

# Medical Product Quality Report – COVID-19 Issues

Issue 9. February 2021

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



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## 1. Summary of findings

In this February 2021 issue, we report on 55 new alerts on COVID-19 products on the Medicines Quality Monitoring Globe. Almost half of the alerts (24), concerned diverted, substandard or falsified (SF) COVID-19 vaccines. Out of the 24 articles on vaccine incidents, two were on degradation issues, 5 were on stolen COVID-19 vaccines and the remaining articles were on falsified vaccines or injections with purported COVID-19 vaccines. Falsified vaccines were directly offered to the population but the European Anti-Fraud Office (OLAF) warned that criminals are also approaching national (and regional) authorities.

Although the number of SF alerts on non-vaccine COVID-19 product categories has declined, incidents continue to occur. For example, previously multiple governments have experienced issues with SF masks and in February 2021, one year into the pandemic, the saga continues with reports by the Canadian, USA and Belgian authorities. Throughout February 2021, there were reports of falsified 3M masks, especially in the USA. The company continues to struggle with criminals targeting 3M products and putting falsified versions in the market. Health Canada updated their list of recalled hand sanitisers that may pose health risk to their population and the US FDA continued to send warning letters to manufacturers of SF hand sanitisers.

We urgently need joined-up interventions to reduce the risk of SF COVID-19 medical products on global public health, and more specifically COVID-19 vaccines, through significant enhancements in global capacity for their prevention, detection and response.

## 2. Introduction

During the COVID-19 pandemic, the demand for COVID-19 related medical supplies has inevitably ballooned with an increased need 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)<sup>1</sup>:

- **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’<sup>2</sup> and ‘pirated copyright goods’<sup>3</sup> as used in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement.

The reports presented here were mostly extracted from the Medicines Quality Monitoring Globe ([the MQM Globe is accessible on the IDDO website](#)<sup>4</sup>), 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

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<sup>1</sup>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 March 2, 2021. [https://www.who.int/medicines/regulation/ssffc/A70\\_23-en1.pdf?ua=1](https://www.who.int/medicines/regulation/ssffc/A70_23-en1.pdf?ua=1)

<sup>2</sup>*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#fnt-14](https://www.wto.org/english/docs_e/legal_e/27-trips_05_e.htm#fnt-14)

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

Source: World Trade Organization. Part III — Enforcement of Intellectual Property Rights. Accessed March 18, 2021. [https://www.wto.org/english/docs\\_e/legal\\_e/27-trips\\_05\\_e.htm#fnt-14](https://www.wto.org/english/docs_e/legal_e/27-trips_05_e.htm#fnt-14)

<sup>4</sup>Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe. Web Page. Published 2020. Accessed March 18, 2021. <https://www.iddo.org/medicine-quality-monitoring-globe>

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](#)<sup>5</sup>); 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 ninth issue of the monthly report 'Medical Product Quality Report – COVID-19 Issues' covers information published during the month of February 2021. The previous issues covered publications from January 1<sup>st</sup> 2020 to January 31<sup>th</sup> 2021 are available on the IDDO<sup>6</sup> and MORU<sup>7</sup> websites. We also include publications and reports published prior to February 2021 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](mailto:medicinequality@iddo.org)).

### 3. Scientific literature

#### A. General

[Preprint] Assefa D, Gudeta T. **Utilization of Alcohol-Based Hand Sanitizers and Associated Health Risks among Healthcare Workers during the COVID-19 Pandemic: A Cross-sectional Study.** *Preprint*. Published online February 18, 2021. doi:10.21203/rs.3.rs-205442/v1

Extract. « *According to the present study, due to the reported substandard ABHSs [alcohol-based hand sanitizers] products in the market, getting the product with approved quality was becoming a major problem. The respondents mostly purchased from pharmacy 50 (52.1%), shop 11 (11.5%), another area 1, and obtained from their institution 34 (35.4%).* »

Davlanges E, Tippins A, Espinosa C, et al. **Mitigating SARS-CoV-2 Transmission in Hispanic and Latino Communities—Prince William Health District, Virginia, June 2020.** *J Racial Ethn Heal Disparities*. Published online February 4, 2021:1-9. doi:10.1007/s40615-021-00968-y

Extract. « *However, 46% of survey respondents reported difficulty adhering to COVID-19 prevention practices. Most commonly reported difficulties were an inability to social distance at work (27%) or at essential service providers such as grocery stores or laundromats (17%). An additional constraint reported was procuring masks, gloves, disinfectants, and other cleaning*

