

Medical Product Quality Report – COVID-19 Issues

Issue 7. December 2020

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Centre of Tropical Medicine & Global Health, Nuffield Department of Medicine,
University of Oxford



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1. Summary of findings

Throughout 2020 the MQM Globe database tracked lay press publications related to SF medical products. In the English literature we identified over 469 relevant articles reporting incidents linked to COVID-19 medical products. Those articles included at least 534 different incidents in 60 different countries. Over half of the incidents were linked to substandard and falsified (SF) personal protective equipment (PPE) and sanitisers. The other incidents included medicines, diagnostics and vaccines.

One year after the start of the pandemic incidents with diverted, substandard or falsified COVID-19 supplies continue. For December we report on 37 alerts. Falsified or diverted COVID-19 vaccines were reported in South Africa, Philippines and Brazil. In addition we found many COVID-19 vaccines being offered on the Dark Web. There have been fewer articles reporting on SF COVID-19 diagnostics but incidents do continue. Even though the FDA is warning manufacturers about methanol contamination of sanitizers, new cases continue to occur. Reports on SF PPE remain frequent. Worryingly those PPE are often destined for health care workers. When PPE do not provide the required protection or do not meet the set standards, the health of the health care workers and their contacts are at risk.

Interpol, Europol, US Immigration and Customs Enforcement Homeland Security Investigations and many more national and international organisations have emphasized the public health threat of criminal activities related to COVID-19 vaccines, treatments, and other COVID-19 related supplies. We continue monitoring and data sharing and urge for much more international coordination to mitigate the risks.

2. Introduction

During the COVID-19 pandemic, the demand for COVID-19 related medical supplies has inevitably ballooned with an increased demand for personal protective equipment (PPE), diagnostics and preventive & curative pharmaceuticals. The high demand and related shortages of genuine products contributes to an increased global risk of substandard and falsified (SF) medical products, for COVID-19 and for many other essential medicines. The media have been reporting diverse examples of SF products flooding the market.

This monthly report aims to collate information and reports in the public domain on the quality of medicinal products that are currently in use, or that are being trialled for COVID-19's prevention or treatment. We also include reports on key subjects such as access, affordability or off label use for COVID-19 if they mention concern of the quality of the products. We do not aim to include discussion of the multiple fraudulent claims and quackery.

We use the terminology for different types of poor quality medical products as defined by the World Health Organisation (WHO, 2017)¹:

¹Source: World Health Organisation. Appendix 3 WHO MEMBER STATE MECHANISM ON SUBSTANDARD/SPURIOUS/FALSELY-LABELLED/FALSIFIED/COUNTERFEIT (SSFFC) MEDICAL PRODUCTS WORKING DEFINITIONS. In: Seventieth World Health Assembly. ; 2017. Accessed August 14, 2020. https://www.who.int/medicines/regulation/ssffc/A70_23-en1.pdf?ua=1

- **Substandard medical products**
Also called “out of specification”, these are authorized medical products that fail to meet either their quality standards or their specifications, or both.
- **Unregistered/unlicensed 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.

We emphasise the difference between the use of the terms ‘falsified’ and ‘counterfeit’ medical products. ‘Falsified’ is a broad term including all the various types of deliberate misrepresentation of a medical product from a public health perspective. The term ‘counterfeit’ is specifically linked to intellectual property rights, ‘trademark counterfeit goods’² and ‘pirated copyright goods’³ as used in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement.

The reports presented here were mostly extracted from the Medicines Quality Monitoring Globe ([the MQM Globe is accessible on the IDDO website](#)⁴), a system that scrapes online newspapers (referenced in Google News) for early warnings of SF medical products. In addition, alerts and reports by national and international organisations are included when captured by the members of the team or shared by colleagues. This report also includes scientific literature and policy documents related to COVID-19 medical products quality identified by manual searches in PubMed and Google Scholar. These will be displayed on the Medicine Quality COVID-19 Surveyor to be released in the coming months. We also include preprint of articles. Please note that preprints should be viewed with additional caution as they have not been peer-reviewed. They should not be relied on to guide clinical practice or health-related behaviour and should not be reported in news media as established information.

Please note the caveats for the lay literature ([MQM Globe disclaimer and caveats are accessible on the IDDO website](#)⁵); we include abstracts and extracts from articles that are subject to a take down policy. If we are contacted by a potential rights-holder who objects to the presence of material, we will remove the material in question from the report and Globe until we have been able to assess the case. Where material is removed for valid reasons of

²*Trademark counterfeit goods*: any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation.

Source: World Trade Organization. Part III — Enforcement of Intellectual Property Rights. Accessed August 14, 2020. https://www.wto.org/english/docs_e/legal_e/27-trips_05_e.htm#fnt-14

³*Pirated copyright goods*: any goods that are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production, and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation.

Source: World Trade Organization. Part III — Enforcement of Intellectual Property Rights. Accessed August 14, 2020. https://www.wto.org/english/docs_e/legal_e/27-trips_05_e.htm#fnt-14

⁴Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe. Web Page. Published 2020. Accessed October 16, 2020. <https://www.iddo.org/medicine-quality-monitoring-globe>

⁵Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe disclaimer and caveats. Web Page. Published 2020. Accessed October 19, 2020. <https://www.iddo.org/medicine-quality-monitoring-globe-disclaimer-and-caveats>

copyright, its removal will be considered as lasting until copyright in the material expires, or until the rights-holder agrees that the material can be reinstated.

This seventh issue of the monthly report 'Medical Product Quality Report – COVID-19 Issues' covers information published during the month of December 2020. The previous issues covered publications from January 1st to November 30th 2020 and are available on the IDDO⁶ and MORU⁷ websites. We also include publications and reports published prior to December 2020 that were missed in the previous issues of the report. We are developing a system for scraping regulatory authority and international organisation websites for alerts. Any remarks or additions to content are greatly appreciated (please write to medicinequality@iddo.org).

3. Scientific literature

3.1. General

[preprint] Arpita R, Nishant N, Singh D, Kulkarni N, Chaurasia S, Pathak L. **Knowledge, attitudes, and practices towards COVID-19 pandemic among residents of Jharkhand state, India: An online survey.** *Preprint*. Published online December 1, 2020. doi:10.21203/RS.3.RS-116495/V1

Extract. « *Markets are these days floated with various kind of sanitizers with reports coming that many not following specifications required for prevention against COVID-19. It is imperative for public to understand type of sanitizers to be used so that they do not stay in swag that they are adequately protected after using any sort of sanitizer available in the market.* »

Barua M, Kumar S, Mishra V, Mohanty A, Joshi HS. **Unmasking N95 for COVID-19 health-care workers in India.** *J Fam Med Prim Care*. 2020;9(12):5852. doi:10.4103/JFMPC.JFMPC_1839_20

Extract. « *As India faces massive shortage of FFRs [Filtering Facepiece Respirator] amid this COVID-19 pandemic, many counterfeits and uncertified respirators are finding their way into the health-care system. Counterfeits and uncertified respirators are two distinct entities. Counterfeits are a fraudulent imitation of a genuine product. They may be recognized by having a high index of suspicion, verifying manufacturers & trademarks from certifying agencies and purchasing from authorized retailers. Uncertified respirators present a different problem. Although manufacturers do test FFRs in their laboratories for quality, it is possible that certification may be delayed due to procedural reasons or bureaucracy.* »

Hashimoto T, Sawano T, Ozaki A, Tsubokura M, Tsuchiya T. **Need for more proactive use of pharmacists in the COVID-19 pandemic following lessons learnt from the Great East Japan Earthquake.** *J Glob Health*. 2020;10(2). doi:10.7189/jogh.10.020397

Extract. « *Maintaining an appropriate and sustainable supply of medical and health service products, including drugs, vaccines and sanitary materials, is of paramount importance in any crisis that impacts on public health in any population. In the past, quackery spread during the Great Plague, and after World War 2 shortage of anti-infective agents and analgesics caused the spread of substandard and counterfeit drugs, leading to negative health impacts, including deaths. In this regard, during the*

