Medical Product Quality Report – COVID-19 Issues

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MORU Tropical Health Network

UNIVERSITY OF OXFORD

IDDO INFECTIOUS DISEASES DATA OBSERVATORY

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Contents

1. Summary of findings

Since the onset of the COVID-19 pandemic, we have reported on incidents in over 60 countries (see figure 1). The number of PPE incidents has decreased compared to the early months of the pandemic. However new incidents continue. Two incidents involved gloves allegedly coming from Malaysia. Criminals continue to falsify masks and respirators of genuine mask and respirator manufacturers such as 3M and Venus Safety and Health Private Ltd.
Several warning letters were sent by the US FDA to Mexican businesses that try to import methanol contaminated hand sanitisers into the United States.

Even before the emergency use authorization of Regeneron's monoclonal antibody therapy, the dark web was allegedly selling the product. Similarly, the Australian National University found 22 COVID-19 vaccines sold on the dark web. Challenges that come with the arrival of the COVID-19 vaccines or any COVID-19 treatment are likely to increase. As demand outstrips supply, it opens doors to theft, diversion, falsification and substandard products. We remain very concerned at the global risk of substandard and falsified COVID-19 vaccines and urge much more international coordination to mitigate this risk.

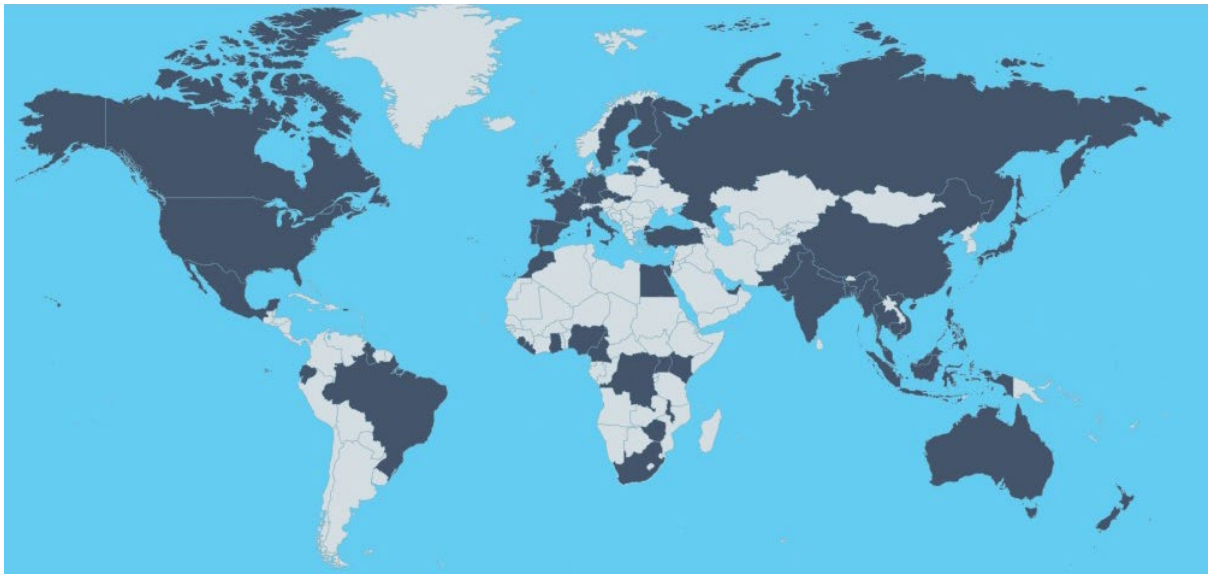

Figure 1. Countries with recorded incidents of poor quality medicines and medical products linked to COVID-19 from January to November 2020. IMAGE CREDITS JS MAP BY AMCHARTS[1].

DARK BLUE COUNTRIES ARE COUNTRIES FOR WHICH DATA ARE AVAILABLE IN THE MEDICINE QUALITY MONITORING GLOBE ON INCIDENTS OF POOR QUALITY PRODUCTS LINKED TO COVID-19. ONLY ENGLISH ARTICLES ARE DESCRIBED IN THIS MONTHLY COVID-19 ISSUES. THE DATA ARE GEOGRAPHICALLY HETEROGENEOUS AND AN IMPORTANT CAVEAT IS THAT NO REPORTS FROM A COUNTRY DOES NOT IMPLY THAT MEDICAL PRODUCT QUALITY THERE IS GOOD BUT THAT THERE ARE NO ACCESSIBLE DATA FROM THAT COUNTRY, OR THAT ARTICLES WERE NOT PUBLISHED ON THE ENGLISH GOOGLE NEWS AND THUS NOT INCLUDED IN OUR SYSTEM. SIMILARLY, REPORTS OF POOR QUALITY MEDICAL PRODUCTS IN A COUNTRY DOES NOT IMPLY THAT MEDICAL PRODUCT QUALITY THERE IS UNIVERSALLY GRAVE IN COMPARISON TO ELSEWHERE. COUNTRIES WITH REPORTS SHOULD BE LAUDED FOR FACILITATING SUCH REPORTING.

[1]amCharts. Interactive Visited Countries Map. Published 2014. Accessed December 11, 2020. https://www.amcharts.com/visited_countries/

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)[2]:

- **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'[3] and 'pirated copyright goods'[4] as used in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement.

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[2]Source: 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

[3]*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

[4]*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.

The reports presented were mostly extracted from the Medicines Quality Monitoring Globe (the MQM Globe is accessible on the IDDO website[5]), a system that scrapes online newspapers (referenced in Google News) for early warnings of substandard and falsified 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[6]); 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 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 sixth issue of the monthly report 'Medical Product Quality Report – COVID-19 Issues' covers information published during the month of November. The previous issues covered publications from January 1st to October 31th 2020 and are available on the IDDO[7] and MORU[8] websites. We also include publications and reports published prior to November 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).