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<sup>5</sup>Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe disclaimer and caveats. Web Page. Published 2020. Accessed March 18, 2021. <https://www.iddo.org/medicine-quality-monitoring-globe-disclaimer-and-caveats>

<sup>6</sup>Infectious Diseases Data Observatory. Medical Product Quality Reports. Medical Product Quality Reports. Published 2020. Accessed March 18, 2021. <https://www.iddo.org/mq/research/medical-product-quality-reports>

<sup>7</sup>MORU Tropical Health Network. Medical Product Quality Report - Covid-19 issues. Medicine Quality. Published 2020. Accessed March 18, 2021. <https://www.tropmedres.ac/research-areas/medicine-quality/medicine-quality>

supplies; qualitative evaluation participants described prolonged stockouts at local stores, price gouging, and poor-quality items for sale. Participants compensated for this by reusing items they knew should not be reused (disposable masks and gloves) and substituting with household materials (vinegar as disinfectant, pantyliners as mask filters). »

Dellasega M, Vorrath J. **A Gangster's Paradise? Transnational Organised Crime in the Covid-19 Pandemic.** *Stift Wiss und Polit - SWP.* 2020;(66):1-9.

doi:10.18449/2020C66

Abstract. « *Since the outbreak of the Covid-19 pandemic, certain illegal business practices, such as the trade in counterfeit medical products, have been experiencing a boom. Other typical sources of income for organised crime (OC) temporarily dried up due to lock-downs, travel restrictions and border closures. With the changing infection dynamics and increasingly localised countermeasures, the situation has demanded constant adaptation from many businesses – and criminal organisations are no exception. The effects of the pandemic on OC are not only short-lived, however: the economic, social and political consequences can also impact OC in the medium term. In addition to shifts in illegal (drug) markets, the potential for criminal exploitation could increase as a result of the health crisis and the influence of criminal groups on the state and society could grow. Some of these developments are already visible. The associated risks require increased scrutiny by political decision-makers and law enforcement agencies and more targeted international cooperation.* »

Dyer C. Covid-19: **Government wasted millions on poor quality PPE, spending watchdog finds.** *Br Med J.* 2021;372:n399. doi:10.1136/bmj.n399

Extract. « *The UK government wasted hundreds of millions of pounds of taxpayers' money on poor quality and unusable personal protective equipment (PPE) while leaving frontline workers insufficiently protected from covid-19, the parliamentary public spending watchdog has concluded.[...] The report highlighted "the appalling situation of staff having to care for people with covid-19 or suspected covid-19 without sufficient PPE to protect themselves from infection." The committee heard "compelling evidence from organisations representing frontline workers that stocks ran perilously low, single use items were reused, some was not fit for purpose—including reports of expired, substandard, deficient or even insect-infected supplies—and staff were in fear that they would run out.* »

Forouzandeh P, O'Dowd K, Pillai SC. **Face masks and respirators in the fight against the COVID-19 pandemic: An overview of the standards and testing methods.** *Saf Sci.* 2021;133:104995. doi:10.1016/j.ssci.2020.104995

Abstract. « *The COVID-19 outbreak has resulted in a shortage of personal protective equipment (PPE) throughout the world. This shortage has resulted in an increase in production of PPE to meet the demand, and as a result, several substandard equipment has entered the market. With face masks and respirators now beginning to see widespread use throughout the world, the standards and test with which they are required to undertake have become points of interest. The filtration efficiency of the masks is a key testing element that examines its ability to filter particles, bacteria and viruses; this examines the penetration efficiency percentage of each with lower results being preferable. Masks are also subjected to NaCl testing method, which allows a range of particle sizes to be examined and their penetration to be observed. The masks must also show considerable resistance to fluids and flames, to prevent the penetration of liquids and to be non-flammable. Various PPE testing protocols such as biological, chemical, fluid and flame resistances, protective ensemble, facepiece fit testing, NIOSH NaCl method and impact protection have been discussed. In addition, various tests involving bacterial and viral filtration efficiencies are also discussed. Differential pressure is examined to ascertain the comfort, airflow and breathability of the masks, whilst fit testing is examined to ensure a correct fit of the mask.* »

Ippolito M, Ramanan M, Bellina D, et al. **Personal protective equipment use by healthcare workers in intensive care unit during the early phase of COVID-19**

**pandemic in Italy: a secondary analysis of the PPE-SAFE survey.** *Ther Adv Infect Dis.* 2021;8:1-10. doi:10.1177/2049936121998562

