

Medical Product Quality Report – COVID-19 Issues

Issue 8. January 2021

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Centre of Tropical Medicine & Global Health, Nuffield Department of Medicine,
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1. Summary of findings

With the deployment of COVID-19 vaccines combined with other public health interventions, people hope that 2021 will see a sustained global reduction in the incidence of COVID-19 infection. In order to be successful, existing and new challenges need to be tackled. Therefore, we continue monitoring and data sharing to collect early warnings of potential problems with substandard and falsified (SF) COVID-19 medical products.

Issues with SF personal protective equipment remain a problem. Across the globe customs continue to seize unregistered and falsified masks. Those masks continue to reach hospitals where people's health is put at risk. In Thailand several companies were raided producing falsified or substandard gloves, or repacking and reselling used gloves. Similarly, for hand sanitisers and disinfectants the problems that were encountered in the beginning of the pandemic persist, for some products the ethanol content is too low and/or are often contaminated with methanol. The United States Food and Drug Administration has put a countrywide import alert on all alcohol-based hand sanitizers coming from Mexico. In South-Africa, ivermectin is used for COVID-19 and sold on the black market even though the product is not registered for human use.

As anticipated, we have sadly seen an increase in incidents and problems with SF COVID-19 vaccines. In January we identified 20 different incidents of degraded, stolen or apparently falsified COVID-19 vaccines. Two reports described degraded Moderna vaccines and another issue with a batch of the Moderna vaccine, leading to a high number of allergic reactions post-administration of uncertain aetiology. We are aware of three reports in January in the public domain on COVID-19 vaccine theft in the USA. In addition, another incident is more controversial, in which a physician in Texas was charged with the theft of Moderna COVID-19 vaccine doses. The physician claimed his intention was to vaccinate people in high risk groups before the remaining vaccine expired. In several countries, there have been incidents of criminals trying to physically sell purported COVID-19 vaccines, sometimes injecting the victims with unknown substances. Online, through text messages, the dark web and social media, many COVID-19 vaccines are offered when they are not legitimate outlets.

Within the current monthly Medical Product Quality Report - COVID-19 issues we cover incidents related to a variety of medical products. With the continued global vaccine roll out, we have worked on a specific separate report that lists incidents and problems with COVID-19 vaccines quality, diversions, thefts and scams. That report is primarily based on this and previous issues of the Medical Product Quality COVID-19 issues report. The report is available through the IDDO- and MORU¹-website.

¹ Medicines Quality Research Group (MORU Tropical Health Network). Medicine quality - GLOBAL LITERATURE ON SF COVID-19 VACCINES. MORU Tropical Health Network - Research Areas. Published 2021. Accessed March 1, 2021. <https://www.tropmedres.ac/research-areas/medicine-quality/medicine-quality>

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.

²Source: 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 March 2, 2021. 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 March 2, 2021. https://www.wto.org/english/docs_e/legal_e/27-trips_05_e.htm#nt-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 here 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 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](#)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 eighth issue of the monthly report ‘Medical Product Quality Report – COVID-19 Issues’ covers information published during the month of January 2020. The previous issues covered publications from January 1st to December 31st 2020 and are available on the IDDO⁷ and MORU⁸ 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).

Source: World Trade Organization. Part III — Enforcement of Intellectual Property Rights. Accessed March 2, 2021. https://www.wto.org/english/docs_e/legal_e/27-trips_05_e.htm#nt-14

⁵Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe. Web Page. Published 2020. Accessed March 2, 2021. <https://www.iddo.org/medicine-quality-monitoring-globe>

⁶Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe disclaimer and caveats. Web Page. Published 2020. Accessed March 2, 2021. <https://www.iddo.org/medicine-quality-monitoring-globe-disclaimer-and-caveats>

⁷Infectious Diseases Data Observatory. Medical Product Quality Reports. Medical Product Quality Reports. Published 2020. Accessed March 2, 2021. <https://www.iddo.org/mq/research/medical-product-quality-reports>

⁸MORU 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

Bracci A, Nadini M, Aliapoulios M, et al. **Dark Web Marketplaces and COVID-19: before the vaccine.** EPJ Data Sci. 2021;10(1):1-26. doi:10.1140/epjds/s13688-021-00259-w

Abstract. « *The COVID-19 pandemic has reshaped the demand for goods and services worldwide. The combination of a public health emergency, economic distress, and misinformation-driven panic have pushed customers and vendors towards the shadow economy. In particular, dark web marketplaces (DWMs), commercial websites accessible via free software, have gained significant popularity. Here, we analyse 851,199 listings extracted from 30 DWMs between January 1, 2020 and November 16, 2020. We identify 788 listings directly related to COVID-19 products and monitor the temporal evolution of product categories including Personal Protective Equipment (PPE), medicines (e.g., hydroxyclochine [sic]), and medical frauds. Finally, we compare trends in their temporal evolution with variations in public attention, as measured by Twitter posts and Wikipedia page visits. We reveal how the online shadow economy has evolved during the COVID-19 pandemic and highlight the importance of a continuous monitoring of DWMs, especially now that real vaccines are available and in short supply. We anticipate our analysis will be of interest both to researchers and public agencies focused on the protection of public health.* »

Faiva E, Hashim HT, Ramadhan MA, et al. **Drug supply shortage in Nigeria during COVID-19: efforts and challenges.** J Pharm Policy Pract. 2021;14(1):17. doi:10.1186/s40545-021-00302-1

Extract. « *There is still the inadequacy on the part of the government to check illegal importation, manufacture, and sale of fake, adulterated, substandard and expired goods due to fraudulent drug dealers and some corrupt government officials.* »

Twesigye G, Hafner T, Guzman J. **Making the investment case for national regulatory authorities.** J Pharm Policy Pract. 2021;14(1):1-4. doi:10.1186/s40545-021-00299-7