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

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

[6]Infectious 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

[7]Infectious Diseases Data Observatory. Medical Product Quality Reports. News. Published 2020. Accessed October 10, 2020. https://www.iddo.org/mq/research/medical-product-quality-report

[8] MORU 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

3. Scientific literature

3.1. General

Alves S, Arendse A, Kannenberg S. **COVID-19 collateral damage: Alcohol rub dermatitis as an emerging problem.** *South African Med J*. Published online November 3, 2020. Accessed November 10, 2020. http://www.samj.org.za/index.php/samj/article/view/13135

> Extract. *« Issues with alcohol-based hand sanitisers include the use of non-standard formulas, meaning that methanol is used instead of ethanol, types of alcohol used, such as isopropyl alcohol v. ethanol, and varying amounts of alcohol being used (60 - 80%). »*

[Preprint] Bae J, Gandhi D, Kothari J, et al. **Challenges of Equitable Vaccine Distribution in the COVID-19 Pandemic.** *Preprint*. Published online November 2020. Accessed December 7, 2020. https://www.researchgate.net/publication/346356495_Challenges_of_Equitable_Vaccine_Distribution_in_the_COVID-19_Pandemic

> Extract. *« As several COVID-19 vaccine candidates approach approval for human use, governments around the world are preparing comprehensive standards for vaccine distribution and monitoring to avoid long-term consequences that may result from rush-to-market. In this early draft article, we identify challenges for vaccine distribution in four core areas-logistics, health outcomes, user-centric impact, and communication. Each of these challenges is analyzed against five critical consequences impacting disease-spread, individual behaviour, society, the economy, and data privacy.»* […] *« Insufficient monitoring of the entire supply chain of vaccine production, distribution, and storage also lends itself to attack by bad actors. If a country does not carefully monitor the total pipeline of vaccine distribution, there may be opportunities for theft and counterfeit vaccine delivery. »*

Forman L, Kohler JC. **Global health and human rights in the time of COVID-19: Response, restrictions, and legitimacy.** *J Hum Rights*. 2020;19(5):547-556. doi:10.1080/14754835.2020.1818556

> Extract. *« In the midst of this COVID-19 pandemic, as we experienced with the EVD, the health systems vulnerabilities to corruption are clear. Examples of corruption have been found globally in drug and medical equipment procurement and price gouging of essential supplies, such as hand sanitizer and 3M masks. The European Medicines Agency (EMA) and the WHO have both issued public warnings about the increase in the circulation of falsified medicines. The risk of falsified medicines is not only for those products that may potentially treat COVID-19 but also for other drugs and products, particularly when shortages exist. Newton and Bond (2020) explained that the circulation of substandard and falsified products is heightened when shortages are taking place and quality assurance standards are lax. They advanced the importance of information-sharing among countries to ensure that global demand and supplies are being met and noted that countries need to ensure sufficient regulatory controls. They also pointed out that this will be even more critical once valid COVID-19 treatments are available. Governments and health institutions are also under pressure to purchase and import quickly needed medical equipment and supplies for COVID-19 through emergency procurement processes. The Organisation for Economic Co-operation and Development (OECD) has reported a number of bribery cases in the health industry and the risk of the purchase of inferior or falsified goods. »*

Handfield R, Finkenstadt DJ, Schneller ES, Godrey AB, Guinto P. **A Commons for a Supply Chain in the Post-COVID-19 Era: The Case for a Reformed Strategic National Stockpile.** *Milbank Q*. Published online November 2, 2020:1468-0009.12485. doi:10.1111/1468-0009.12485

Extract. *« Current proposals call for augmenting a system that has failed to deliver the needed response to COVID-19. These proposals do not address the key attributes for pandemic plan renewal: flexibility, traceability and transparency, persistence and responsiveness, global independence, and equitable access. We offer a commons-based framework for achieving the opportunities and risks which are responsive to a constellation of intelligence assets working in and across focal targets of global supply chain risk. »*

Jacobs J, Kühne V, Lunguya O, Affolabi D, Hardy L, Vandenberg O. **Implementing COVID-19 (SARS-CoV-2) Rapid Diagnostic Tests in Sub-Saharan Africa: A Review.** *Front Med*. 2020;7:557797. doi:10.3389/fmed.2020.557797

Extract. *« the ECDC [European Centre for Disease Prevention and Control] reported several COVID-19 RDT [Rapid Diagnostic Test] devices with fraudulent documentation and unsubstantiated claims. Antibody tests with insufficient clinical performance data have been compiled by the FDA in a "removed" list and the WHO and FDA recently warned against falsified COVID-19 IVDs [Invitro Diagnostic] and reagents. It can be expected that in low- regulated countries such practices will become more frequent and NRLs [national reference laboratories] should inform healthcare workers and the community.* »

Kumar B, Pinky SD. **Addressing economic and health challenges of COVID-19 in Bangladesh: Preparation and response.** *J Public Aff*. Published online November 18, 2020. doi:10.1002/pa.2556

Extract. *« There is a raised concern on the safety of the healthcare workers as Physician's mortality rate in Bangladesh holds the highest in the world (4%). So far a total of 105 doctors died of novel coronavirus while rendering service to the nation as frontline warriors (Sakib, 2020). Shortage of PPE, substandard PPE flooding the market, lack of hospital's infection control measures, proper disposal of safety gears, and lack of training among healthcare professionals are said to have contributed to the high death and infection rates. »*

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. »*

Miller FA, Young SB, Dobrow M, Shojania KG. **Vulnerability of the medical product supply chain: the wake-up call of COVID-19.** *BMJ Qual Saf*. 2020;0:bmjqs-2020-012133. doi:10.1136/bmjqs-2020-012133

Introduction. *« The COVID-19 pandemic has brought the long-standing vulnerability of the medical product supply chain into sharp focus. Global shortages of medical products accompanied the global spread of the disease, joined by high prices, the proliferation of suspect dealers and dramatic interventions by governments, philanthropy and industry in oftentimes-unsuccessful attempts to secure solutions. Much attention has focused on personal protective equipment (PPE). But reported shortages have extended much further—to testing supplies, dialysis materials, pharmaceuticals and a wide range of commodities essential for daily care*

delivery—both for patients with and without COVID-19. PPE shortages have received particular attention because they endanger the healthcare workforce. But all product shortages endanger patients due to delays in care, rationing or denial of care, the use of substandard products, or heightened risk of error when using replacement products—risks that extend to increased mortality. Medical product shortages threaten the goal to deliver the right care to the right person at the right time—and have done so for decades. The COVID-19 pandemic has highlighted more than ever that these systemic risks can no longer be ignored. It may also mean that new solutions have become more possible. »