Extract. « *The Chinese outbreak caused a lack of supplies in non-producer countries, like Italy, and this could explain the need for an extended use of PPE, in order to prevent stock failures. Avoiding shortages of supplies is pivotal, especially during public health emergencies, when risky phenomena, such as counterfeiting or use of unregistered PPE, may rapidly spread and further reduce safety.* »

**Jung J. Preparing for the Coronavirus Disease (COVID-19) Vaccination: Evidence, Plans, and Implications.** *J Korean Med Sci.* 2021;36(7).

doi:10.3346/jkms.2021.36.e59

Extract. « *Major countries are operating vaccine safety monitoring systems, but are strengthening their organizations and systems specifically to respond to COVID-19. The United States has already established a surveillance system, such as V-safe, and the baseline of adverse reactions is constantly being monitored and measured through the vaccine safety datalink. The UK collects vaccine adverse events through the 'yellow card scheme' and has created a specialized internet-based reporting tool for COVID-19. [...] The Yellow Card Scheme, The Medicines and Healthcare products Regulatory Agency: The system collects and monitors information on safety concerns about medicines, medical devices and e-cigarettes. This includes all adverse events as well as concerns related to product quality or counterfeit products. System contains COVID-19 yellow card reporting page.* »

**Oliver D. Covid-19: NHS trusts deny restricting PPE during pandemic.** *BMJ.* 2021;372:n442. doi:10.1136/bmj.n442

Extract. « *NHS trusts have denied issuing instructions to staff to restrict their use of personal protective equipment (PPE) during the pandemic, despite hundreds of reports from doctors that trusts did so last year. Trusts also denied that they had issued warnings to staff who had raised concerns about PPE supplies being inadequate, despite reports from doctors that this had happened, an investigation by The BMJ has found. Many trusts said that they had reminded staff periodically of the need to adhere to locally adopted national guidelines from national organisations such as Public Health England over PPE specification and to use PPE wisely or appropriately. The UK parliamentary public spending watchdog reported this week that the government had wasted hundreds of millions of pounds on poor quality and unusable PPE that left frontline workers insufficiently protected from covid-19.* »

**Rahaman MM. Deconstructing free trade: An analysis of the implications of the disruption on global medical supply chains during the COVID-19 crisis.**

Published online 2020. Accessed March 17, 2021. <https://www.diva-portal.org/smash/get/diva2:1522359/FULLTEXT02.pdf>

Extract. « *Another problem emerging from the affected medical supply chain is the proliferation of falsified and substandard medical products. A decreasing supply of medical products coupled with a worsening pandemic created a problem of a sudden increase in inferior medical products. [...] Panic buying present opportunities for fraudsters to fill the gap between overwhelming demand and shortage of supply. The pandemic has made it incredibly easy for fraudsters to get away with and profit from falsified medical products. Some of the scammers include new suppliers who had previously been denied government authorization. The urgency of the problem and the inability to travel to fields of operations for quality audits to expose health systems to fake medical products. At the same time, while government regulators may be conscious of these risks, political pressure to deliver goods often lead to fast-tracked approval of products. [...] The insights outlined in this section have demonstrated the vulnerabilities of developing countries in accessing Covid-19 health supplies. After lagging behind their counterparts during the initial response to the pandemic, they are now at risk of being left behind in access to vaccines. As such, this literature has demonstrated the need for aligning international trade and global supply chains with their health improvement initiatives.* »



Valcheva KS. **Prosecution and public awareness: key lines of defence against falsified medicinal products during pandemic.** Knowl - Int J. 2020;40(1):279-284. Accessed March 12, 2021. <https://ikm.mk/ojs/index.php/KIJ/article/view/3895/3745>

Extract. « *The medicinal shortages combined with the lack of awareness in the society pose serious threat as panicked people turn to unauthorised and dangerous sources to buy pharmaceuticals and medical products. Their irrational and dangerous behaviour facilitate and significantly contribute to the uncontrolled spread of fakes as Internet provides perfect conditions for the unscrupulous dealers. The public is overwhelmed by a constant flow of disinformation that contain misleading and potentially dangerous recommendations and online offers for —miracle curesll. The disrupted legitimate supply chains provide further options for illegal structures to exploit the fear of the society and profiteer from the global crisis. [...] If policymakers engage more actively to strengthen their legal and regulatory frameworks against falsified medicinal products, their efforts would result in better preparedness and response in case of future health crises and in increased trust in governments and healthcare systems.* »