⁶Infectious Diseases Data Observatory. Medical Product Quality Reports. Medical Product Quality Reports. Published 2020. Accessed January 13, 2021. <https://www.iddo.org/mq/research/medical-product-quality-reports>

⁷MORU Tropical Health Network. Medical Product Quality Report - Covid-19 issues. Medicine Quality. Published 2020. Accessed December 8, 2020. <https://www.tropmedres.ac/research-areas/medicine-quality/medicine-quality>

Coronavirus Disease 2019 (COVID-19) pandemic, which has spread rapidly around the world including Japan, constructing stable supply chains of resources such as drugs and other daily necessities should be essential for preventing undesired outcomes. »

Jarrett S, Wilmansyah T, Bramanti Y, et al. **The role of manufacturers in the implementation of global traceability standards in the supply chain to combat vaccine counterfeiting and enhance safety monitoring.** *Vaccine*. 2020;38(52):8325. doi:10.1016/j.vaccine.2020.11.011

Abstract. « The counterfeiting of vaccines is an increasing problem globally with the safety of persons vaccinated, the trust in vaccines generally and the associated reputation of vaccine manufacturers and regulatory agencies at risk. This risk is especially critical with the on-going development of COVID-19 vaccines. The ability to track and trace vaccines through the vaccine supply chain down to persons vaccinated has to be enhanced. In this context of traceability, the global immunization community has recently set the barcoding of the primary packaging of vaccines, specifically vaccine vials and pre-filled syringes, as a top priority. Emerging vaccine manufacturers are already engaged in investigating ways to incorporate barcoding in their labelling and packaging using GS1 international standards. A specific pilot taking place in Indonesia by the national vaccine manufacturer, Bio Farma, shows the innovation of barcoding on primary packaging already underway with a relatively modest level of investment and success at this stage. This article highlights the efforts of industry and governments on the value of traceability and introduction to 2D barcodes. Access to financial resources and support from the international immunization community would accelerate such innovations leading to enhanced security of the vaccine supply chain. »

Khor WP, Olaoye O, D'arcy N, et al. **The need for ongoing antimicrobial stewardship during the COVID-19 pandemic and actionable recommendations.** *Antibiotics*. 2020;9(12):1-12. doi:10.3390/antibiotics9120904

Extract. « Another challenge during the pandemic response in many countries is combating falsified and substandard medicines and pharmaceutical supplies. [...] Past studies have shown that falsified or substandard antimicrobials are highly likely to promote the emergence and spread of AMR. Recent studies have also shown that the resistance of Escherichia coli and Mycobacterium smegmatis to rifampin occurred as a result of exposure to substandard medicines; this presents a potential threat to tuberculosis treatment. Over the years, it has been recognised that addressing the problem of substandard or falsified medicines will require the united action of all relevant stakeholders including government bodies, policy makers, regulatory and law enforcement agencies, public health professionals, patients and the general public. Pharmacists play a pivotal role in combating falsified and substandard medicines by working on strengthening supply chain procurement processes to ensure uninterrupted access to safe and effective medicines during the pandemic. »

Mason AN. **Pharmacy Internal Controls: A Call for Greater Vigilance during the COVID-19 Pandemic.** *Pharmacy*. 2020;8(4):216. doi:10.3390/pharmacy8040216

Abstract. « For businesses that store physical goods, managing product inventories and financial cost accounting controls are critical. Pharmacies are under considerable scrutiny, due to the nature of their merchandise, making internal controls even more vital. Due to the emergence of COVID-19 and government mitigation strategies, the US economy has seen significant macro- and microeconomic effects. COVID-19 has changed the pharmacy working environment, which could theoretically increase rates of employee drug diversion. Therefore, better inventory management could reduce the misuse of pharmaceutical drugs from fraudulent and drug diversion activities. The author explored secondary findings to create a multidisciplinary conceptual analysis of the reasons why internal controls executed with greater diligence may be needed to avoid damaging financial, legal, and health outcomes. The author also provides a review of available internal control methods that can be used to mitigate diversion. »

Shiferie F, Kassa E. **The scourge of substandard and falsified medical products gets worse with COVID-19 pandemic.** *Pan Afr Med J.* 2020;37. doi:10.11604/pamj.2020.37.344.26322

Abstract. « *Although health professionals, communities, governments and global institutions work closely to halt the spread of COVID-19 and mitigate its societal impact, COVID-19 remains a challenge to many countries around the world. In addition to its direct health, economic and social consequences, the pandemic has also resulted in unforeseen consequences in Africa especially in East African countries. COVID-19 might increase the demand and consumption of Substandard and Falsified (SF) medical products in three major ways. The first way is due to the inability of vulnerable segment of the population to access healthcare services as they used to do before. The second way people get exposed to SF medical products is due to fear of being quarantined, isolated and traced. Yet another way is related to import permits for medical products. Concerned regulatory bodies shall intervene aggressively in ensuring the safety, quality and effectiveness of medical products before we face a parallel pandemic from SF medical products.* »

Tongyam C, Potiwiput S, Tumkhanon K, et al. **Authenticity Screening for N95 Filtering Facepiece Respirator by Field Emission Scanning Electron Microscope in Comparison with Particulate Filtration Efficiency Analysis.** *J Microsc Soc Thail.* 2020;33(2):1-5. Accessed January 8, 2021. <https://www.tci-thaijo.org/index.php/mmres/>

Abstract. « *Wearing face masks has become mandatory for many countries around the world as a mean to curb the spread of the SARS-CoV-2 virus transmission. During this difficult time the N95 FFR stock becomes an overnight commodity. The filtration efficiency of the mask is an important concern to protect medical professionals. By description, N95 filtering facepiece respirator (FFR) is a mask that is certified to filter over 95% of the particle size of 0.3 microns. Those numbers are considered to be able to filter out microorganisms and the majority of dust particles and air pollution. Counterfeited FFR's flooded the market and put medical professionals at risk. As the filtration efficiency depends on the physical characteristics and chemical properties of respirator materials, the analysis of fiber topology should shed lights on how to screen counterfeited FFRs from genuine ones. In this study, fiber topology and physical appearances of each filter layer were revealed using low accelerating voltage FE-SEM analysis of four commercial N95 FFR models. The particulate filtration efficiency (PFE) test was operated as means to identify genuine FFRs. The investigation revealed that each layer of N95 FFRs was fabricated in different fiber sizes. The outer and inner layers were larger fibers and with added water repellent capability and the filter in the middle layer was fabricated with smaller fibers. Results from testing of filtration efficiency showed that each mask sample showed a filtration capacity ranging from 94-98% of 0.3 microns particles. Additionally, the SEM image library of authentic fiber images could be used to quickly screen counterfeited FFRs from genuine ones.* »

Ostapenko OI, Pinkevich T V. **Criminal-legal counteraction to medicines and medical devices illegal circulation in Russian Federation.** *Eurasian J Biosci.* 2020;14(2):6889-6895.

Abstract. « *The purpose of the article is to develop theoretical provisions that characterize the criminal-legal nature and legal significance of crimes in the field of illicit trafficking in medicines and medical products, as well as to determine the optimal means of criminal-legal impact on these socially dangerous acts. The leading approach to the study of this problem is a system-structural analysis, which allows identifying promising ways to optimize the criminal law counteraction to illegal trafficking of medicines and medical products. The article identifies the sufficient to criminalize level of public danger of crimes related to illegal turnover of drugs and medical devices, determines the international legal framework for combating these crimes; specifies legally significant signs of crimes in the sphere of illegal turnover of drugs and medical products; highlights key aspects of differentiation of criminal responsibility for committing these crimes; the main directions of optimization of criminal-legal counteraction to crimes in the sphere of illegal turnover of medicines and medical products are defined. The materials of the article can be useful in the daily activities of law enforcement agencies, as well as for the legislative process.* »

Weerth C. **World Customs organization's role during the covid-19-pandemic: declarations, information distribution, guidance and leadership.** *Механізми публічного управління.* 2020;27:44-56. doi:10.32836/2310-9653-2020-4.8

Extract. « Again it is urged by all stakeholders that all medical supplies must be delivered with a high priority and the trade in essential goods such as medication and food must be upheld and ensured over borders that are closed for humans in order to stop the spread of COVID-19. INTERPOL and EUROPOL and others are warning over new criminal approaches and counterfeit products in the COVID-19 pandemic.