Extract. « *Regardless, the COVID-19 pandemic has brought into sharp relief the need to invest in regulatory systems strengthening to ensure timely access to safe, effective, quality-assured, and affordable medical products. A strong regulatory system helps facilitate a robust response to pandemics and other health emergencies, as opposed to initiating an emergency response without the requisite systems in place.* »

Tung LT. **Success in combating a pandemic: Role of fast policy responses.** World Dev Perspect. 2021;21:1-4. doi:10.1016/j.wdp.2020.100285

Extract. « *In the context of combating an outbreak of the COVID-19 pandemic, the policies of social distancing and travel restriction that were adopted resulted in a rapid increase in demand for essential goods. Many households stored food and essential products. Speculative behaviour in relation to market prices took place in markets for items such as rice, face masks and antiseptic liquids. However, the government's solutions were very effective and it acted quickly to stop speculation and price manipulation in the market. [...] Because of the efficient and fast responses of the government, during the social distancing period, the supply of essential products far exceeded market demand in Vietnam. In addition, market regulators imposed heavy fines on those engaging in price manipulation and took further action such as withdrawing business licences, and confiscating products; the police even arrested the people involved. The behaviour of supplying poor quality medical products (including counterfeit ones) was successfully prevented by the public agencies.* »

Ukuhor HO. **The interrelationships between antimicrobial resistance, COVID-19, past, and future pandemics.** *J Infect Public Health.* 2021;14(1):53-60. doi:10.1016/j.jiph.2020.10.018

Extract. « Counterfeit medicines are partly responsible for AMR because they contain and deliver sub-optimal doses of the active ingredient in antimicrobial drugs. The implication is that when patients and healthcare providers use antimicrobials appropriately, counterfeit drugs will undermine their efforts and AMR would develop. The WHO suggests 10.5% prevalence of medicines available in Low and Middle Countries is counterfeit. This evaluation was corroborated by a study that reported that about half of the counterfeit drugs present worldwide are antimicrobials, mainly generic. Additionally, there is reduced drug quality because of poor storage conditions, age, having none, too little, or too much of the active ingredients. This may be premeditated or the consequences of poor manufacturing practices. Adulterated inactive “excipients” in drugs can also be dangerous to those who consume them. »

3.2. Seizures/Surveys/Case Reports/Reviews

Delaloye J-R, Vernez D, Suarez G, et al. **Distribution of low quality filtering facepiece respirators during the COVID-19 pandemic: an independent analysis of the situation in Switzerland.** *Swiss Med Wkly.* 2021;151(0304):1-9. doi:10.4414/smw.2021.20459

Abstract. « (*) **BACKGROUND.** SARS-CoV-2 is a respiratory virus. Transmission occurs by droplets, contact and aerosols. In medical settings, filtering facepiece (FFP) respirators are recommended for use by personnel exposed to aerosol-generating procedures. During the COVID-19 pandemic, the demand for FFP respirators exceeded their supply worldwide and low-quality products appeared on the market, potentially putting healthcare workers at risk. (*) **AIMS.** To raise awareness about variations in quality of imported FFP respirators in Switzerland during the COVID-19 pandemic, to draw attention to the current directives regulating the market launch of FFP respirators in Switzerland, to provide practical support in identifying suspicious products or documents and, finally, to offer strategies aimed at reducing the distribution of low-quality FFP respirators in the future. (*) **METHODS.** Three Swiss laboratories, Spiez Laboratory and Unisanté in partnership with TOXpro SA individually set up testing procedures to evaluate aerosol penetration and fit testing of FFP respirators imported into Switzerland during COVID-19 pandemic. Additionally, Spiez Laboratory visually inspected the products, examined the certification documents and crosschecked the product information with international databases. (*) **RESULTS.** Between 31 March and 15 June 2020, 151 FFP respirators were analysed. The initial assessment performed before testing allowed a reduction of up to 35% in the number of FFP respirators sent to Spiez Laboratory for evaluation, for which product information found to be faulty. After filtration efficiency evaluation and fit testing, 52% and 60% of all products tested by Spiez Laboratory and Unisanté-TOXpro SA, respectively, did not meet the minimum performance requirements established independently by the three Swiss laboratories. (*) **CONCLUSION.** The demand for FFP respirators exceeded the supply capacity from established suppliers of the Swiss market. New production and import channels emerged, as did the number of poor-quality FFP respirators. FFP respirators remaining in stocks should be checked for conformity before being used, or eliminated and replaced if quality does not meet standards. »

4. International organisations

An additional publication from prior to January 2021

INTERPOL. Assessment of COVID-19 Pandemic Impact on Illicit Medication in East Africa.; 2020. Accessed February 16, 2021. <https://enact-africa.s3.amazonaws.com/site/uploads/2020-12-03-Covid-19-illicit-medications-east-africa-pdf.pdf>

Extract. « It is the activities of OCGs [Organised crime groups] in the COVID-19-era illicit medications market in East Africa that are enabling increased levels of addiction to powerful painkilling medications and leading to deaths resulting from fake medications for chronic as well as life threatening conditions. This trade is also amplifying the impact of COVID-19 on East African healthcare systems. The trade in black market medications originally intended for hospitals has increased the difficulties for healthcare systems to cope with any subsequent second or third wave of COVID-19. »

5. Miscellaneous

The Partnership for Safe Medicines. **Watch Out For COVID-19 Vaccine Scams.** Accessed February 15, 2021. <https://www.safemedicines.org/covid-vaccine-scams>

Extract. «There has been a huge upsurge in scams since the start of the global COVID-19 outbreak. Fake treatments, fake versions of real treatments, fake medical products including personal protective equipment, and fraud surrounding everything from unemployment payments to business relief aid. COVID-19 vaccines are modern medical miracles produced in record time with a high effectiveness rate. Everyone should get one, but the rollout will take time. In the meantime COVID scammers are preying on the public to try and make a buck, and in some cases, endangering their lives. »

PSM is describing three broad categories of COVID-19 vaccine crime: 1) Vaccines Signups Dangled For Financial And Identity Theft, 2) Diversion: Shots For Sale Where They Shouldn't Be, 3) Fake Substances Sold As Vaccines.