Moyo G. **The Bane of Financial Crime and Corruption amid Covid-19 Pandemic in Zimbabwe.** *Glob J Manag Bus Res*. 2020;20(5):37-45. Accessed December 4, 2020. https://journalofbusiness.org/index.php/GJMBR/article/view/3259

Abstract. *« This article focuses on the bane of corruption and financial crime amid the coronavirus aka Covid-19 pandemic in Zimbabwe. It argues that the arrival of Covid-19 pandemic in the country has further exacerbated the already deep seated and systemic problem of corruption and financial crime in that country. A review of emerging financial crime and corruption since the onset of the pandemic in early 2020 suggests that the public procurement, government relief programs, and the Covid-19 lockdown measures enforcement agents are especially prone to corruption and financial crime. Reports have emerged of public officials, private companies and entrepreneurs abusing the coronavirus crisis to enrich themselves, their political allies, parties, families and friends. This article concludes that accountability and transparency tools coupled with political will could prove to be the key antidotes against financial crime and corruption in Zimbabwe. The data utilized for this study were sourced from Covid-19 trackers and press reports as well as key informant interviews. »*

O'Byrne C, Kenny F, Eustace S, Gibbons J. **Knowledge of face masks and attitudes to re-sterilisation among healthcare workers.** doi:10.21203/rs.3.rs-117257/v1

Abstract. « (*)Introduction: COVID-19 was declared a pandemic in March 2020. With the sudden surge in demand for personal protective equipment (PPE), significant concerns regarding the ongoing availability emerged. One solution proposed is re-sterilization of respirator masks and this has been commenced in some parts of the world. On review of the literature, very little is documented regarding knowledge of masks and the attitudes of healthcare workers towards using re-sterilised masks. (*)Methods: A comprehensive questionnaire was used to assess general knowledge and attitudes around facemasks and respirators. (*)Results: There were 190 respondents. There were significant gaps in knowledge and understanding of when particular face masks should be worn. One third had significant concerns about ongoing availability. One third had concerns about the quality of the masks as the pandemic continued. Only 10% of respondents underwent formal face-fitting. 80% of respondents stated they would wear a re-sterilised mask. A further 15% would use a re-sterilised mask but required certain reassurances. 5% of our respondents would not use a re-sterilised mask under any circumstances. (*)Discussion: Ensuring an adequate understanding of face masks is crucial among HCWs and this study highlights a need for further education. It also demonstrates a general acceptability among HCWs towards the use of re-sterilised face masks. »

[Preprint] Omar I, Debe M, Jayaraman R, Salah K, Omar M, Arshad J. **Blockchain-based Supply Chain Traceability for COVID-19 PPE.** *Preprint*. Published online November 12, 2020:1-17. doi:10.36227/TECHRXIV.13227623.V1

Abstract. *« The COVID-19 pandemic has severely impacted many industries, in particular the healthcare sector exposing systemic vulnerabilities in emergency preparedness, risk mitigation, and supply chain management. A major challenge during the pandemic was related to the increased demand of Personal Protective Equipment (PPE) resulting in critical shortages for healthcare and frontline workers. The lack of information visibility combined with the inability to precisely track product movement within the supply chain requires an robust traceability solution.*

Blockchain technology is a distributed ledger that ensures a transparent, safe, and secure exchange of data among supply chain stakeholders. The advantages of adopting blockchain technology to manage and track PPE products in the supply chain include decentralized control, security, traceability, and auditable time-stamped transactions. In this paper, we present a blockchain-based approach using smart contracts to transform PPE supply chain operations. We propose a generic framework using Ethereum smart contracts and decentralized storage systems to automate the processes and information exchange and present detailed algorithms that capture the interactions among supply chain stakeholders. The smart contract code was developed and tested in Remix environment, and the code is made publicly available on Github. We present detailed cost and security analysis incurred by the stakeholders in the supply chain. Adopting a blockchain-based solution for PPE supply chains is economically viable and provides a streamlined, secure, trusted, and transparent mode of communication among various stakeholders. »

Parihar J, Grewal K. **Unlocking the mental health crisis in health-care providers during COVID-19 pandemic.** *Indian J Med Spec*. 2020;11(4):173. doi:10.4103/injms.injms_123_20

Extract. *« The cause of this psychological burden on the HCPs [health-care providers] is multifold and includes personal, professional, and social reasons. Concerns about the risk of infection to self and their families increased working hours, inadequate safety in the form of shortage or substandard personal protective equipment (PPE), discomfort due to perse wearing PPE or inability to access food, water or lavatory because of being in PPE for long hours, being in quarantine/isolation, and separation from families are some of the reasons for psychological distress among health professionals. It has been observed that those HCPs working in the frontline in COVID-19 or infectious disease wards, intensive care units, and emergency departments and are involved in the direct care of COVID patients are relatively more affected than others. »*

Ray A. **Managing supply chain aspects of the COVID-19 pandemic in India.** *Indian Chem Eng*. Published online November 16, 2020:1-6. doi:10.1080/00194506.2020.1845989

Abstract. *« Technological interventions in times of crises, such as for the COVID-19 pandemic in India, require attention to supply chain aspects for effective delivery of goods and services, especially in critical care. Especially in the initial stages, such delivery is complicated by potential shortages of emergency supplies, which arise due to several reasons. First, suddenly overwhelmed hospitals and local authorities are not equipped to effectively forecast surges in demand. Manufacturing capacities are often constrained by limited availability of raw material in the absence of adequate advance planning. Logistics options for goods movement are significantly reduced. All this is compounded by the shortage of manpower to service production and logistics during extreme lockdown scenarios. A structured approach is shown to deliver tangible benefits and overcome key challenges. »*

Extract. *« By way of illustration of these fifth vertical (Supply Chain) issues, the market prices of sanitisers shot up severalfold as soon as the number of infected cases began to rise and it was publicly apparent that this was the first line of defense. There were also media reports of spurious sanitisers causing harm to users. In the early days, several hospitals reported stockouts of gowns and N-95 protective masks, along with other PPE. In the absence of approved drugs specific to COVID-19 treatment, initially identified therapeutic options like hydroxychloroquine were in short supply. Respiratory failure being a common mode of death for severely afflicted patients, ventilators and oxygen concentrators were sought at every point of treatment – and there simply was not enough manufacturing capacity in the country. CSIR [Council of Scientific and Industrial research] resolved not only to quickly develop technologies and products to market to bridge the demand-supply gaps, but also to move them quickly into bulk commercial production in a campaign mode with identified industrial partners. »*