This paper reviews the different initiatives, co-operations, declarations, lists and databases of the International Organizations and Intergovernmental Organizations that are newly emerging and are containing info on trade restrictions and trade facilitation during the COVID-19 pandemic and crisis. All information and free online databases are of the utmost importance to give insight, guidance and help in a global public health and economic emergency but mostly are pointing at the importance of trade facilitation – a topic that is not new but of the highest importance in times of a global emergency for all stakeholders to deliver medical supplies and necessary goods such as food to humans in need.»

Additional publications prior to December 2020

Hasen G, Suleman S. **Regulatory authorities' preparedness to avert poor quality alcohol-based hand sanitizers during COVID-19 pandemic in Ethiopia: A commentary.** *Pharm Pharmacol Int J.* 2020;8(6):322-323. doi:10.15406/ppij.2020.08.00312

Abstract. « The World Health Organization recommends the use of ethyl alcohol or isopropyl alcohol-based hand sanitizers to control the spread of the COVID 19 pandemic. As a result, a number of temporary guidelines and policies are being claimed among different countries of the world by waiving restrictions on the production of hand sanitizers which allow manufacturers, including alcohol beverage manufacturers, to produce alcohol-based hand sanitizers in midst of the COVID-19 pandemic. Under such circumstances, there will be a high chance of producing substandard and counterfeit alcohol-based sanitizers by unscrupulous firms. In addition, the fragile regulatory authority coupled with the risk of using poor quality sanitizers highly requires the active preparedness of regulatory authorities in resource-limited settings, including Ethiopia. Therefore, the current commentary highly recommends the regulatory authority of Ethiopia to actively counterpart the spread of poor quality sanitizers. Moreover, assessment of the quality of alcohol-based hand sanitizer circulating in Ethiopia, a low-income country should be undertaken as soon as possible to assure its quality. »

Kumar Bp S, Paul P, Ghosh S, Bn R, Roy AD. **General awarness (sic) and safety measures to combat covid-19.** *Int J Res Pharm Pharm Sci.* 2020;5(6):2455-2698. doi:10.5281/zenodo.4347072

Extract. « There are so many cheap quality sanitizers which contain methanol are available in the market, which is harmful for the health. According to our study statistical analysis shows that 89.77% participants were aware about this and rest 10.23% participants were (sic) have no knowledge about sanitizers. »

3.2. Seizures/Surveys/Case Reports/Reviews

Richards GC. **Alcohol-based hand sanitisers: a warning to mitigate future poisonings and deaths.** *BMJ Evidence-Based Med.* Published online December 1, 2020:bmjebm-2020-111568. doi:10.1136/bmjebm-2020-111568

Extract. « There was a 157% increase in poisonings from alcohol-based hand sanitisers reported to the National Poisons Information Service in the UK between January and September 2019 and January and September 2020. Two case studies have also described accidental poisonings from the ingestion of

hand sanitisers at home by children in Australia and the USA during the SARS-CoV-2 pandemic. The US CDC reported 15 poisonings and four deaths associated with the ingestion of hand sanitisers that were intentionally made with methanol instead of ethanol or isopropanol during the COVID-19 outbreak, and the FDA is taking action by regularly updating their “should not use” list of hand sanitisers to protect the public from further harm. This *BMJ EBM Coroners’ Concerns to Prevent Harms* article describes two deaths in England that occurred after the intentional and unintentional ingestion of alcohol-based hand sanitisers in healthcare facilities, and outlines recommendations to mitigate further harms. »

4. International organisations

Europol. **Early Warning Notification - Vaccine-related crime during the COVID-19 pandemic.** Published online December 4, 2020:1-2. Accessed January 15, 2021. <https://www.europol.europa.eu/publications-documents/early-warning-notification-vaccine-related-crime-during-covid-19-pandemic>

Extract. « *The detection of a fake influenza vaccine confirms that criminals seize opportunities as soon as they present themselves. Owing to the pandemic, the demand for the influenza vaccine has been higher than usual and there risks being a shortage. Criminals have reacted quickly by producing counterfeit influenza vaccines. The same scenario is also likely to happen when COVID-19 vaccines do become available. Criminals may attempt to exploit the current global focus on COVID-19 vaccines. Criminals may spread disinformation about vaccines to defraud individuals and companies. When a COVID-19 vaccine does become available, it will likely not be available for sale online. However, fraudulent pharmaceutical products advertised as allegedly treating or preventing COVID-19 are already on sale, both offline and online.* »

Europol. **Medicines and doping substances worth €73 million seized in Europe-wide operation.** Press Release. Published December 10, 2020. Accessed December 16, 2020. <https://www.europol.europa.eu/newsroom/news/medicines-and-doping-substances-worth-€73-million-seized-in-europe-wide-operation>

Extract. « *Europol coordinated operation Shield, a global effort to target trafficking of counterfeit and misused medicines and doping substances. The operation was led by Finland, France, Greece and Italy and involved law enforcement authorities from 27* countries (19 EU Member States and 8 third-party countries), the European Anti-Fraud Office (OLAF), the Pharmaceutical Security Institute and the private sector. The operation took place between March and September 2020. During the operation, law enforcement officers dismantled 25 criminal groups, arrested nearly 700 suspects and seized large amounts of anti-cancer drugs, erectile dysfunction medicines, pseudoephedrine, various doping substances (hormone and metabolic regulators), drugs, painkillers, antioestrogens, antivirals, hypnotics, antihistamines and anxiolytics.[...] COVID-19-related fakes : (*) Almost 33 million medical devices seized (face masks, tests, diagnosis kits) (*) 8 tonnes of raw materials, chemicals and antivirals seized (*) 70 000 litres of hygiene sanitizers seized.* »

Interpol. **INTERPOL warns of organized crime threat to COVID-19 vaccines.** News. Published December 2, 2020. Accessed December 8, 2020. <https://www.interpol.int/News-and-Events/News/2020/INTERPOL-warns-of-organized-crime-threat-to-COVID-19-vaccines>

Extract. « *The INTERPOL Orange Notice outlines potential criminal activity in relation to the falsification, theft and illegal advertising of COVID-19 and flu vaccines, with the pandemic having already triggered unprecedented opportunistic and predatory criminal behaviour. It also includes examples of crimes where individuals have been advertising, selling and administering fake vaccines. 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. 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.* »

Interpol & United Nations Office on Drugs and Crime. **International operation disrupts supply of firearms to terrorists.** News. Published December 21, 2020. Accessed December 23, 2020. <https://www.interpol.int/en/News-and-Events/News/2020/International-operation-disrupts-supply-of-firearms-to-terrorists> and <https://www.unodc.org/unodc/frontpage/2020/December/international-operation-disrupts-supply-of-firearms-to-terrorists.html>

Extract. « A seven-day operation saw law enforcement officers intercept illicit firearms, ammunition and explosives, and disrupt the trafficking networks used to supply terrorists across West Africa and the Sahel. Under Operation KAFO II (30 November - 6 December), coordinated jointly by INTERPOL and the United Nations Office on Drugs and Crime (UNODC), frontline officers targeted smuggling hotspots at airports, seaports, and land borders in Burkina Faso, Côte d'Ivoire, Mali and Niger.[...] Against the backdrop of the current COVID-19 health crisis, officers also seized large quantities of contraband hand sanitizer gels, gloves and drugs, for which the market is flourishing. »

United Nations Office on Drugs and Crime. **Covid-19 Vaccines & Corruption Risks: Preventing Corruption in the Manufacture, Allocation and Distribution of Vaccines.** 2020. Accessed December 14, 2020. https://www.unodc.org/documents/corruption/COVID-19/Policy_paper_on_COVID-19_vaccines_and_corruption_risks.pdf