Krähenbühl C. **COVID vaccines “a test of resilience” for FMD anti-counterfeiting. Securing Industry.** Published January 12, 2021. Accessed March 1, 2021. <https://www.securindustry.com/pharmaceuticals/covid-vaccines-a-test-of-resilience-for-fmd-anti-counterfeiting/s40/a12767/#.YDzShGhKgml>

Extract. « We at Excellis are concerned that a perfect storm is going to hit the industry. A combination of new players, dispensing large numbers of products in non-standard scenarios and at locations where the scanning technology and processes have not yet been established as routine, is highly likely to generate a spike of EU-FMD alerts that manufactures need to deal with. There is a real concern that many manufacturers are even today ill-prepared to deal with the routine number of EU-Alerts in timely manner and that they will be swamped by a flood of new alerts that are likely to arise due to technical issues, processing errors and – inevitably – human error. Ignoring these alerts, even if the vast majority are going to be false alerts, is not an option and manufacturers must ensure that their organisation and processes are ready to scale and flex up to this additional challenge they face once the vaccine roll-out begins in earnest. »

6. Lay literature

6.1 Disclaimer & Notes

The information included below is based on the data used to create the Medicine Quality Monitoring Globe⁹ (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 2020, 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 some the United States Food and Drug Administration (US FDA) medical products alerts. In the future, we will extend this feature for the US FDA and 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 2020 the Globe-report for PPE included sanitisers and disinfectants. From October 2020 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 2020. Therefore caution is required when interpreting the number of alerts or articles over time.

⁹Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe. Web Page. Published 2020. Accessed March 2, 2021. <https://www.iddo.org/medicine-quality-monitoring-globe>

¹⁰Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe disclaimer and caveats. Web Page. Published 2020. Accessed March 2, 2021. <https://www.iddo.org/medicine-quality-monitoring-globe-disclaimer-and-caveats>

¹¹Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe methodology. Web Page. Published 2020. Accessed March 2, 2021. <https://www.iddo.org/medicine-quality-monitoring-globe-methodology>

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 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 being trialled for COVID-19 treatment 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 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. 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 (in December)¹³

- It is highly likely that diverted vaccines will not be stored appropriately and their use is likely to result in people being unprotected when they think they are. To ensure that the system includes articles that are related to diversion and theft of COVID-19 vaccines from legitimate supply chains, we adapted the search terms for Google News searches linked to COVID-19 vaccines.
- For COVID-19 vaccines we include scams and fraudulent claims in this report if involving the direct offer of a COVID-19 vaccine. For all the other product categories, our reporting policy remains the same, and we do not aim to include discussion of the multiple fraudulent claims of efficacy.
- From this report on, we will include incidents related to ventilation equipment in the overall article count. In the first Medical Product Quality Report, we reported on two incidents with ventilators (one in May and one in June) but they were not included into the overall count in subsequent reports. From this report onwards the figures will include these incidents that occurred in May, June, January and any incident that might occur in the coming months.

¹²Hashemian 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>

¹³Infectious Diseases Data Observatory. Medical Product Quality Reports. Medical Product Quality Reports. Published 2020. Accessed March 2, 2021. <https://www.iddo.org/mq/research/medical-product-quality-reports>

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

Since the beginning of the pandemic we have identified 523 relevant articles on quality problems of COVID-19 medical products (Figure 1). For January 2021 we report on 53 articles. Within those articles, 6 alerted on hand sanitisers and disinfectants, 6 on diagnostics, 11 are linked to COVID-19 related treatments, 16 to personal protective equipment (PPE) and 22 to vaccines¹⁴ (Figure 2 and 3). In January 2021, 4 articles covered diverted, substandard or falsified product issues with ventilators and oxygen supply. These are the first articles in the MQM Globe on ventilators and oxygen supply issues since June 2020.

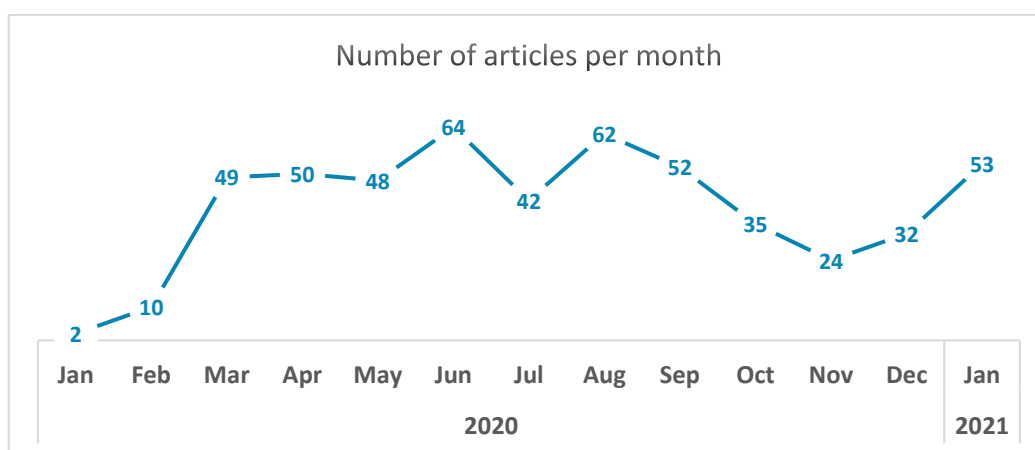


Figure 1. Number of articles on the Medicines Quality Monitoring Globe linked to substandard or falsified COVID-19 supplies by month. AS SOME ARTICLES DESCRIBE MORE THAN ONE CATEGORY OF PRODUCTS, THE SUM OF ALERTS PER MONTH AS SHOWN IN FIGURE 2 AND 3 MAY EXCEED THE SUM OF ARTICLES PER MONTH OF FIGURE 1.