Raza A, Matloob S, Abdul Rahim NF, et al. **Factors Impeding Health-Care Professionals to Effectively Treat Coronavirus Disease 2019 Patients in Pakistan: A Qualitative Investigation.** *Front Psychol*. 2020;11:2910. doi:10.3389/fpsyg.2020.572450

> Extract. *« The participants reported that the PPE that they received was of poor quality. They further briefed that the items (masks, gowns, and shoes) they are receiving are of substandard: HCPs [health-care professionals] infected despite wearing the proper PPEs and following the SOPs. This thing also created a sense of fear among HCPs [Health-care professionals] and doubt about the quality and effectiveness of PPEs. »*

Additional publications prior to November 2020

[Preprint] Sinha M. **COVID-19: State and Local Responses to PPE Shortages.** *SSRN Electron J*. Published online August 17, 2020:152-157. doi:10.2139/ssrn.3675861

> Extract. *« As imported masks flooded the U.S. market, the CDC and FDA were unprepared to rapidly assess the quality of individual products. Healthcare systems, first responders, and others have received donations of unfamiliar mask models, many of them donated and with unclear supply chain provenance. In April, through a widely publicized joint effort with the Commonwealth of Massachusetts, New England Patriots owner Robert Kraft used the team plane to retrieve over one million KN95 face masks from China; some were reportedly identified to be counterfeit. »*

3.2. Seizures/Surveys/Case Reports/Reviews

Kochgaway L, Nair A, Mitra A, Bhargava S, Singh M. **COVID casualty: Bilateral blindness due to ingestion of spurious sanitizer.** *Oman J Ophthalmol*. 2020;13(3):164. doi:10.4103/ojo.ojo_277_2020

> Abstract. *« Intentional ingestion of alcohol-based handrub (ABHR) or sanitizer solution is uncommon. The coronavirus disease-19 pandemic caused by severe acute respiratory syndrome coronavirus 2 has led to lockdowns being put in place in many countries across the globe and resulted in a surge in ABHR usage to maintain hand hygiene. In this communication, we report the case of a 56-year-old male, a chronic alcoholic who presented during the lockdown period, with acute bilateral loss of vision following ingestion of ABHR. The handrub was found to be a nonstandardized sanitizer with no labels mentioning its constituents. Typically, the ingestion of ABHR solutions results in isopropanol or ethanol poisoning, both of which have low toxicity. Based on the clinical history and findings in our patient, a diagnosis of optic neuropathy due to accidental ingestion of sanitizer containing methyl alcohol as an unlisted ingredient was made. Our report underscores the need for strict guidelines, toxicovigilance, and surveillance systems to be in place to prevent such adulterated ABHRs from being commercially available. »*

Waffo Tchounga CA, Sacre PY, Ciza P, et al. **Composition analysis of falsified chloroquine phosphate samples seized during the COVID-19 pandemic.** *J Pharm Biomed Anal*. Published online November 12, 2020:113761. doi:10.1016/j.jpba.2020.113761

> Abstract. *« The proliferation of falsified medicines can cause serious public health issues, particularly in the context of a global pandemic such as the actual COVID-19 pandemic. Our study involved eight chloroquine phosphate medicines seized in Cameroon, Democratic Republic of Congo and Niger during March and May 2020. These suspect samples were first analyzed in a screening phase using field tools such as handheld Raman spectroscopy (TruScan) and then in a confirmation phase using laboratory tools such as hyperspectral Raman imaging and High*

Performance Liquid Chromatography (HPLC). The results confirmed the falsified nature of the samples, highlighting the presence of metronidazole at low dose in four samples (16.6, 15.2, 15.2 and 14.5 mg/tab), too low levels of chloroquine in two samples (2.4 and 20.2 mg/tab), and substitution of chloroquine phosphate by paracetamol in one sample (255.7 mg/tab). The results also confirmed that four samples had been adulterated with paracetamol in trace amounts and two of them presented traces of chloramphenicol."

Selam MN. **Hand Sanitizers Marketed in the Streets of Addis Ababa, Ethiopia, in the Era of COVID-19: A Quality Concern.** *Risk Manag Healthc Policy*. 2020;Volume 13:2483-2487. doi:10.2147/RMHP.S284007

Abstract. *« Hand hygiene is one of the least expensive measures proven to be effective in preventing the transmission of coronavirus disease 2019 (COVID-19). When access to handwashing facilities is limited, hand sanitizers offer a viable alternative for hand hygiene. Since the appearance of the first case of COVID-19 in Ethiopia, the demand for hand sanitizers, especially alcohol-based handrubs (ABHRs), was found to be increased. In the country, more than 100 manufacturers are engaged in the production of ABHRs. Besides, there are similar products without labels available for sale in the streets of Addis Ababa for which their nature and source are not clearly known. Generally, hand sanitizers marketed in the streets of the city are against the country's regulatory requirement. The Ethiopian Food and Drug Authority should inspect manufacturers regularly and evaluate the quality of hand sanitizers in the market, especially those obtained from the streets of the city, and take appropriate measures on those products and manufacturers which fail to meet the regulatory requirements. »*

4. International organisations

Europol. ***How COVID-19-Related Crime Infected Europe during 2020.***; 2020. Accessed December 8, 2020. https://www.europol.europa.eu/publications-documents/how-covid-19-related-crime-infected-europe-during-2020

Extract. *« Counterfeit and sub-standard goods. The pandemic economy has presented new business opportunities for criminals attempting to capitalise on goods high in demand and the fear induced by the COVID-19 virus. The distribution of counterfeit and substandard goods has been one of the key criminal activities during the pandemic. With the onset of the pandemic, the demand for healthcare and sanitary products (masks, gloves, cleaning products, hand sanitizers), as well as personal protective equipment increased significantly. There has been a substantial increase in the sales of substandard masks due to their compulsory use in public spaces and public transport in some of the Member States. Some additional developments, such as the sales of fake 'corona home test kits' and fraudulent pharmaceutical products, advertised as allegedly treating or preventing COVID-19, have been particularly worrying from a public health perspective. Scammers have already offered fake vaccines. »*