Additional publications from prior to February 2021

Jairoun AA, Al-Hemyari SS, Shahwan M. **The pandemic of COVID-19 and its implications for the purity and authenticity of alcohol-based hand sanitizers: The health risks associated with falsified sanitizers and recommendations for regulatory and public health bodies.** *Res Soc Adm Pharm.* 2021;17(1):2050-2051. doi:10.1016/j.sapharm.2020.04.014

Abstract. « *With the beginning of the pandemic of COVID-19 throughout the world, the demand and consumption of hand sanitizers has increased, which had led to a sharp crunch in these products at all levels. This shortage has led to an increase in the prevalence of falsified alcohol-based hand sanitizers, including the illegal addition of methanol to hand sanitizers and the production of hand sanitizers with an alcohol concentration of less than 60%. These findings indicate that regulatory and public health bodies should take an active role in ensuring the safety and quality of antimicrobial products such as alcohol-based hand sanitizers at every stage of the products' lifecycle, including distribution, manufacture and import.* »

## **B. Seizures/Surveys/Case Reports/Reviews**

[Preprint] Bracci A, Nadini M, Aliapoulios M, et al. **Dark Web Marketplaces and COVID-19: The vaccines.** Published online February 26, 2021. Accessed March 11, 2021. [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3783216](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3783216)

Abstract. « *The ongoing COVID-19 vaccination campaign has so far targeted less than 3% of the world population, and even in countries where the campaign has started many citizens will not receive their doses for many months. There is clear evidence that previous shortages of COVID-19 related goods (e.g., masks and COVID-19 tests) and services pushed customers, and vendors, towards illicit online trade occurring on dark web marketplaces. Is this happening also with vaccines? Here, we report on our effort to continuously monitor 102 dark web marketplaces. By February 26, we found 33 listings offering a COVID-19 vaccine, seven of which offering officially approved vaccines. The number of currently active listings is 11, including one listing selling the Pfizer/BioNTech vaccine, one listing the AstraZeneca/Oxford vaccine, and 9 listings selling vaccines of unspecified type. Illicit trade of uncertified COVID-19 vaccines poses a concrete threat to public health and risks to undermine public confidence towards vaccination.* »

## 4. International organisations

Europol. **COVID-19 chiefs of police working group meets to talk pandemic and fighting crime threats** . Newsroom. Published February 15, 2021. Accessed March 5, 2021. <https://www.europol.europa.eu/newsroom/news/covid-19-chiefs-of-police-working-group-meets-to-talk-pandemic-and-fighting-crime-threats>

Extract. « *As the pandemic has changed the landscape of crime, law enforcement has had to adapt their approaches to the accelerated shifts in criminal modi operandi and market focus. The COVID-19 chiefs of police working group is an important initiative for law enforcement agencies to work together in monitoring the situation and coordinating the appropriate responses. [...] Some of the priority areas discussed: the risks of criminals taking advantage of vaccination campaigns rolling out across the world to sell fake vaccines. Although still limited, some offers of fake vaccines have appeared on the dark web.* »

European Anti-Fraud Office. **OLAF warns against fraudsters offering COVID-19 vaccines**. Press release No7/2021. [https://ec.europa.eu/anti-fraud/media-corner/news/15-02-2021/olaf-warns-against-fraudsters-offering-covid-19-vaccines\\_en](https://ec.europa.eu/anti-fraud/media-corner/news/15-02-2021/olaf-warns-against-fraudsters-offering-covid-19-vaccines_en). Published February 15, 2021. Accessed March 10, 2021.

Extract. « *The European Anti-Fraud Office (OLAF) has warned governments to be on their guard against offers to provide them with COVID-19 vaccines. These offers are very often fake, and should be reported. [...] We are hearing reports of fraudsters offering to sell vaccines to governments across the EU. These offers come in many different forms. For example, fraudsters may offer to sell large quantities of vaccines, deliver a sample in order to pocket the first advance payment and then vanish with the money. They may deliver batches of fake vaccines. Or they falsely may purport to represent legitimate business and claim to be in the possession of or have access to vaccines.* »

An additional publication from prior to February 2021

European Anti-Fraud Office. **OLAF investigation keeps dangerous hand sanitiser off the shelves**. Media corner. Published December 15, 2020. Accessed March 29, 2021. [https://ec.europa.eu/anti-fraud/media-corner/news/15-12-2020/olaf-investigation-keeps-dangerous-hand-sanitiser-shelves\\_en](https://ec.europa.eu/anti-fraud/media-corner/news/15-12-2020/olaf-investigation-keeps-dangerous-hand-sanitiser-shelves_en)

Extract. « *Almost 140,000 litres of hand sanitiser have been seized so far in the European Union thanks to information provided by the European Anti-Fraud Office (OLAF). The hand sanitiser originated from Turkey and contained dangerously high levels of methanol.* »

## 5. Miscellaneous

Taylor D. **Experts Warn Crime Gangs Capable of Selling Fake Vaccines**. Voanews. <https://www.voanews.com/covid-19-pandemic/experts-warn-crime-gangs-capable-selling-fake-vaccines>. Published February 26, 2021. Accessed March 12, 2021.