NOTE (1) SINCE NOVEMBER '20, 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.

NOTE (2) SEARCH TERMS FOR COVID-19 VACCINES THEFT AND DIVERSION HAVE BEEN ADDED, THE OBSERVED RISE IN THE NUMBER OF ARTICLES FROM JANUARY '21 CAN BE AT LEAST PARTIALLY DUE TO THIS CHANGE.

NOTE (3) COMPARED TO THE PREVIOUS REPORTS THE NUMBER OF ARTICLES CHANGED FOR MAY AND SEPTEMBER: FOR MAY IT INCREASED BY ONE, ADDING AN ARTICLE FROM THE CATEGORY OF VENTILATION EQUIPMENT WHICH WAS NOT INCLUDED PREVIOUSLY; FOR THE MONTH OF SEPTEMBER THE ARTICLE COUNT DECREASED BY ONE SINCE ONE ARTICLE HAS ERRONEOUSLY BEEN COUNTED DOUBLE.

In the following sections each category of products is discussed separately. However, some articles report on several product categories issues. We identified a study that covers multiple categories (Bracci A et al., 2021¹⁵; report ID 913513). The study found offers on the dark web of PPE, medicines, vaccines, ventilators and diagnostics and even includes 'scamming guides', fake medical records and medical frauds (including fake vaccines). The authors of the article describe trends and they link spikes in the number of products for specific categories of COVID-19 supplies to different stages and events during the pandemic. The researchers urge policymakers to consider the impact of dark web marketplaces on public health and now especially in the light of

¹⁴ We do not include report ID 895651, as it was published on the 31st of December 2020. The report was only loaded later into our system, therefore we report on it in the vaccine section of this January issue. We include it in the numbers (article and alert count) for December 2020.

¹⁵Bracci A, Nadini M, Aliapoulos M, et al. Dark Web Marketplaces and COVID-19: before the vaccine. EPJ Data Sci. 2021;10(1):1-26. doi:10.1140/epjds/s13688-021-00259-w

the progressively global vaccine distribution. In Mexico authorities reported that they had found over 400 fake websites that offer vaccines, masks, rapid tests and oxygen (report ID 892039).