Interpol. ***COVID-19 Pandemic Protecting Police and Communities: Guidelines for Law Enforcement.*** *Second Edition.* .; 2020. Accessed December 14, 2020. https://www.interpol.int/en/News-and-Events/News/2020/COVID-19-crime-INTERPOL-issues-new-guidelines-for-law-enforcement

Introduction. *« Since the outbreak of COVID-19, law enforcement has played a crucial role in supporting efforts to control the disease and promote safer communities, as well as combating threats from criminals taking advantage of the outbreak to increase or diversify their activities. As of October 2020, more than one million people had died as a result of COVID-19, including hundreds of police officers. INTERPOL, in accordance with international best practices including the WHO's recommendations, urges its member countries to follow these updated guidelines in order to enhance the safety and effectiveness of law enforcement support in the context of the*

COVID-19 outbreak. These recommendations also incorporate information about increased illegal activity and/or intent across a range of crime areas. It is essential for law enforcement and communities they serve to work together to effectively address the COVID-19 threat. Respecting and protecting individuals' rights and encouraging local cooperation, not only facilitates compliance with law enforcement officers' requests, but also ensures the centrality of human rights in shaping the pandemic response. In the context of COVID-19, INTERPOL is publishing this second edition of the COVID-19 Guidelines for Law Enforcement. Recognizing the response to COVID-19 varies from one country to another due to cultural, economic and social differences, the updated Guidelines seek to integrate best practices drawn from law enforcement across the globe. This guidance from lessons learned is aimed at supporting member countries which are continuing to develop and review their response strategies. »
Extract of the press release. *« Criminal targeting of legitimate vaccines. In addition, as legitimate vaccines move closer to delivery, the targeting of storage facilities and distribution networks by criminal networks can also be expected, and the updated guidelines highlight the need for secure storage and delivery of supplies. "High demand combined with a limited supply will make COVID-19 vaccines the equivalent of liquid gold to organized crime networks as soon as one is available."(Jürgen Stock, INTERPOL Secretary General). "This is why it is essential for action to be taken now, to both protect the legitimate supply chain for when the vaccine is ready, and to prevent the production and distribution of fake COVID-19 vaccines. "As the global COVID-19 situation continues to evolve, so must the law enforcement response and these updated guidelines provide a useful reference document for frontline officers to protect themselves and the communities they serve," concluded Secretary General Stock. »*

World Health Organization. ***Technical Specifications of Personal Protective Equipment for COVID-19.***; 2020. Accessed December 8, 2020. https://www.who.int/publications/i/item/WHO-2019-nCoV-PPE_specifications-2020.1

Overview. *« This document provides interim guidance on the quality, performance characteristics and related standards of personal protective equipment (PPE) to be used in the context of COVID-19. This includes WHO Priority Medical Devices, specifically: surgical masks, non-surgical masks, gloves, goggles, face shields, gowns and N95 masks. It is intended for procurement agencies, occupational health departments, infection prevention and control departments or focal points, health facility administrators, biomedical and materials engineering, PPE manufacturers and public health authorities at both national and facility levels. »*

5. Miscellaneous

U.S. Immigration and Customs Enforcement, Homeland Security Investigations. **Operation Stolen Promise - an initiative targeting COVID-19 Fraud.** Operation Stolen Promise. Published 2020. Accessed December 16, 2020. https://www.ice.gov/topics/operation-stolen-promise

Abstract. *« 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. »

6. Lay literature

6.1 Disclaimer & Notes

The information included below is based on the data used to create the Medicine Quality Monitoring Globe[9] (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[10].

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[11]. 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

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

[10] Infectious 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

[11]Infectious 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

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 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 trialled[12], 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 its wide occurrence on the black market.

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 issues[13]

Non-COVID-19 medicines, containing hidden API(s) that are used or trialled for COVID-19 are 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 (Figure 2-4) in November may, at least partially, be due to this change.

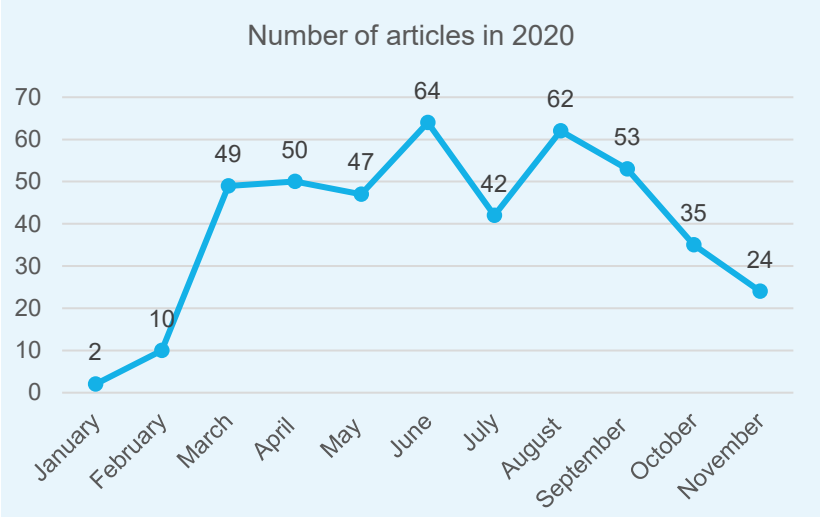
[12]Hashemian SRM. Evaluation the effects of Oxycodone administration on pain control in patients with COVID-19. Iranian Registry of Clinical Trials. Published June 8, 2020. Accessed October 9, 2020. https://en.irct.ir/trial/48534

[13]Issues 1 to 5 covering January up to October 2020. Infectious Diseases Data Observatory. Medical Product Quality Reports. News. Published 2020. Accessed October 10, 2020. https://www.iddo.org/mq/research/medical-product-quality-report

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

Since the beginning of the pandemic we have identified over 431 relevant articles on quality problems of COVID-19 medical products (see figure 2). For November we report on 24 articles linked to SF COVID-19 supplies alerted through the MQM Globe database. Within those articles, 2 alerted on falsified vaccines, 4 on diagnostics, 8 are linked to hand sanitisers and disinfectants, 9 to personal protective equipment (PPE), and 10 report on COVID-19 related treatments (see figure 3 and 4). Since June, the MQM Globe has not identified any reports linked to ventilation equipment.