Extract. « With COVID-19 vaccines being approved for use in different parts of the globe, the scale and complexity of their manufacture, allocation and distribution globally will be unprecedented. This will also present corruption risks that may threaten vital public health goals. These risks include the entry of substandard and falsified vaccines into markets, theft of vaccines within the distribution systems, leakages in emergency funding designated for the development and distribution of vaccines, nepotism, favouritism, and corrupted procurement systems. These corruption risks must be identified and mitigated by public institutions to help advance access to safe and effective COVID-19 vaccines by the population, including the most vulnerable and marginalized groups. The United Nations Convention against Corruption provides a solid global framework for these efforts. »

World Health Organisation

| Medical Product Alert | |
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| <p>N°7/2020: Falsified HARVONI (Ledipasvir/sofosbuvir) identified in the WHO regions of the Americas and Europe</p> <p>2020 December 8</p> | <p>« This WHO Medical Product Alert relates to one batch of confirmed falsified HARVONI (Ledipasvir/sofosbuvir) identified in Brazil and Turkey. Falsified Harvoni was identified in Brazil in May 2020 and in Turkey in November 2020. WHO has received recent information that suggests these products are still in circulation. Available information indicates that these falsified medicines were supplied at patient level. The WHO Global Surveillance and Monitoring System database has prior records of other falsified Harvoni batches. Consistent reporting is essential to determine the scope and scale of such falsified products. »</p> <p>https://www.who.int/news/item/08-12-2020-medical-product-alert-n-7-2020</p> |

5. Miscellaneous

Mackey TK. **Risk of cyber superspreaders and influencers on product integrity: COVID-19 and beyond.** *The Brand Protection Professional, BPP.* <https://bpp.msu.edu/magazine/risk-of-superspreaders-and-influencers-on-product-integrity-covid19-and-beyond-december2020/>. Published December 2020. Accessed January 8, 2021.

Extract. « A key question that parallels the real-world epidemiological characteristics of COVID-19 superspreader events is whether these same dynamics apply to information transmission online, particularly how online contagion starts and spreads, and what individuals or organizations are behind these “digital outbreaks”. Some early evidence is emerging, particularly in the context of COVID-19 misinformation about drugs, vaccines, and other treatments, which can impact consumer perception and demand for these health products (Morrison and Heilweil, 2020). [...] Hence, the spread of misinformation about COVID-19 can have knock-on effects that can lead to greater and unsubstantiated demand for COVID-19-related treatments, including products that may be in shortage, are not approved for use by regulatory agencies or that lack scientific evidence about their safety and efficacy. This can also open the door for fraudsters and counterfeiters who seek to fill the gap between misinformation and ensuing consumer demand that cannot be met by legitimate sources, as evidenced by numerous reports of counterfeit COVID-19 tests, medications, and protective personal equipment being seized by customs officials (CBP, 2020; Sutton, 2020). However, the strategies used by these “influencers” and their impact on public safety has not yet been explored sufficiently in the broader product integrity and anti-counterfeiting area. »

U.S. Immigration and Customs Enforcement (ICE) Homeland Security Investigations (HSI). **Operation Stolen Promise 2.0.** Published December 2020. Accessed January 18, 2021. <https://www.ice.gov/topics/operation-stolen-promise>

Extract. « U.S. Immigration and Customs Enforcement (ICE) Homeland Security Investigations (HSI) launched Operation Stolen Promise (OSP) in April 2020 to protect the Homeland from 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 and expansive federal criminal investigative authorities; its strong intelligence analysis capabilities and resources; its expansive 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 U.S. and global marketplaces. In response, HSI has initiated Operation Stolen Promise 2.0, which expands the focus of OSP to address this emerging public health threat. »

Fight the Fakes. **Updated statement regarding COVID-19 and falsified medical products. Updates.** Published December 2020. Accessed January 19, 2021. <http://fightthefakes.org/updated-statement-regarding-covid-19-and-falsified-medical-products/>

Extract. « The Fight the Fakes Alliance and its members would like to stress that the risk of falsified versions of such vaccines being advertised is imminent. With approved diagnostics, treatments and vaccines it is now more important than ever to only purchase medical products from trusted, authorized sources. Particularly buying COVID-19 medical products from unknown, unauthorized online sellers or online pharmacies bears a high risk of purchasing falsified products. Using medical products that have not been approved for COVID-19 without medical supervision pose a significant risk to patient’s well-being and safety. Any misleading and deliberately fake information on COVID-19 circulating on social media and media has been described as an infodemic by the WHO. The Fight the Fakes Alliance is calling on all its members and the broader global health community to raise awareness of falsified medical products promising to treat, protect from or cure COVID-19. We are no longer just fighting a virus, but now also an ever-growing infodemic »

Additional publications prior to December 2020

Farrell G, Johnson SD. **Preventing a Coronavirus Vaccine Crime Wave.** *UCL JDI Spec Ser COVID-19.* 2020;(24):1-2. Accessed January 4, 2021. https://www.ucl.ac.uk/jill-dando-institute/sites/jill-dando-institute/files/vaccine_crime_wave_no_24_final.pdf

Extract. « *Huge increases in theft and robberies can be expected, including interceptions of shipments, counterfeiting and other fraud, and black-markets (with high prices), promoting corruption and organised crime. Monetary costs will be in the billions. Human costs will arise as vaccine distribution is disrupted and delayed, and as counterfeits are used by unsuspecting victims. Vaccine distribution will be hindered and effectiveness reduced. If reinfection and virus mutations extend the vaccination process, they will potentially also extend the crime.* »

Nikolovska M, Johnson S. **Covid19 and Medical Counterfeits.** *UCL JDI Spec Ser COVID-19.* 2020;(10):1-2. Accessed January 4, 2021. https://www.ucl.ac.uk/jill-dando-institute/sites/jill-dando-institute/files/medical_counterfeits_final_no_10.pdf

Extract. « *Criminals have been exploiting the COVID-19 pandemic by selling fake medical and health products online or door-to-door. Such fraudulent goods have included COVID-19 testing kits, medicines that treat, prevent or cure COVID-19, and COVID-19 protective equipment, such as face masks and hygiene products. Relevant stakeholders have been urging caution and promoting public awareness of the existence of such illicit goods. However, fear around the pandemic can trigger impulsive and protective behaviours, increasing people's vulnerability to such scams.* »

Queensland Department of Natural Resources Mines and Energy. **Fake disposable respiratory protective equipment supplied to Queensland Coal Mines.** Mines safety alert. Published March 14, 2020. Accessed January 8, 2021. <https://www.rshq.qld.gov.au/safety-notices/mines/fake-disposable-respiratory-protective-equipment-rpe-supplied-to-queensland-coal-mines>

Extract. « *It has come to our attention that current demand for respiratory protection has resulted in sub-standard or "fake" respirators entering the industry that, despite being appropriately branded, have not been manufactured in accordance with a relevant standard or equivalent international scheme (i.e. ANZS, NIOSH etc). It can be difficult to distinguish between authentic and fake RPE devices. The packaging and the appearance of these "fake" respirators can be very deceptive. The packaging will often list a protection factor (eg. P2, KN95 or N95) and include fraudulent labelling of the relevant certification body. Examples of some of the fake RPE encountered are provided below.* »

6. Lay literature

6.1 Disclaimer & Notes

The information included below is based on the data used to create the Medicine Quality Monitoring Globe⁸ (MQM Globe). It contains publicly available information on the quality of medical products from non-peer-reviewed lay literature. We report the information as it is stated in the articles and can thus be biased towards the authors perspective. It does not necessarily reflect our vision or judgment on the issue. Also, this information usually will not have scientific confirmation. Therefore, the information needs to be interpreted with the greatest caution. We regard the reports as early warnings of potential problems. No or few articles from a region does not imply that the medical product quality there is good, but probably reflects a lack of accessible information. Full disclaimer and caveats can be found at [MQM Globe disclaimer and caveats](#)⁹.

The Google News search tool is used to capture data from online news sources. Articles matching the search terms are loaded into a database and curated by trained analysts. Because the Globe system extracts newspaper articles from journals referenced in Google News only, reports not referenced in Google News would not be captured. [Please consult the IDDO website for full methodology](#)¹⁰. On the 20th of March, the search terms were adapted to capture more papers on substandard and falsified (SF) medical supplies for COVID-19 from Google News. In addition, the Globe system captures the United States Food and Drug Administration (US FDA) medical products alerts. In the future, we will extend this feature to other regulatory authorities.

