India, Iran (Islamic Republic of), Israel, Malaysia, Philippines, Saudi Arabia, Singapore, Taiwan Province of China, Thailand, and United Arab Emirates.

17 Case 1: Interpol, "Unmasked: International COVID-19 fraud exposed", 14 April 2020; Case 2: Based on UN-ODC field office assessment (May 2020); Case 3: Clarín Policiales, "Coronavirus en Argentina: fabrican ilegalmente alcohol en gel y barbijos para venderlos en medio de la pandemia", 24 April, 2020. Available at <u>https://www.clarin.</u> <u>com/policiales/coronavirus-argentina-fabricaban-ilegalmente-alcohol-gel-barbijos-venderlos-medio-pandemia 0</u> <u>DuXj4_vne.html</u>; Case 4: For further information see: <u>http://www.sipa.gov.ba/assets/photos/press/1586349607-</u> <u>naručili-milione-maski-iz-firme-koja-proizvodi-liftove.pdf</u>.

18 UNODC, *Combating Falsified Medical Product-Related Crime: A Guide to Good Legislative Practices* (Vienna, 2019). Available at https://www.unodc.org/documents/treaties/publications/19-00741_Guide_Falsified_Medical_Products_ebook.pdf.

19 WHO, "Improving the quality of medical products for universal access" (2020). Available at <u>https://www.who.</u> <u>int/medicines/regulation/fact-figures-qual-med/en/</u>.

Ndomondo-Sigonda, M., Miot, J., Naidoo, S., Dodoo, A. and Kaale, E., "Medicines Regulation in Africa: Current State and Opportunities. Pharmaceutical Medicine", *Pharmaceutical Medicine*, vol. 31. No. 6. (2017), pp. 383-397.

21 Ekeigwe, A., "Drug manufacturing and access to medicines: the West African story. A literature review of challenges and proposed remediation", *AAPS Open*, vol. 5. No. 3, (2019). Available at <u>https://link.springer.com/</u> article/10.1186/s41120-019-0032-x.

Mages, R. and Kubic, T., "Counterfeit Medicines: Threat to patient health and safety", *Pharmaceutical Law and Policy*. vol. 18 No. 1-4, (2016) pp. 163-177.

23 UNODC, *Combating Falsified Medical Product-Related Crime: A Guide to Good Legislative Practices* (Vienna, 2019), p. 1. Available at <u>https://www.unodc.org/documents/treaties/publications/19-00741_Guide_Falsified_Medical_Products_ebook.pdf</u>.

UNODC, Combating Falsified Medical Product-Related Crime: A Guide to Good Legislative Practices (Vienna, 2019), p. 1.

An assessment of the impact of Covid-19 on the drug supply chain has shown that lockdown measures have increased control in trafficking routes in some countries with increased levels of seizures and have decreased in others with drastic decreases in drug seizures. UNODC, *COVID-19 and the Drug Supply Chain: from production and trafficking to use* (Vienna, 2020), p. 25.

26 UNODC, CYBERCRIME AND COVID-19: Risks and Responses (2020). Available at <u>https://www.unodc.org/documents/Advocacy-Section/UNODC - CYBERCRIME AND COVID19 - Risks and Responses v1.2 - 14-04-2020 - CMLS-COVID19-CYBER1 - UNCLASSIFIED BRANDED.pdf</u>.

27 Schneider, M. and Nam, N. H. T., "Africa and Counterfeit Pharmaceuticals in time of COVID-19", *Journal of Intellectual Property Law and Practice* (2020).

This included WHO, Interpol and the Council of Europe. Other stakeholder groups, such as the Permanent Forum on International Pharmaceutical Crime (PFIPC) also conducted such training (see note 66 as an example).

29 Fenwick, T., Seville, E. and Brunsdon, D., *Reducing the Impact of Organisational Silos on Resilience: A Report on the impact of silos on resilience and how the impacts might be reduced* (New Zeeland, Resilient Organisations Research Programme, 2009). Available at <u>https://www.resorgs.org.nz/wp-content/uploads/2017/07/silos.pdf</u>.

30 WHO, *Global Surveillance and Monitoring System for substandard and falsified medical products* (Geneva, 2017). Available at <u>https://www.who.int/medicines/regulation/ssffc/publications/GSMSreport_EN.pdf?ua=1</u>.

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