Figure 2. 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 table 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 in November may, at least partially, be due to this change.



As highlighted in the previous issues of the Medical Product Quality Reports, the COVID-19 pandemic has disrupted the supply chain and criminals were very quick to shift their activities. Products that are only indirectly linked to the COVID-19 crisis are also affected. One of the articles in the MQM Globe illustrates this with a case of stolen flu vaccines in Mexico (report ID 818239). As have several other governments, the Mexican government has warned for a scarcity of flu vaccines due to the pandemic. The article continues that in October, shortly after the announcement, 10,000 doses of flu vaccine were stolen. In November the Federal Commission for the Protection against Sanitary Risk warned about the online illegal sale of 'Vaxigrip', a flu vaccine.

The black market is another example of how criminals are taking advantage of the COVID-19 crisis. Research of the Australian National University found 645 COVID-19 related products listed for sale on the dark web (report ID 803482). One third of the listed products were unique entries (i.e. accounting for products that were repeated on different sites). Half of the unique listed products were sanitizers and PPE, including masks, gloves and gowns. One third of the unique listed products were medicines including hydroxychloroquine, azithromycin and favipiravir. Vaccines and antidotes accounted for six per cent of all listed products.

At the beginning of November the results of the Canadian project Purify were announced (report ID 793903). The Canada Border Services Agency, Health Canada and the Royal Canadian Mounted Police worked together to "*enhance the identification, interception and tracking of unauthorized or counterfeit COVID-19 health-related products in British Columbia*". Between March 20th and June 30th of this year, 380 shipments were hold including 48,000 COVID-19 test kits, 4.5 million units of PPE, and 33,000 prescription tablets and pills.
In the USA, the US Customs and Border Protection seized, amongst others, over 107,000 FDA-prohibited COVID-19 test kits, 750,000 falsified face masks and 11,000 FDA-prohibited chloroquine tablets since last June (report ID 815477).

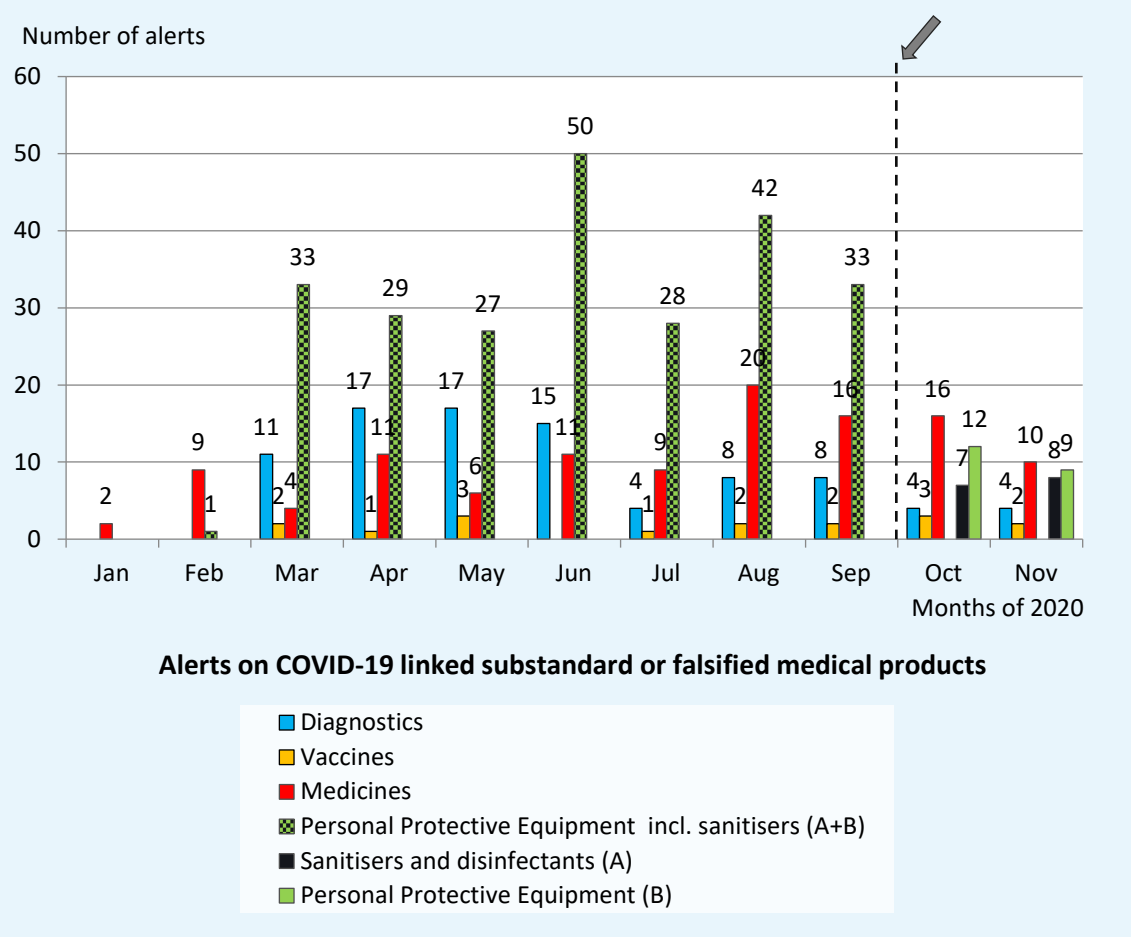


Figure 3. Number of alerts on the Medicines Quality Monitoring Globe by category of products and by month.
ALERTS ARE FOR SUBSTANDARD OR FALSIFIED PRODUCTS LINKED TO COVID-19. AS SOME ARTICLES DESCRIBE MORE THAN ONE CATEGORY OF PRODUCTS, THE SUM OF ALERTS PER MONTH MAY EXCEED THE SUM OF ARTICLES PER MONTH REPORTED IN TABLE 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 IN NOVEMBER MAY, AT LEAST PARTIALLY, BE DUE TO THIS CHANGE.