The articles discussed in the sections below are available in the Globe-reports, in this report's annexes, or on the online MQM Globe using the report ID (six digits code). The MQM Globe-reports are generated with pre-defined search terms, which enable quick access to reports of (a) COVID vaccines, (b) COVID diagnostics, (c) Personal Protective Equipment (PPE), (d) Sanitisers and disinfectants, (e) COVID medicines, and (f) Ventilators and Positive end-expiratory pressure. Only the relevant articles included in the MQM Globe-reports are selected for the current COVID-19 report. For alerts from January to September the Globe-report for PPE included sanitisers and disinfectants. From October onwards sanitisers and disinfectants are grouped in a separate Globe-report. The search terms applied to search the Globe database to compile the Globe-reports were revised in October & November. Therefore caution is required when interpreting the number of alerts or articles over time.

In this report we share details of articles captured by the MQM Globe that are linked to medical products potentially used in the context of COVID-19 or to active pharmaceutical ingredients (APIs) that are being trialled for COVID-19 treatment and/or prevention. In theory there is a distinction between (a) SF incidents that are due to or increased by the COVID-19 epidemic; and (b) incidents that would have happened in any case. It can be difficult to make the distinction between the two types of incidents and some reports cited below are

⁸Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe. Web Page. Published 2020. Accessed October 16, 2020. <https://www.iddo.org/medicine-quality-monitoring-globe>

⁹Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe disclaimer and caveats. Web Page. Published 2020. Accessed October 19, 2020. <https://www.iddo.org/medicine-quality-monitoring-globe-disclaimer-and-caveats>

¹⁰Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe methodology. Web Page. Published 2020. Accessed October 19, 2020. <https://www.iddo.org/medicine-quality-monitoring-globe-methodology>

not directly linked to the treatment of COVID-19. Nevertheless we have included them as they represent crossover risks and help to assess the evolution of the alerts on these medical products over time. Although oxycodone is trialled¹¹, we do not include issues related to oxycodone as the system would become swamped by reports on its inappropriate use and cases of pills laced with fentanyl due to their wide occurrence on the black market. Non-COVID-19 medicines, containing hidden API(s) that are used or trialled for COVID-19 are, since the November 2020 issue, no longer included in the COVID-19 reports (e.g. hidden sildenafil in sexual enhancement supplements). Only medicines for which the stated API is used or trialled for COVID-19 are included in the COVID-19 report (e.g. falsified 'Viagra'). The observed decrease of the number of articles/alerts (Figure 1-3) may at least partially be due to this change.

For this report, we only included data that were published in English. For articles in French, Spanish, Mandarin, and Vietnamese; please consult the online MQM Globe. We will continuously work to improve the MQM Globe and plan to add in articles in other languages to this report. Any remarks or additions to content are encouraged (please write to medicinequality@iddo.org).

Changes in search strategy since the last Medical Product Quality Report - COVID-19 issues¹²

None

6.2 Articles on substandard or falsified medical products for COVID-19: main characteristics

Throughout 2020 the MQM Globe database tracked lay press publications related to SF medical products. In the English literature we identified over 469 relevant articles reporting on incidents linked to COVID-19 medical products (Figure 1). For December we report on 31 articles. Within those articles, 2 alerted on diagnostics, 5 on falsified vaccines, 5 are linked to hand sanitisers and disinfectants, 11 to COVID-19 related treatments and 14 to personal protective equipment (PPE) (Figure 2 and 3). Since June, the MQM Globe has not identified any reports linked to SF ventilation equipment.

In the following sections each category of products is discussed separately. However, some articles report on several product categories issues. On the 10th of December results of the Europol coordinated project Shield were released¹³ (report ID 839814). During the operation, running from March to September 2020, nineteen EU member states and eight third-party countries worked together to target traffic of falsified and misused medicines, and doping substances. Many of the seizures involved COVID-19 related supplies such as raw materials and chemicals, face masks, COVID-19 tests and diagnostic kits, sanitisers, and antivirals.

¹¹Hashemian SRM. Evaluation the effects of Oxycodone administration on pain control in patients with COVID-19. Iranian Registry of Clinical Trials. Published June 8, 2020. Accessed October 9, 2020. <https://en.irct.ir/trial/48534>

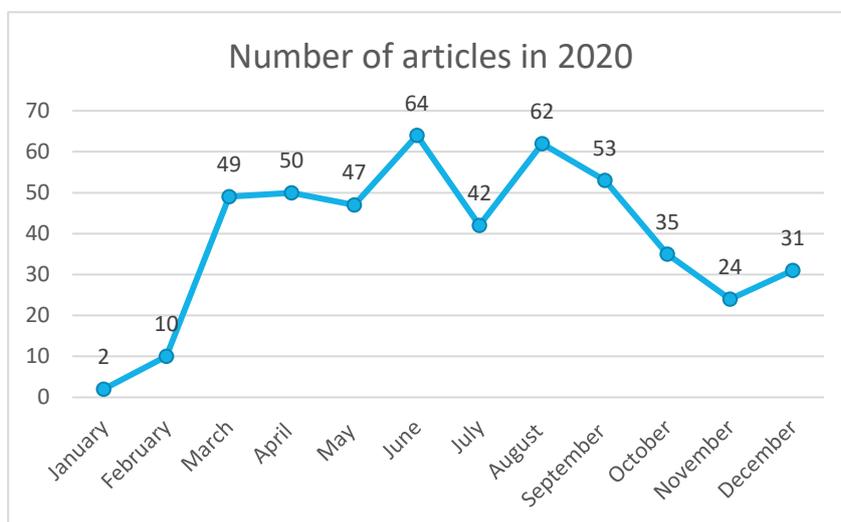
¹²Infectious Diseases Data Observatory. Medical Product Quality Reports. Medical Product Quality Reports. Published 2020. Accessed January 13, 2021. <https://www.iddo.org/mq/research/medical-product-quality-reports>
Lay literature

¹³Europol. Medicines and doping substances worth €73 million seized in Europe-wide operation. Press Release. Published December 10, 2020. Accessed December 16, 2020. <https://www.europol.europa.eu/newsroom/news/medicines-and-doping-substances-worth-€73-million-seized-in-europe-wide-operation>

By beginning of December 2020 “Nearly 20 factories selling substandard face masks, disinfectants and hand sanitisers have been busted in the UAE [United Arab Emirates] since the outbreak of the virus” according to the Legal Group Advocates and Legal Consultants in the United Arab Emirates (report ID 834891). The seizures of SF masks and hand sanitizers were not discussed in detail except for a seizure that concerned 2,000 boxes, each containing 120 falsified N95 respirators.

In April 2020, the US Immigration and Customs Enforcement (ICE) Homeland Security Investigations (HSI) launched Operation Stolen Promise, a law enforcement and private sector partnership (report ID 838504). As of beginning of December there were 1,727 COVID-19 related seizures such as unauthorised COVID-19 test kits, unauthorised pharmaceuticals and falsified masks¹⁴. In December 2020 Operation stolen Promise 2.0 was launched to focus on “new and evolving public health threat posed by the illicit sale and distribution of counterfeit or unauthorized vaccines and treatments.”

Figure 1. Number of articles on the Medicines Quality Monitoring Globe linked to substandard or falsified COVID-19 supplies by month. AS SOME ARTICLES DESCRIBE MORE THAN ONE CATEGORY OF PRODUCTS, THE SUM OF ALERTS PER MONTH AS SHOWN IN FIGURE 2 AND 3 MAY EXCEED THE SUM OF ARTICLES PER MONTH OF FIGURE 1. NOTE THAT SINCE NOVEMBER, NON-COVID-19 MEDICINES CONTAINING HIDDEN API(S) THAT IS/ARE USED OR TRIALLED FOR COVID-19 ARE NO LONGER INCLUDED IN THE COVID-19 REPORTS. ONLY MEDICINES FOR WHICH THE STATED API IS USED OR TRIALLED FOR COVID-19 TREATMENT ARE INCLUDED IN THE COVID-19 REPORT. THE OBSERVED DECREASE OF THE NUMBER OF ARTICLES ON MEDICINES CAN BE AT LEAST PARTIALLY DUE TO THIS CHANGE.