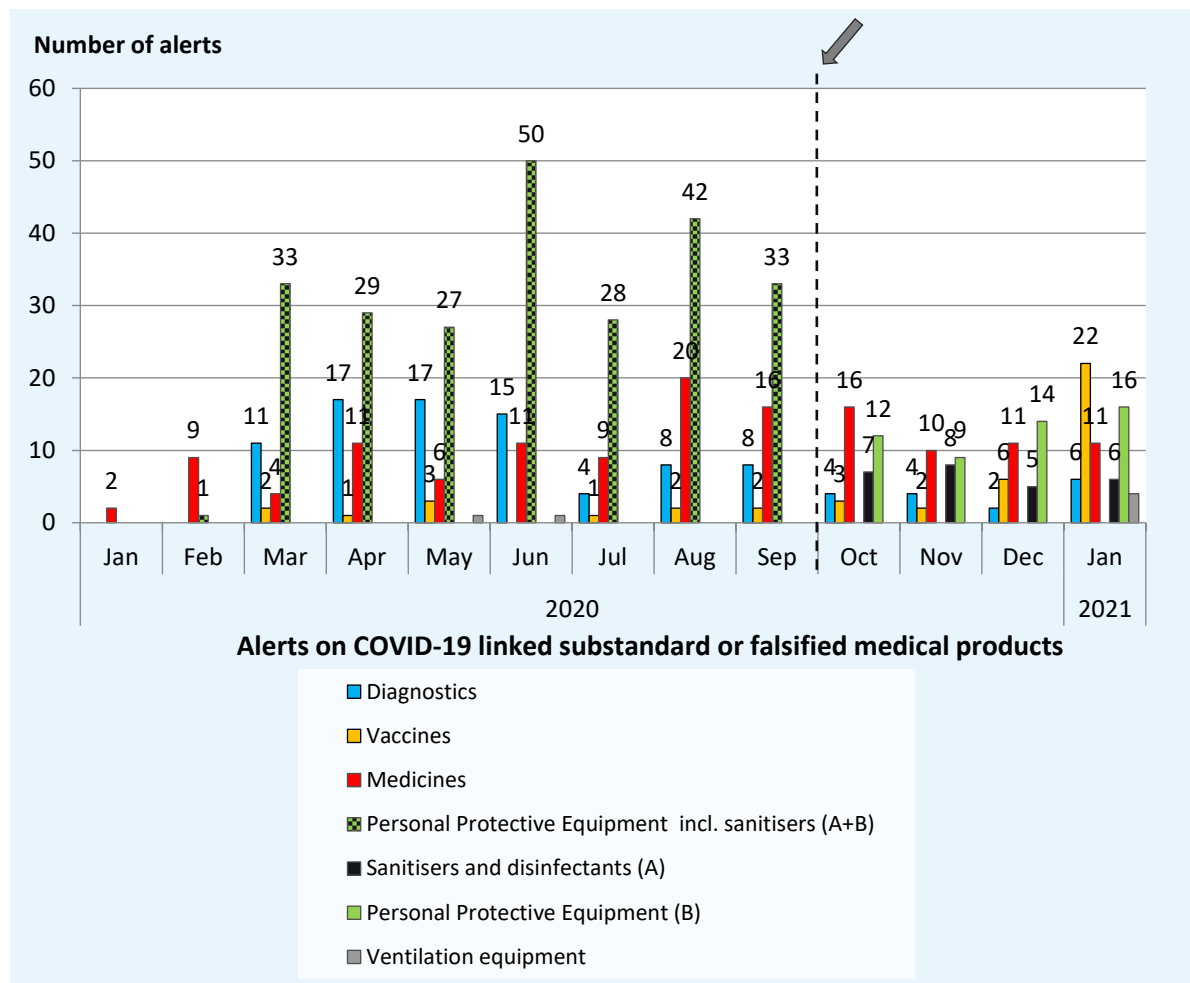


Figure 2. Number of alerts on the Medicines Quality Monitoring Globe by category of products and by month.

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 (1). 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.

NOTE (2). SEARCH TERMS FOR COVID-19 VACCINES THEFTS AND DIVERSION HAVE BEEN ADDED, THE OBSERVED RISE IN THE NUMBER OF ARTICLES FROM JANUARY '21 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)
 ■ Ventilation equipment

Number of alerts

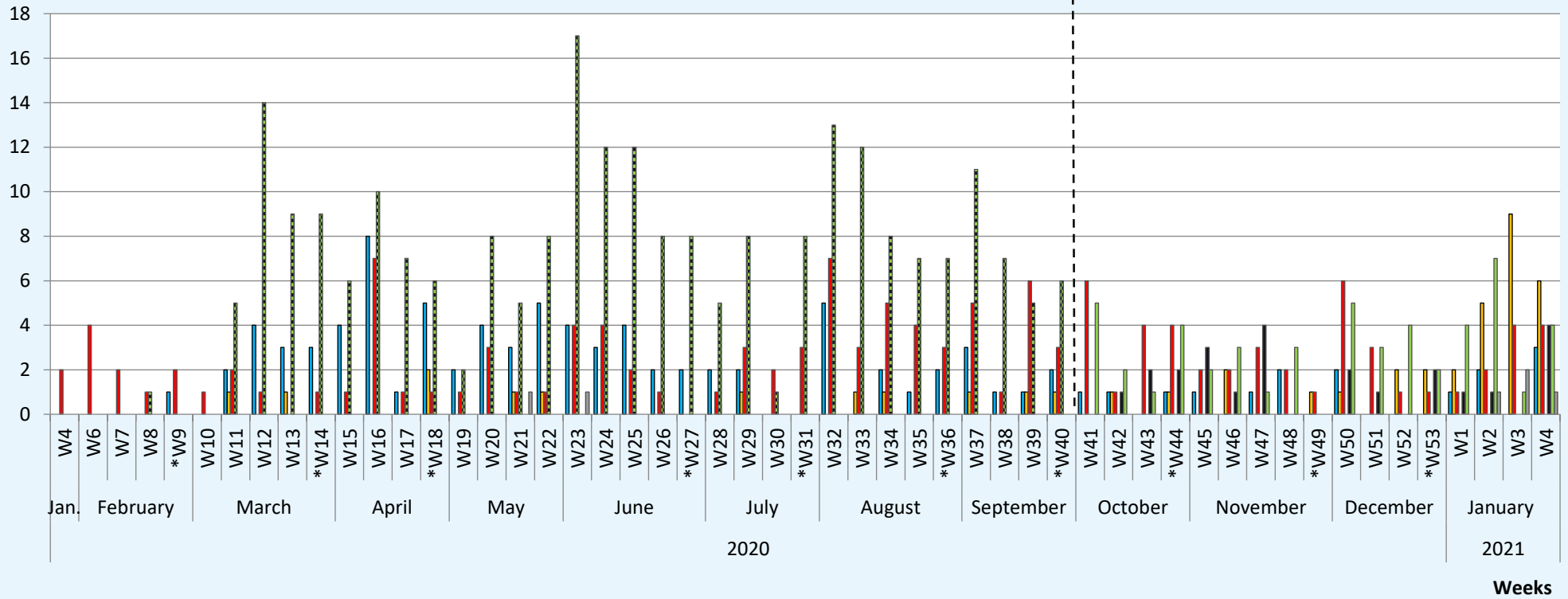


Figure 3. Number of alerts on the Medicines Quality Monitoring Globe by category and by week.

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 (1). 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.

NOTE (2). SEARCH TERMS FOR COVID-19 VACCINES THEFTS AND DIVERSION HAVE BEEN ADDED, THE OBSERVED RISE IN THE NUMBER OF ARTICLES FROM JANUARY '21 CAN BE AT LEAST PARTIALLY DUE TO THIS CHANGE.

6.3 Vaccines

In the United States of America (USA) in a community vaccination clinic, vaccination was halted due to an 'abnormally high number' of allergic reactions after a shot of a particular batch of the Moderna vaccine (report ID 897789). The California Department of Public Health called for a pause in the administration of 330,000 doses from the batch and an investigation was opened, but we were unable to find the results of that investigation.

Two articles describe degraded Moderna vaccines in the USA. The first¹⁶ (report ID 895651) reports on a pharmacist in Wisconsin who intentionally removed COVID-19 vaccine vials from the hospital's refrigeration to render them ineffective. Allegedly over 500 doses had to be thrown away but 57 patients received a dose from the tampered vaccine. They have been notified and are allegedly not at risk of any adverse health effects. The second article is about health authorities that halted the use of the Moderna COVID-19 vaccine since the quality of the vials could no longer be guaranteed due to temperature control issues (report ID 900582). The vaccines need to be kept at 2-8°C, however the temperature was too low for 12,000 doses in Michigan and too high for 4,400 doses in Maine.