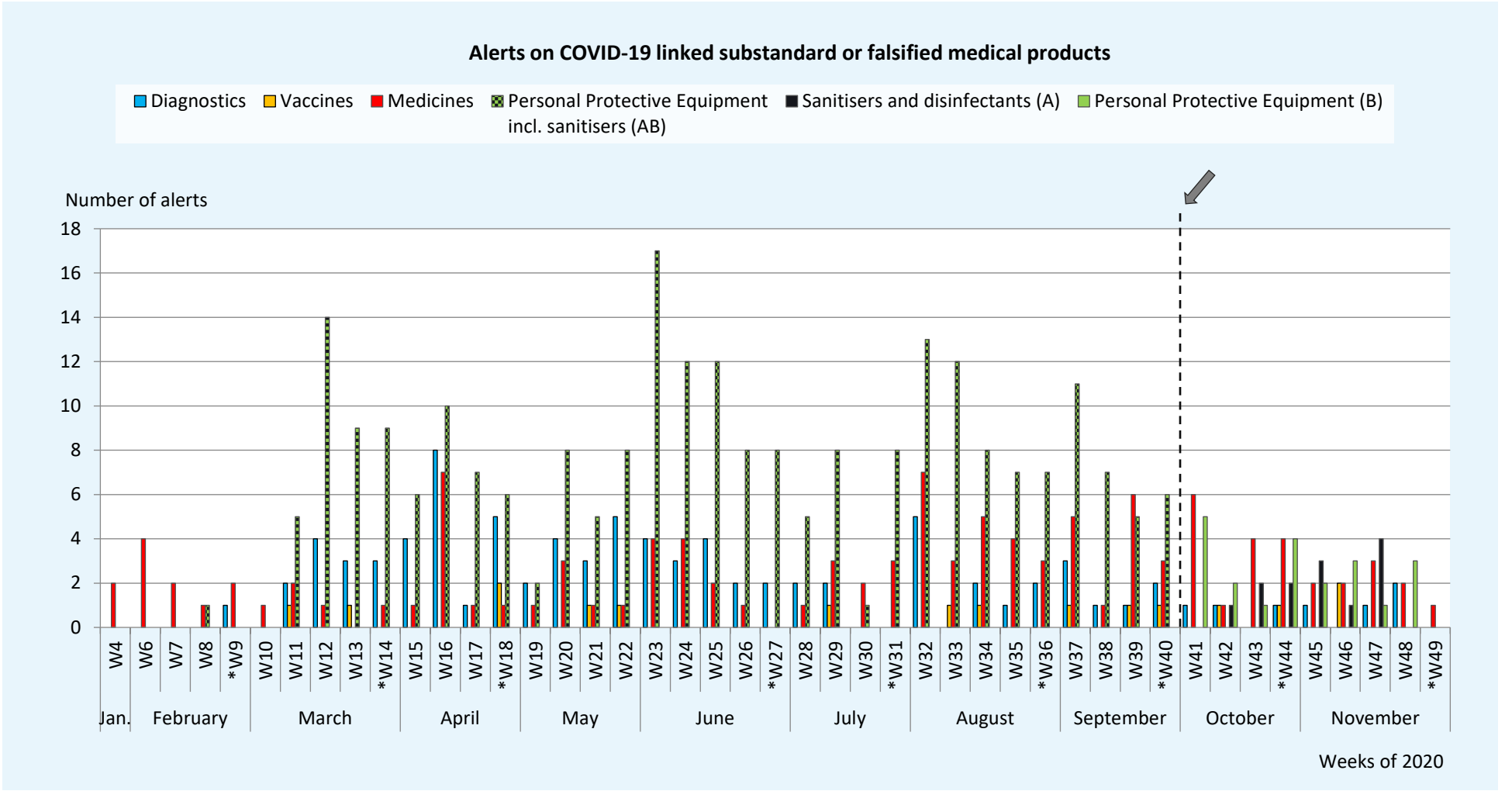


Figure 4. Number of alerts on the Medicines Quality Monitoring Globe by category and by week.

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 Monday 30th of November 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 table 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 in November may, at least partially, be due to this change.

6.3 Vaccines

For the month of November, 2 articles reported on diverted and falsified COVID-19 vaccines, both discussing products sold on the Dark Web. The first article reports on investigations by Bloomberg News (report ID 835199). One vaccine advertisement claimed that a lab technician had access to the "*successful Covid vaccine for $25,000*". Another seller is selling vaccines for $77,000 as the "*only option to stave off death*". The seller claimed the vaccine was validated by Israel's Minister for Science and Technology. The second article reports on research of the Australian National University that found 22 COVID-19 vaccines sold on the dark web (report ID 803482). There is not much information on the origin or the composition of the vaccines. Many were said to come from China, for example the alleged Sinovac and Sinopharm vaccines. The average price of the COVID-19 vaccines on the darknet was found to be 5,393 AUD. The most expensive one was sold as "*COVID-19 Antidote for sale*" at 24,598 AUD and is allegedly shipped from the United States. The Australian Therapeutic Goods Administration and Australian Border Force warned about illegal import and supply of vaccines that will lead to civil and criminal penalties.

With the encouraging results of some of the coronavirus vaccines recently released, interest in the vaccines has increased. The supply is limited and the demand is very high, providing a dangerous situation for criminals to operate and seriously undermine public health. Apart from the above described incidents, the MQM Globe[14] holds many articles discussing the challenges of the distribution of the COVID-19 vaccines: describing the possible shortages and the concurrent threats of theft, diversion, price gouging, falsification, and some of the solutions to overcome the challenges such as blockchain technology to monitor the COVID-19 vaccine supply chain.

6.4 COVID-19 diagnostics

In section 6.2 of this report we reported results published on past seizures in the USA (report ID 815477) and Canada (report ID 793903). In mid-November 11,000 rapid COVID-19 tests were seized in an airport in Mexico (report ID 818239). An article from September in India, mentions the withdrawal of SF COVID-19 antibody test kits coming from China after complaints of non-performance of the tests (report ID 810419). Indeed in previous Medical Products Quality Report issues we reported on problems with test kits in Rajasthan and the Punjab[15], but in this article also the state of Karnataka is mentioned.