¹⁴U.S. Immigration and Customs Enforcement (ICE) Homeland Security Investigations (HSI). Operation Stolen Promise 2.0. Published December 2020. Accessed January 18, 2021. <https://www.ice.gov/topics/operation-stolen-promise>

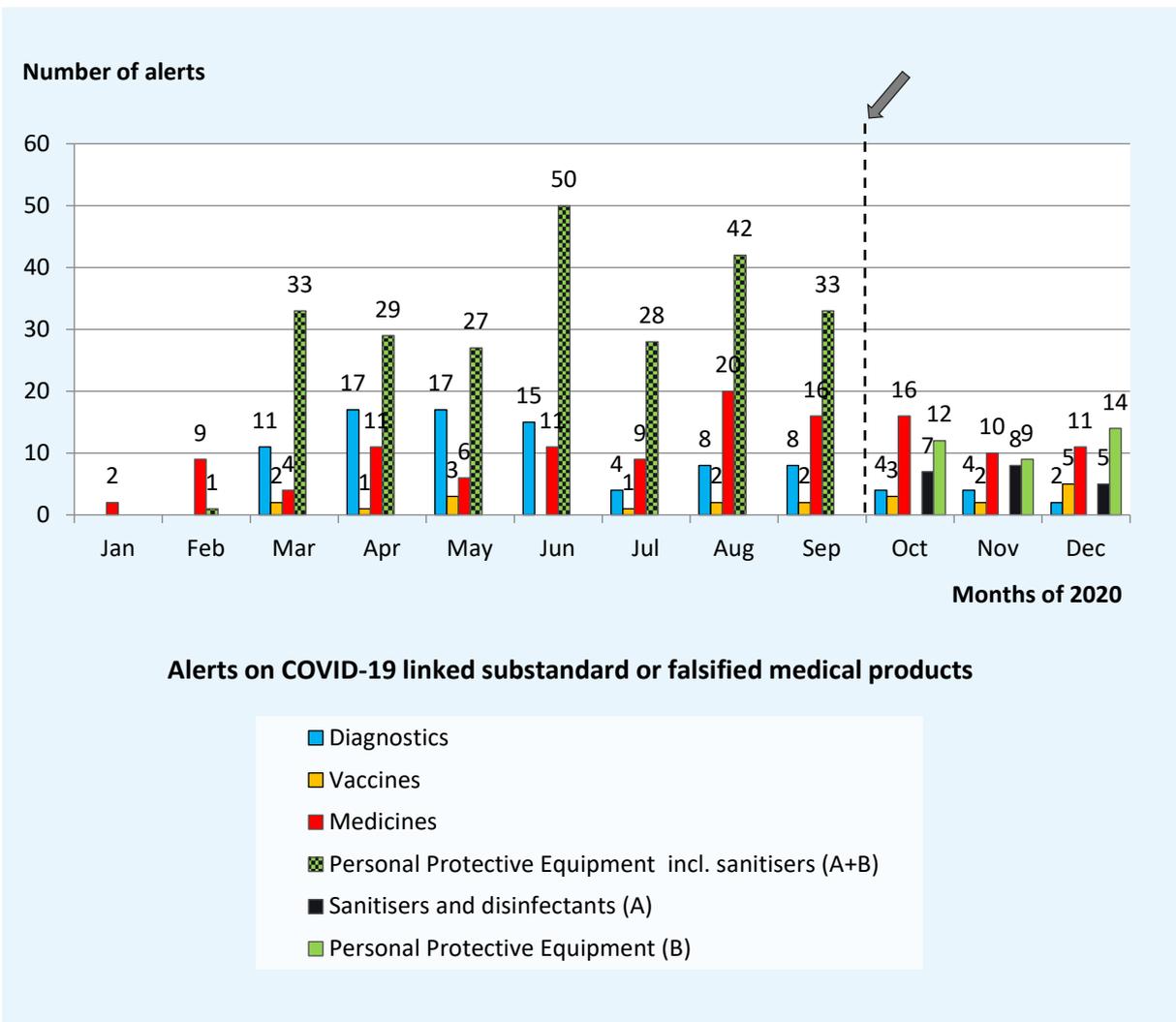


Figure 2. Number of alerts on the Medicines Quality Monitoring Globe by category of products and by month. ALERTS ARE FOR SUBSTANDARD OR FALSIFIED PRODUCTS LINKED TO COVID-19. AS SOME ARTICLES DESCRIBE MORE THAN ONE CATEGORY OF PRODUCTS, THE SUM OF ALERTS PER MONTH MAY EXCEED THE SUM OF ARTICLES PER MONTH REPORTED IN FIGURE 1. THE ARROW INDICATES THE END OF SEPTEMBER WHEN THE CATEGORY OF “PERSONAL PROTECTIVE EQUIPMENT INCL. SANITISERS” WAS SPLIT IN TWO DISTINCT CATEGORIES: (A) SANITISERS AND DISINFECTANTS, AND (B) PERSONAL PROTECTIVE EQUIPMENT.

NOTE THAT SINCE NOVEMBER, NON-COVID-19 MEDICINES CONTAINING HIDDEN API(S) THAT IS/ARE USED OR TRIALLED FOR COVID-19 ARE NO LONGER INCLUDED IN THE COVID-19 REPORTS. ONLY MEDICINES FOR WHICH THE STATED API IS USED OR TRIALLED FOR COVID-19 TREATMENT ARE INCLUDED IN THE COVID-19 REPORT. THE OBSERVED DECREASE OF THE NUMBER OF ARTICLES ON MEDICINES CAN BE AT LEAST PARTIALLY DUE TO THIS CHANGE.

Alerts on COVID-19 linked substandard or falsified medical products

■ Diagnostics
 ■ Vaccines
 ■ Medicines
 ■ Personal Protective Equipment incl. sanitisers (AB)
 ■ Sanitisers and disinfectants (A)
 ■ Personal Protective Equipment (B)

Number of alerts

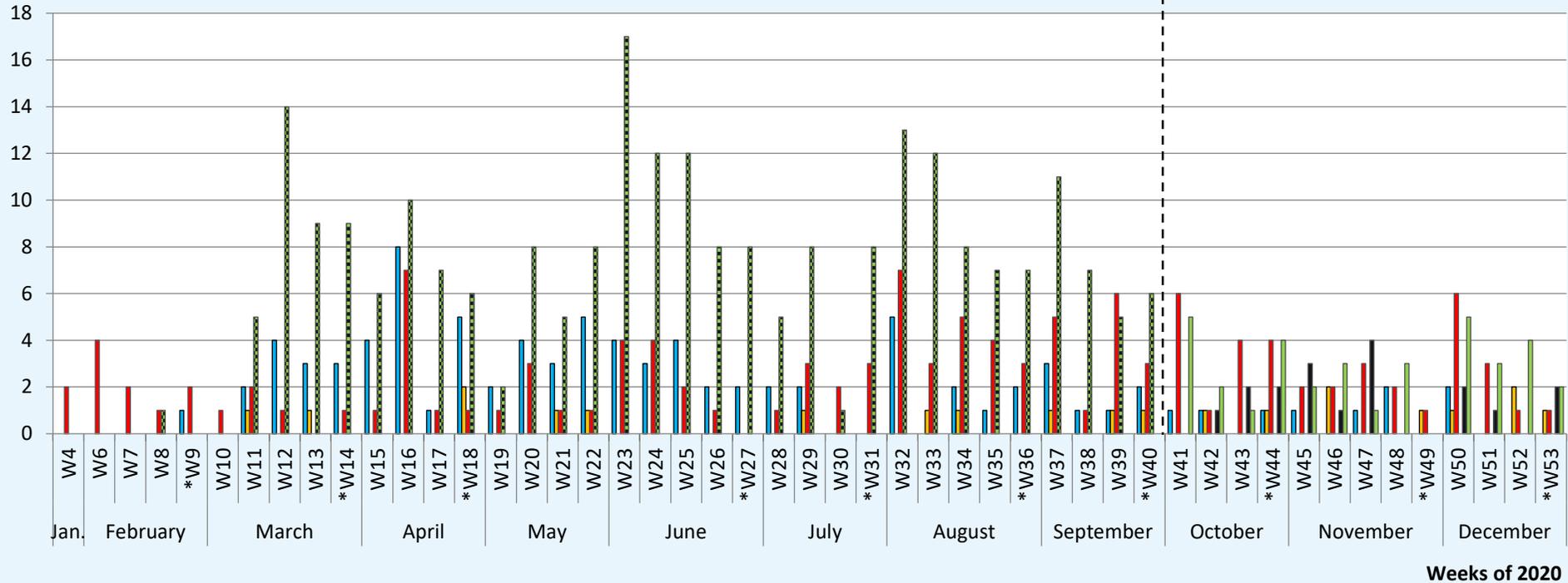


Figure 3. Number of alerts on the Medicines Quality Monitoring Globe by category and by week.