In several countries, there have been incidents of criminals trying to physically sell purported COVID-19 vaccines, sometimes injecting the victims with unknown substances. In the United Kingdom (UK) there were at least 2 cases reported. On the 30th of December a 92 year old was injected with an unknown substance at her home by someone claiming to work for the National Health Service (NHS) (report ID 881071). The victim paid 160 pounds. In mid-January a street vendor tried to sell a 61 year old a COVID-19 vaccine for 170 pounds (report ID 893684). In Finland a woman was arrested at the end of January after she tried to sell door-to-door COVID-19 vaccines for 150 euros (report ID 917132). In Ecuador, a health centre allegedly administered fake COVID-19 vaccines to up to 70,000 people (report ID 910241). The vaccines were sold to the patients as a course of three doses at approximately 12 euros per dose. In Costa Rica, with the arrival of the first doses of the genuine COVID-19 vaccine, criminals were offering falsified vaccines (report ID 922769). In the USA a man was arrested for advertising COVID-19 vaccines for 400 USD and introducing other misbranded drugs in the market (report ID 904241). We already reported on this case in the [first Product Quality Report on Covid-19 issues](#). However, the man was alleged to continue criminal practices.

Mexican authorities warned about organized crime fake vaccination campaigns and the selling of illegal vaccines. In mid-January the alert concerned Pfizer vaccines (report ID 892039) and in the end of January it concerned reports of the illicit sales of the Moderna vaccine (report ID 907667). The fake COVID-19 vaccines were allegedly sold via social networks and illegal webpages. The authorities warn that these

¹⁶ Report ID 895651 was published on the 31st of December 2020. The report was only loaded later into our system, therefore we report on it in the vaccine section of this January issue. However, we include it in the numbers (article and alert count) for December 2020.

Source: Romo V. Pharmacist Arrested, Accused Of Destroying More Than 500 Moderna Vaccine Doses. NPR. <https://www.npr.org/2020/12/31/952536531/pharmacist-arrested-accused-of-destroying-more-than-500-moderna-vaccine-doses?t=1614099235033>. Published December 31, 2020. Accessed February 24, 2021.

products are from ‘dubious origin’ and are a threat for patients’ health. Another article reported that Mexico’s National Council of Private Security allegedly confirmed that on several locations there are laboratories set up by organized crime groups, Mexican cartels, to produce fake COVID-19 vaccines (report ID 897295). This raises concerns that those cartels will try to gain a market share in the COVID-19 vaccine market. Some local communities, may trust cartels for providing stolen vaccines. However, authorities are concerned firstly with the theft of vaccines (and their degradation) and secondly that the cartels may switch to providing falsified vaccines.

For the month of January 2021, we are aware of three reports so far in the public domain of COVID-19 vaccine theft. The first article published on the 14th of January stated that police were investigating the reported theft of 2 vials of the Moderna vaccine from a hospital in Florida, USA (report ID 936933). The second article, on the 19th of January, reported on the theft of 4 doses of the Pfizer/BioNTech vaccine in a public hospital in Cuernavaca, Mexico, allegedly by or with the help of a hospital employee (report ID 943497). The third article, on the 26th of January, concerns the theft of three doses of the Moderna vaccine destined for first responders in one of Florida’s counties, USA (report ID 936949). Allegedly a paramedic helped a supervisor to ‘steal’ the vaccine and subsequently “*forged the vaccine screening and consent forms*”.

In addition, in Texas, USA, there was a report of a physician who was charged with the theft of Moderna COVID-19 vaccine doses (report ID 936936). The intention of the physician who vaccinated people in high risk groups before the vaccine expired has been controversial and discussed in other reports¹⁷ published later in February.

Through text messages, online, in emails and on messaging apps people have been lured into buying purported COVID-19 vaccines. It is not always possible to make the distinction between cases of financial scams, falsified COVID-19 vaccines or diverted COVID-19 vaccines. We report on the cases that were present in the MQM Globe. In the UK text messages have been sent out stating to be from the NHS, claiming the victims are eligible for a COVID-19 vaccine and in parallel asking for personal information and bank details (report ID 909286). One article found seven different offers for purported COVID-19 vaccines (report ID 877299): doses offered for 500 to 1,000 USD on the dark web place Agartha; another dark web website with alleged vaccines from the “Wuhan Institute of Science”; offers on Telegram for supposed Moderna Inc (180 USD), Pfizer/BioNTech (150 USD) and AstraZeneca (110 USD) COVID-19 vaccines.

An article published on the 21st of January 2021 reports that the black market of COVID-19 vaccines has grown 400% since December 2020 (report ID 902237). Another article reports on the black market being flooded with products linked to COVID-19 since the start of the pandemic (report ID 890850). Purported COVID-19

¹⁷Crist C. **Texas Doctor Fired for Giving Away Expiring Vaccines.** *WebMD.* <https://www.webmd.com/vaccines/covid-19-vaccine/news/20210214/texas-doctor-fired-for-giving-expiring-vaccines>. Published February 16, 2021. Accessed February 24, 2021.

Kilander G. **Doctor says he was wrongly fired for giving expiring Covid vaccine to his wife.** *The Independent.* <https://www.independent.co.uk/news/world/americas/covid-vaccine-expiring-houston-texas-b1801122.html>. Published February 12, 2021. Accessed February 24, 2021.

vaccines, such as those from Pfizer/BioNTech and Moderna, are for sale. Prices are often in bitcoins, and can go from 4,000 to 24,000 Australian dollars. A professor from the Australian National University stated that these are likely to be scams without a vaccine being available.