In the media there has been much discussion about falsified COVID-19 test results and the sales of COVID-19 negative test certificates to students, travellers and others. We do not report on these events because it would lead us to far from the monitoring of substandard and falsified COVID-19 medical products. But it is clear that another

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

[15]Infectious Diseases Data Observatory. Medical Product Quality Reports. News. Published 2020. Accessed October 10, 2020. https://www.iddo.org/mq/research/medical-product-quality-reports. Rajasthan (report ID 729474) described in the September issue. Punjab (report ID 633611) described in the July issue.

'new' global black market has emerged that is likely to expand and needs to be addressed.

6.5 Personal protective equipment

'Max Care', a company with a registered trademark for rubber gloves, alerted about falsified rubber gloves (report ID 811404). Subsequently the Malaysian Domestic Trade and Consumer Affairs Ministry seized 80 boxes of falsified Max Care rubber gloves and 1,815 empty boxes. The fraudulent sellers were buying and repacking gloves from overseas. The differences between the genuine and the falsified gloves were related to "*their quality, thickness, colour, packaging and information printed on the box*".

In the UK, the National Health Service sent out a quality alert to general practitioners (GPs) in the South West of England (report ID 816932), as a number of unopened boxes of 'Sanique' protective gloves allegedly contained used gloves. Bright Way Holdings, based in Malaysia, is stated as manufacturer on the box, but the company denied having manufactured or supplied the gloves. Also Medequip, a community equipment supplier, stated they are not involved in the manufacturing or procurement of the gloves. An investigation is continuing. The same article points out other issues that GPs in the UK experienced in recent months: expired face masks, non-sterile gowns that "*did not meet minimum standards for fluid resistance*", and aprons made from "*repurposed bin bags*".
During several routine checks conducted by trading standards officials in the UK in different locations, 1,600 masks were found to be non-compliant (report ID 794413). Problems encountered were masks with false claims of EU approval, false claims on the level of protection, falsified paperwork, and labelling issues such as not providing the name and address of the manufacturer or importer.

In China a man has been found guilty for the production of falsified 3M masks (report ID 816287). The business has existed since May 2018. In November 2019, the Chinese police received reports of online sales of falsified masks and after investigation "*they seized around 50,000 fake items, including 3M labels, packaging and certificates, from a mask manufacturing factory*".
In previous issues we already reported on the multiple incidents with falsified 3M mask worldwide. Incidents have also been reported previously for the Indian mask manufacturer, Venus Safety and Health Private Ltd. During the pandemic the company sent at least 38 legal notices to manufacturers of falsified Venus masks and they registered seven cases of police raids leading to seizures of 47,000 falsified masks (report ID 798410). At the beginning of November Indian police raided a manufacturing unit and seized around 7,500 falsified Venus respirators (report ID 798410). A man was accused of producing masks out of inferior quality cloth and selling the masks branded as Venus or 3M.

Previous issues of the Medicine Product Quality Reports on COVID-19 included several articles on governments that faced problems for sourcing PPE. Now the Belgian government has started legal actions against four suppliers, which together

have supplied 25 million FFP2 masks: IC Pharma, UltraZonic, Life medical and Qingdao LuoTa Management (report ID 802796). The Belgian Ministry of Health did not provide more details. The company UltraZonic, communicated that it had received masks of substandard quality and has started legal actions against its supplier.

6.6 Sanitisers and disinfectants

In mid-November an article reported on the US FDA claiming that Mexican manufacturers are profiting from the COVID-19 pandemic to import low quality hand sanitizers into the USA (report ID 807738). Indeed, in October and November the FDA continued to send out several warning letters about quality concerns of hand sanitizers. The six warning letters retained by the MQM Globe were all destined to Mexican businesses (report ID 791002, 791003, 791004, 807246, 807248, 807313). The goods were detained and refused admission at the USA border because they were adulterated and not approved by the US FDA. All hand sanitisers were stated to contain 70% ethanol but analysis showed that the ethanol content ranged from 0% to only 37% v/v. In addition all the sanitisers contained methanol ranging from 2.1% to 74% v/v. These results raise serious concerns on the quality assurance in those manufacturing facilities.

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 (API) as medicines that are approved, trailed or used by patients in the context of COVID-19. We included all those type of products even if for certain APIs the efficacy is not proven in the treatment of COVID-19 patients.

Since the 21st of November the monoclonal antibody therapy of Regeneron Pharmaceuticals Inc obtained emergency use authorization in the USA[16]. Even before the 11th of November an article reported on advertisements on the dark web allegedly selling the product (report ID 835199).

Two different past incidents illustrate how a product has been reported in the media and shortly thereafter criminal activities were reported (report ID 818239). In June 2020 people tried to smuggle 3,000 illegal doses of hydroxychloroquine into Paraguay. In September, in Venezuela there were cases of price gouging of remdesivir. A doctor allegedly sold remdesivir to patients for $800 a vial.

In 2018 an investigation was launched in Spain against a criminal organization for online distribution of medicines (report ID 806006). In October 2020 a man was

[16]U.S. Food & Drug Administration. FDA Authorizes Monoclonal Antibodies for Treatment of COVID-19. Press Announcements. Published November 21, 2020. Accessed December 11, 2020. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibodies-treatment-covid-19

arrested in Germany. He "*was the head of the illegal medicines distribution racket in a significant number of countries throughout the world*" and was selling alleged COVID-19 medicines amongst many other products.

In the Philippines, the FDA warned the public about 4 falsified over-the-counter medicines (report ID 796355). One of them is 'Neozep Forte', a phenylephrine, chlorphenamine, paracetamol combination tablet. The falsified product had a different "*logo, security mark and knurling*".

In the USA, Nostrum Laboratories Inc. launched a recall for metformin that might have been contaminated with N-nitrosodimethylamine (report ID 790944).

In Senegal, ceftriaxone injections were seized together with other illicit medicines (report ID 806065). No further details were provided.

The US FDA and the Federal Trade Commission were alerted about a product that is marketed as Vitamin C derived from amla fruit, but allegedly is derived from other plants (report ID 827230). Fusion Health and Vitality LCC recalled voluntarily 'Immune Boost Sublingual Vitamin D3' (report 814170). The Vitamin D product contained statements that would lead to classification of the product by the FDA as unapproved new medicine.

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 report, containing the annexes, and/or consult the online MQM Globe[17], using the report ID in the search box.

[17]Infectious Disease Data Observatory. Medicine Quality Monitoring Globe: https://www.iddo.org/medicine-quality-monitoring-globe