ALERTS ARE FOR SUBSTANDARD OR FALSIFIED PRODUCTS LINKED TO COVID-19. WEEK 4 STARTS ON MONDAY 20TH OF JANUARY 2020 AND WEEK 49 ENDS ON THURSDAY 31TH OF DECEMBER 2020. WEEKS WITH AN ASTERISK ARE OVERLAPPING 2 MONTHS, EACH TIME THE WEEK IS ATTRIBUTED TO THE EARLIEST MONTH. AS SOME ARTICLES DESCRIBE MORE THAN ONE CATEGORY OF PRODUCTS, THE SUM OF ALERTS PER MONTH MAY EXCEED THE SUM OF ARTICLES PER MONTH REPORTED IN FIGURE 1. (*) THE ARROW INDICATES THE END OF SEPTEMBER WHEN THE CATEGORY OF "PERSONAL PROTECTIVE EQUIPMENT INCL. SANITISERS" WAS SPLIT IN TWO DISTINCT CATEGORIES: (A) SANITISERS AND DISINFECTANTS, AND (B) PERSONAL PROTECTIVE EQUIPMENT. (*) NOTE THAT SINCE NOVEMBER, NON-COVID-19 MEDICINES CONTAINING HIDDEN API(S) THAT IS/ARE USED OR TRIALLED FOR COVID-19 ARE NO LONGER INCLUDED IN THE COVID-19 REPORTS. ONLY MEDICINES FOR WHICH THE STATED API IS USED OR TRIALLED FOR COVID-19 TREATMENT ARE INCLUDED IN THE COVID-19 REPORT. THE OBSERVED DECREASE OF THE NUMBER OF ARTICLES CAN BE AT LEAST PARTIALLY DUE TO THIS CHANGE.

6.3 Vaccines

At the beginning of December Interpol issued a global alert to their 194 member countries to warn of the threat of organized crime for COVID-19 vaccines both off- and online (see section 4. *International Organisations*). Various articles in our MQM Globe database¹⁵ report on this Interpol warning. Governmental officials and experts, in countries from USA and Canada to UK and Angola, are translating the warning to their local communities. They repeat the risk of falsification, theft and illegal advertising of COVID-19 vaccines. In this report we only describe the incidents identified during the month of December. The MQM Globe holds 5 different articles on diverted and/or falsified COVID-19 vaccines for December.

An article reported on a notice that was published by Interpol on falsified COVID-19 vaccines in South Africa (report ID: 865724). In November three people were arrested allegedly importing unregistered COVID-19 vaccines from China.

In mid-December, although no vaccine has been validated by the Philippines' FDA, in a district in Manila what were alleged COVID-19 vaccines were sold and administered (report ID 855225). One of the offered vaccines was allegedly the Chinese vaccine made by Sinopharm.

In the second half of December there was an alert in Brazil on falsified corona vaccines allegedly sold in a market in Rio (report ID 890939). One of the testimonies said that the packaging stated "*SARS-CoV-2 Vaccine, inactivated 4µg/0.5mL*" from the company Beijing Institute of Biological Products Co. Ltd and was sold for R\$ 50 (approximately US \$9). Investigations are ongoing. According to the Portuguese version of the article there is a suspicion that the story might be a "*fake news*".

Two articles discuss the offer of multiple COVID-19 vaccines on the Dark Web, many allegedly being the Pfizer vaccine. The article in the beginning of December (report ID 830853) reports on a vaccine sold for \$1,300 "*a piece*". In addition it reports on a variety of claims of vendors who describe themselves as pharmacists, having acquired the product from the government and others also claiming to have a stockpile of 560 doses. In the middle of December another article (report ID 841777) reported on similar issues on the Dark Web. One coronavirus vaccine was offered for \$250. Another offer claimed the need for 14 doses, each at 0.01 bitcoin (approximately \$350), to attain full coverage. It is unlikely that these vendors are legitimate. If there is no product the buyers are victim of fraudulent sales, but if the buyer receives a product, (s)he cannot be sure of what was in the vial. The product could be a toxic substance or it can be inactive, leaving the buyers to believe themselves to be immunized against COVID-19 when they have not.

¹⁵Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe. Web Page. Published 2020. Accessed January 14, 2021. <https://www.iddo.org/medicine-quality-monitoring-globe>

6.4 COVID-19 diagnostics

Since the beginning of the COVID-19 crisis falsified, substandard or unregistered COVID-19 diagnostics have been circulating. An illustration is given by the results of the Europol coordinated project Shield mentioned in section 6.2 of this report (report ID 839814). The seizures performed between March and September 2020 included COVID-19 tests and diagnostic kits. Even though the MQM Globe currently holds fewer articles on these products compared to the beginning of the pandemic, seizures continue. On the first of December US customs seized a shipment coming from Mexico containing “251 illicit COVID-19 testing kits” (report ID 842418).

6.5 Personal protective equipment

The Medical Product Quality Report of September¹⁶ reported on a case in Taiwan where a company was importing and repacking over 3 million Chinese masks as ‘Carry Mask’ and selling them as “*Made in Taiwan*”. In mid-December the owner of the company was sued for this case (report ID 847198). In addition, the article reports that the owner of Carry Mask is still under investigation for the distribution of unauthorized children’s masks.

In the Philippines, 10 Chinese nationals were arrested for selling falsified ‘Heng De’ face masks and face shields (report ID 835632). They were operating in 3 different shopping malls. The falsified face masks only had printing in blue whereas the genuine product has a gold embossed logo.

In Thailand the police, the FDA and the Thai Industrial Standards Institute raided a factory producing medical products without permission (report ID 863689). They seized 10,161 boxes containing 7.61 million gloves. The Chinese owner and 11 Cambodian workers were detained. They also allegedly imported substandard gloves from China.

In South Africa, the University of Cape Town published the results of mask analysis; none of the masks tested provided the required protection putting at risk the health care workers (report ID 847945). The nursing union demanded the withdrawal of at least 12 brands of KN95 face masks. In South Africa law-enforcement agencies seized a large quantity of falsified N95 masks (report 865724).

In December, the Organized Crime and Corruption Reporting Project (OCCRP) reported on a case of falsified N95 masks in Egypt that dates from the beginning of the pandemic (report ID 891327). In at least 15 out of the 27 isolation hospitals, treating severe COVID-19 patients, medical staff were using expired and falsified masks. The masks were bought in 2007 by the Ministry of Health. An Egyptian company High Tech For Projects and Trading S.A.E. allegedly bought and imported the masks from Xiantao Fushi Protective Products Co., a Chinese manufacturer. The masks were labelled as TY 0424, which corresponds to a falsified version according to the list of

¹⁶Infectious Diseases Data Observatory. Medical Product Quality Reports. Medical Product Quality Reports. Published 2020. Accessed January 13, 2021. <https://www.iddo.org/mq/research/medical-product-quality-reports>

the US National Institute for Occupational Safety and Health (NIOSH). The packing misrepresented a NIOSH approval, falsely claimed them to be N95 and did not give an expiry date.