Finally, we share an article on online COVID-19 vaccine scams (report ID 902346). The author illustrate how registration of online domains is an indicator for future scams. For COVID-19 vaccines, there was a strong increase in the first quarter of 2020. Domain registrations contain words such as “Moderna”, “Pfizer” and “BioNTech” and the domain registrations spiked in parallel with the progress in the development of these vaccines. The article mentions the example of an active site that is promoting CoronaVac, the Sinovac vaccine. Apart from the sale of fake vaccines, the author shares other types of vaccine-scams such as paying to jump the vaccination queue or to get a spot on a ‘priority list’, the sales of ‘excess’ or alternative vaccines, buying other patients appointments, etc.

Another worrying phenomena

In addition to the incidents on SF COVID-19 vaccines registered by the MQM Globe, several articles were published on the stolen Pfizer/BioNTech COVID-19 vaccine data in Europe in December 2020¹⁸. Prior to leaking, the hackers allegedly manipulated the data¹⁹.

6.4 COVID-19 diagnostics

In India there was a recall of the COVID-19 antigen test kits provided by Alphine Biomedicals due to concerns over false-positive results (report ID 918805). In the USA there was a report on the COVID-19 test made by Curative (report ID 893142), with concerns over false negative results, therefore the test has been restricted for use under specific conditions only.

We highlighted in section 6.2 of this report that COVID-19 test kits remain for sale online on the dark web or on dubious websites (report ID 892039 and 913513). In the USA a man was charged for advertising and selling COVID-19 test kits through social media, in March and April 2020 (report ID 886689). He claimed to have stored the test kits in ultra-cold storage. During a raid at his home test kits were found on room temperature. An article on seizures performed by the US Custom and Border Protection (CBP) highlighted the seizure of falsified thermometers (report ID 906822).

¹⁸ Strubbs J. **Hackers steal Pfizer/BioNTech COVID-19 vaccine data in Europe, companies say.** *Reuters - Technology news.* <https://www.reuters.com/article/uk-ema-cyber/hackers-steal-pfizer-biontech-covid-19-vaccine-data-in-europe-companies-say-idUKKBN28J1VF>. Published December 9, 2020. Accessed February 15, 2021.

¹⁹ Davis J. **Hackers Leak COVID-19 Vaccine Data Stolen During EU Regulator Breach.** *Health IT Security.* <https://healthitsecurity.com/news/hackers-leak-covid-19-vaccine-data-stolen-during-eu-regulator-breach>. Published January 13, 2021. Accessed February 15, 2021.

Davis J. **COVID-19 Vaccine Data Manipulated Before Leak to Impair Public Trust.** *Health IT security.* <https://healthitsecurity.com/news/covid-19-vaccine-data-manipulated-before-leak-to-impair-public-trust>. Published January 19, 2021. Accessed February 15, 2021.

6.5 Personal protective equipment

In Zambia, Medical Stores Limited disclosed it distributed substandard gloves (report ID 880092). Allegedly, the Ministry of Health authorized the distribution of the gloves even though the required standards were not met.

For January, the MQM Globe holds 3 articles on SF gloves in Thailand. Authorities raided an unregistered factory in a district in the North of Bangkok and seized 2 million pieces of substandard medical gloves packed in 12,000 boxes, a 'plastic-sealing machine' and 'two industrial scales' (report ID 883298). The company was manufacturing substandard gloves, and they also allegedly sold used gloves. It seems as if the criminal activity of repacking and reselling used gloves is on the rise again with the new increase in COVID-19 cases in Thailand (report ID 891101). In a warehouse in the North of Bangkok, the police seized 654 bags of used rubber gloves and packing equipment such as 30,000 empty boxes. In Bangkok the police seized 100,000 falsified blue-dyed medical gloves and found dye containers and a washing machine (report ID 889796). Allegedly white gloves were dyed blue to mimic more expensive nitrile rubber gloves.

Many reports continue to describe problems with SF masks across the globe. In Bangladesh, as the market is flooded with falsified medical masks, the newspaper The Daily Star calls the Directorate General of Drug Administration to take action against illegal factories producing substandard and falsified masks (report ID 880750). Their report explains how small local factories give contracts to garment factories without passing on the appropriate guidelines and working conditions. The garment factories produce "*low-grade, non-woven surgical masks*" in unhygienic conditions, after which the substandard masks are sold at very low prices.

In the Philippines, the Bureau of Customs reported on the seizure of unregistered face shields and masks together with other items (report ID 916835). Some of the masks were labelled as 'AIDELAI', a prohibited brand. In Hong Kong, customs have seized 330,000 falsified 3M N95 respirators ready to leave the country (report ID 899195).

At the beginning of December the US CBP seized at JFK Airport two different shipments counting for 144,000 falsified 3M N95 masks (report ID 893901). At the end of December the Cincinnati US CBP seized 21 shipping boxes with 10,080 falsified masks (report ID 882079). The shipment did not pass the "*3M Safe Guard product authentication process*", and the masks came from China but were falsely labelled as 3M Mask Model 1860 made in the USA. An article reported that due to COVID-19 the US CBP seized products they were not seizing prior to the pandemic, for PPE the examples were masks and thermometers (report ID 906822). They highlight that it is worrying that some of the N95 masks were destined for hospitals. There are multiple example of hospitals receiving falsified masks. Cleveland Clinic, USA, discovered that some of the N95 mask supplied between November 2020 and end of January 2021 were falsified (report ID 911078). 3M sued The Maplewood company in Florida, USA, for selling 10,000 falsified N95 masks (report ID 911078). Amongst other clients the company was selling to a Minnesota hospital.

The online sale of falsified PPE continues. In the USA a man was prosecuted for having advertised and selling N95 masks and other products through social media in

March 2020 (report ID 886689). In the United Arab Emirates, the Dubai police seized many falsified products over the past year: “*more than 400,000 surgical masks, 25,000 gloves, 1,000 goggles and other protective uniforms*” (report ID 886520). The products were from unknown origin and were promoted and sold online and through social media.