Health Canada warned against companies selling unauthorised PPEs (report ID 859256), in particular the company Maskopia, former Medkem Canada Inc. that allegedly sells PPE such as masks, gloves and gowns without licence, and that made false or misleading claims. For example, they claimed to be approved by Health Canada as a manufacturer for surgical masks and are allegedly selling non-medical masks as medical masks. Provincial day-care centres in Quebec have been reported as using substandard MC9501 masks between May and November (report ID 859961). Quebec's workplace health and safety authority deemed the filtration capability insufficient.

Multiple articles reported on seizures of falsified masks in the USA. Most of the seizures involved falsified 3M respirators and were performed by custom agents. During the first week of December, over 100,000 falsified 3M N95 masks were seized in Texas by the US Customs and Border Protection (CBP) and the US ICE HSI (report ID 838504). The masks were destined for hospital workers. Another article reports on seizures of falsified masks in Arizona (report ID 867638). Between mid-November and the end of December, HSI and US CBP seized more than 200,000 masks, all intended for hospital workers and medical staff. Another shipment coming from Hong Kong and destined for Jamaica was seized by the US CBP in Ohio where the shipment was transiting (report ID 845172). The US CBP applied the "*3M Safe Guard product authentication process*" and thirty-eight boxes containing 6,080 masks appeared to be falsely labelled as 3M Disposable Respirators Model 8210.

Another case of falsified 3M respirators was encountered by the state of Minnesota (report ID 858111). The state intended to buy 500,000 N95 respirators from the company Supply Link Inc. Before concluding the transaction the state sent a sample to 3M for verification and the sample appeared to be a falsified version of the 3M Respirators Model 1860. The company Supply Link Inc claims to be victim of a "*professional counterfeit operation*" and started an investigation.

6.6 Sanitisers and disinfectants

The Indian Central Drugs Standard Control Organization (CDSCO) released their monthly routine quality tests on a range of pharmaceutical products results for November. Two hand sanitizers were declared as "*Not of Standard Quality*" after failing the tests for the assay of ethyl/isopropyl alcohol and/or acidity, and/or limit of non-volatile residue: Xerorub Hand Santizer and Pure-hand Zenitizer (report ID 848258).

In the USA, Shane Erickson Inc. recalled 3 brands of hand sanitizers because of concerns that there might be methanol contamination within the IMC Wash Free Hand Sanitizer, Wash Free Hand Sanitizer and Thrifty White Pharmacy Hand Sanitizer (report ID: 867578). The products were manufactured in China and distributed across the USA to wholesalers and retail customers. The products have been added to the

US FDA's Do-Not-Use-List¹⁷ of hand sanitizers. At the end of December the list contained 224 lines, each potentially including several products.

The US FDA send a warning letter to the Mexican company Broncolin concerning the quality of its hand sanitizers (report ID 867207). The goods were detained and refused admission at the USA border because they were adulterated and not approved by the US FDA. The Herbacil Antiseptic Hand Sanitizer was stated to contain 70% ethanol but analysis showed that the ethanol content ranged from 0.4% to only 4.7% v/v and the methanol from 66% to 75% v/v.

6.7 COVID-19 medicines

In this section we share details of articles captured by the MQM Globe that contain the same active pharmaceutical ingredient as medicines that are approved, trialed or used by patients in the context of COVID-19. We included all those type of products even if for certain treatments the efficacy is not proven in the prevention or treatment of COVID-19 patients.

An article published in December mentions SF chloroquine in Senegal (report ID 836690¹⁸). The article refers to news published in July 2020 reporting on 2 incidents, one on substandard chloroquine that was smuggled from Guinea into Senegal and one on falsified chloroquine Niruquine, a product highlighted in the WHO Alert N°4¹⁹. In India a criminal allegedly sold diluted plasma as COVID-19 treatment (report ID 843934). The family contacted the blood bank after the patient died and found out they had been tricked by the vendor. The Indian CDSCO released the monthly routine quality tests on a range of pharmaceutical products results for November (report ID 848258). For COVID-19 medicines, the article only lists Telmisartan and two paracetamol products declared as “*Not of Standard Quality*” after failing the tests for dissolution or related substances²⁰.

Janssens issued an alert in the US on falsified Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide), an antiretroviral (report ID 865867). The product was found in 3 pharmacies and was procured from unauthorized distributors. Darunavir/cobistat and emtricitabine/tenofovir are all trialed for their use

¹⁷United States Food and Drug Administration. FDA updates on hand sanitizers consumers should not use. Viewed 12 January 2021, Available from <https://www.fda.gov/drugs/drug-safety-and-availability/fdaupdates-hand-sanitizers-consumers-should-not-use>

¹⁸The report ID also references to SF chloroquine in Cameroon. Incidents in Cameroon are reported in previous issues of the Medical Product Quality Report – Covid-19 issues: Issue 1 covering January to June 30, and issue 2 covering July. Source: Infectious Diseases Data Observatory. Medical Product Quality Reports. Medical Product Quality Reports. Published 2020. Accessed January 13, 2021. <https://www.iddo.org/mq/research/medical-product-quality-reports>

¹⁹World Health Organization. Medical Product Alert N°4/2020 - Annex. Medical Product Alert. Published April 9, 2020. Accessed January 13, 2021. https://www.who.int/docs/default-source/essential-medicines/drug-alerts20/drug-alert-4/update-n4-2020-annex-en.pdf?sfvrsn=44895ab0_8

²⁰Central Drugs Standard Control Organization. List of Drugs, Medical Devices and Cosmetics declared as Not of Standard Quality/Spurious/Adulterated/Misbranded, for the Month of November-2020. Drug Alert List. Published December 15, 2020. Accessed January 13, 2021. https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=Njc2NQ==

against SARS-CoV-2, but the combination of all four products is not.

In December the US CBP revealed that together with the local police and US HSI they had seized more than one million falsified sildenafil, Viagra, tablets at a seaport in Los Angeles (report ID 850803).

During 2020, the national police service of the Republic of Ireland, seized many drugs, almost double the value of 2019 (report ID 844349). The seized products included €950,000 worth of the medicine ketamine.

Quality issues during the production process

AvKARE, a pharmaceutical distributor, recalled 2 products in the USA: 100-count bottles of 100mg Sildenafil tablets and 1,000-count bottles of 100mg Trazodone tablets (report ID 840715). During the bottling at a 3rd party facility a “product mix-up” occurred.

Due to a packaging issue leaving “holes” in the bottom of multiple bottles GlaxoSmithKline USA had to recall 5 brands of Excedrin (Aspirin/paracetamol/caffeine), representing 433,600 bottles (report ID 862732).

In Japan a serious case of substandard itraconazole 50 'MEEK' of the manufacturer Kobayashi Kako Co. was reported (report ID 843376, 851679). Due to an error in the production process itraconazole has been contaminated with rilmazafone hydrochloride, a sleep-inducing substance. In December, 2 deaths were reported following the intake of the product, although for one case there was not necessarily a causal relationship between the intake of the medicine and the death (report ID 851679). The batch was produced in July and released on the market from September onwards. There are 133 reported cases of adverse drugs reactions such as loss of consciousness and memory. Several traffic accidents are linked to the intake of the contaminated itraconazole tablets. The recall of the product is ongoing. The company acknowledged the error and started an investigation.

7 Annexes

The annexes contain the reports generated by the MQM-Globe using pre-defined search terms. The report IDs (six digits code) discussed in section 6 ‘Lay literature’ are detailed in the annexes. To consult the report IDs, please see the extended version of this report²¹, containing the annexes, and/or consult the online MQM Globe²², using the report ID in the search box.

²¹Infectious Diseases Data Observatory. Medical Product Quality Reports. Medical Product Quality Reports. Published 2020. Accessed January 13, 2021. <https://www.iddo.org/mq/research/medical-product-quality-reports>

²²Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe. Web Page. Published 2020. Accessed October 16, 2020. <https://www.iddo.org/medicine-quality-monitoring-globe>