6.6 Sanitisers and disinfectants

After seizures of falsified sanitisers in two shops, a unit producing falsified hand sanitizers was discovered in Kochi, India (report ID 881124). Two thousand litres of falsified hand sanitisers were seized together with mixing/fillers/sealing machines, bottles, lids and labels.

In the UK, there were two recalls for hand sanitizers sold online (report ID 930762): ‘Ibcccndc Instant Hand Sanitiser’ only contained 7% v/v ethanol and was contaminated with 37% methanol, and ‘Yucky Hands Hand Sanitizer’ contained only 42.3% v/v ethanol.

An article reported that in the past year the U.S. CBP seized falsified hand sanitisers containing 79% water and only 8% alcohol (report ID 906822). In addition they seized falsified Clorox bottles (sodium hypochlorite), with a genuine label but not the correct content. The US FDA sent warning letters to three Mexican companies (Ignacio Reyes Gonzalez, Laboratorios Jaloma and Grupo Plast Y-Kosas) concerning the quality of their hand sanitizers (report ID 909057, 909058 and 909059). The goods were detained and refused admission at the USA border because they were adulterated and not approved by the US FDA. The hand sanitizers were contaminated with methanol and had lower ethanol contents than stated: 70 or 80% stated ethanol but analysis showed the ethanol content ranged from 0.87% to only 32% v/v and the methanol from 15% to more than 63% v/v. In past Medical Product Quality Reports – COVID-19 issues, we reported several times on similar incidents with hand sanitizers coming from Mexico. In January 2021, the US FDA has put a countrywide import alert on all alcohol-based hand sanitizers coming from Mexico²⁰.

²⁰ U.S. Food & Drug Administration. **FDA Takes Action to Place All Alcohol-Based Hand Sanitizers from Mexico on Import Alert to Help Prevent Entry of Violative and Potentially Dangerous Products into U.S., Protect U.S. Consumers.** Press Announcements. Published January 26, 2021. Accessed February 25, 2021. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-action-place-all-alcohol-based-hand-sanitizers-mexico-import>

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, trialled 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.

Chloroquine and hydroxychloroquine: As in many other countries chloroquine and hydroxychloroquine are not approved for the treatment of COVID-19 patients in South Korea (report ID 899036). Allegedly the products were found in two Korean online shops, but it is not clear whether the products were genuine or falsified. One of the offered products was Lariago, a brand of chloroquine manufactured by Ipca Laboratories, India. Allegedly the online shops are buying the medicines themselves from overseas online shops to sell on.

Ivermectin: Published studies give insufficient evidence to justify the use of ivermectin for COVID-19 patients. In South Africa ivermectin is not registered for human use and the South African Health Products Regulatory Authority (Sahpra) prohibited its use in December 2020 after the medicine was promoted on multiple social media platforms as a ‘cure’ for COVID-19 (report ID 880929). In early January an article reported that despite being prohibited, the medicine was allegedly being dispensed at a private hospital in South Africa (report ID 880929). However, the hospital denied having used ivermectin. In the second half of January another article reported that due to the growing demand for ivermectin, the medicine is now available on the black market (report ID 906344). A third article on South Africa reported that the police intercepted ivermectin during different incidents at the OR Tambo International Airport (report ID 917866). In mid-January a man was caught with 24,000 tablets and at the end of January a man was found with 18,085 tablets of ivermectin. At the same airport other people were arrested with other unregistered medicines, some stated to contain amoxicillin.

Tacrolimus: Strides Pharma Inc has launched a countrywide recall for Tacrolimus (capsules, 100mg) in the USA (report ID 886351). According to the US FDA it concerns 960 bottles and the recall is classified as Class III recall (“*situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences*”).

Sildenafil: In the USA the police halted a car in which they found 98 tablets of falsified ‘Sildamax’ (report ID 899039). During multiple incidents falsified ‘Viagra’ has been seized by US CBP. In Cincinnati approximately 10,350 tablets came in through two shipments from the Middle East. The labels stated the products were made in the USA but allegedly the products may have come from Hong Kong and China (report ID 890267). In Louisville two shipments were seized with 618 bottles, containing 18,540 tablets, of misbranded Viagra (report ID: 912017)

Miscellaneous: The US CBP seized a shipment arriving from Laos containing commercial quantities of various medicines with no ‘FDA notification’, including 15,000 amoxicillin tablets, 5,000 Norpramin Paracetamol and Verikhai-I Paracetamol tablets and 500 Dexamethasone Acetate pills (report ID 900515).

6.8 Ventilation equipment

Apart from the period from January to June 2020, the MQM Globe did not hold articles reporting on problems with ventilators and accessories. For January 2021, we report four articles: one on ventilators and three on oxygen. One article reports that ventilators are for sale on the dark web (report ID 913513). The other article reports on oxygen that is for sale in Mexico through online platforms (report ID 892039). Apparently many of these websites offering COVID-19 products are fake but this is difficult to ascertain without investigation or attempts to buy the product.

In January in Mexico, there was a shortage of oxygen supplies which allegedly led to a rise in oxygen-related thefts. We report on two separate incidents that happened on the same day. In Sonora state an armed man stole seven oxygen tanks from a government hospital (report ID936950). At the time of publication of the article, the police were looking for the man and his companion driving the getaway car. In Tultepec, at the north of Mexico City, police halted a stolen truck containing 44 oxygen tanks and arrested two suspects (report ID943497 and 936950).

There are also reports on scams to sell oxygen but we do not report on these.

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 March 3, 2021. <https://www.iddo.org/mq/research/medical-product-quality-reports>

²²Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe. Web Page. Published 2020. Accessed March 3, 2021. <https://www.iddo.org/medicine-quality-monitoring-globe>