Extract. « *International crime fighting agencies say organized crime groups have all the networks and methods needed to smuggle falsified, substandard and stolen COVID-19 vaccines across Africa. [...] Meyer says there won't be enough vaccines, and as infection rates and deaths spike in some countries, criminals will introduce fakes into supply chains. [...] Ho Tu Nam said criminal organizations have been waiting eagerly for immunization programs to start, and for vaccine shortages. "Now people are aware that the vaccine exists; people know it's being rolled out in certain countries, and I think it's a perfect time for those syndicates to come in and say, 'We have the vaccine; you're not getting it in the hospitals, you're not getting it in your private clinics, so come to us.'" she said. And they have been successful in the past. Schneider says groups dealing in black market vaccines do their best to make their products look legitimate.* »

## 6. Lay literature

### 6.1 Disclaimer & Notes

The information included below is based on the data used to create the Medicine Quality Monitoring Globe<sup>8</sup> (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](#)<sup>9</sup>.

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](#)<sup>10</sup>. 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 of 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) Ventilation equipment. Only the relevant articles included in the MQM Globe-reports are selected for the current COVID-19 report.

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

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<sup>8</sup>Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe. Web Page. Published 2020. Accessed March 18, 2021. <https://www.iddo.org/medicine-quality-monitoring-globe>

<sup>9</sup>Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe disclaimer and caveats. Web Page. Published 2020. Accessed March 18, 2021. <https://www.iddo.org/medicine-quality-monitoring-globe-disclaimer-and-caveats>

<sup>10</sup>Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe methodology. Web Page. Published 2020. Accessed March 18, 2021. <https://www.iddo.org/medicine-quality-monitoring-globe-methodology>

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<sup>11</sup>, 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.

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](mailto:medicinequality@iddo.org)).

### **Changes in methodology since the last Medical Product Quality Report - COVID-19 issues (January 2021)<sup>12</sup>**

There are no changes in methodology since the last 'Medical Product Quality Report – COVID-19 issues' in January 2021. Please read more about the changes in methodology since the first report that was published in July 2021 in Annex A.

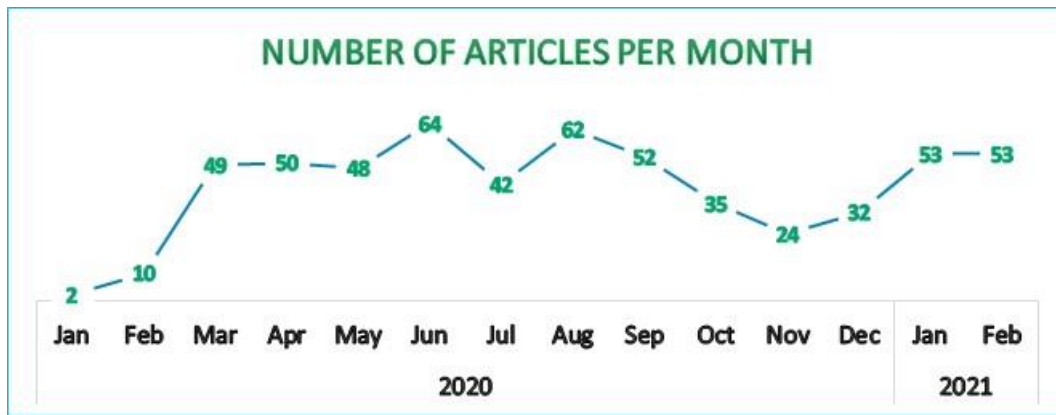
## **6.2 Articles on substandard or falsified medical products for COVID-19: main characteristics**

Since the beginning of the pandemic we have identified 576 relevant articles on quality problems of COVID-19 medical products (Figure 1). For February 2021, we report on 55 articles. Within those articles, 2 alerted on diagnostics, 8 on hand sanitisers and disinfectants, 9 are linked to COVID-19 related treatments, 12 to personal protective equipment (PPE) and 24 to vaccines (Figure 2 and 3). There were no articles detected for ventilation equipment.

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<sup>11</sup>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>

<sup>12</sup>Infectious 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>

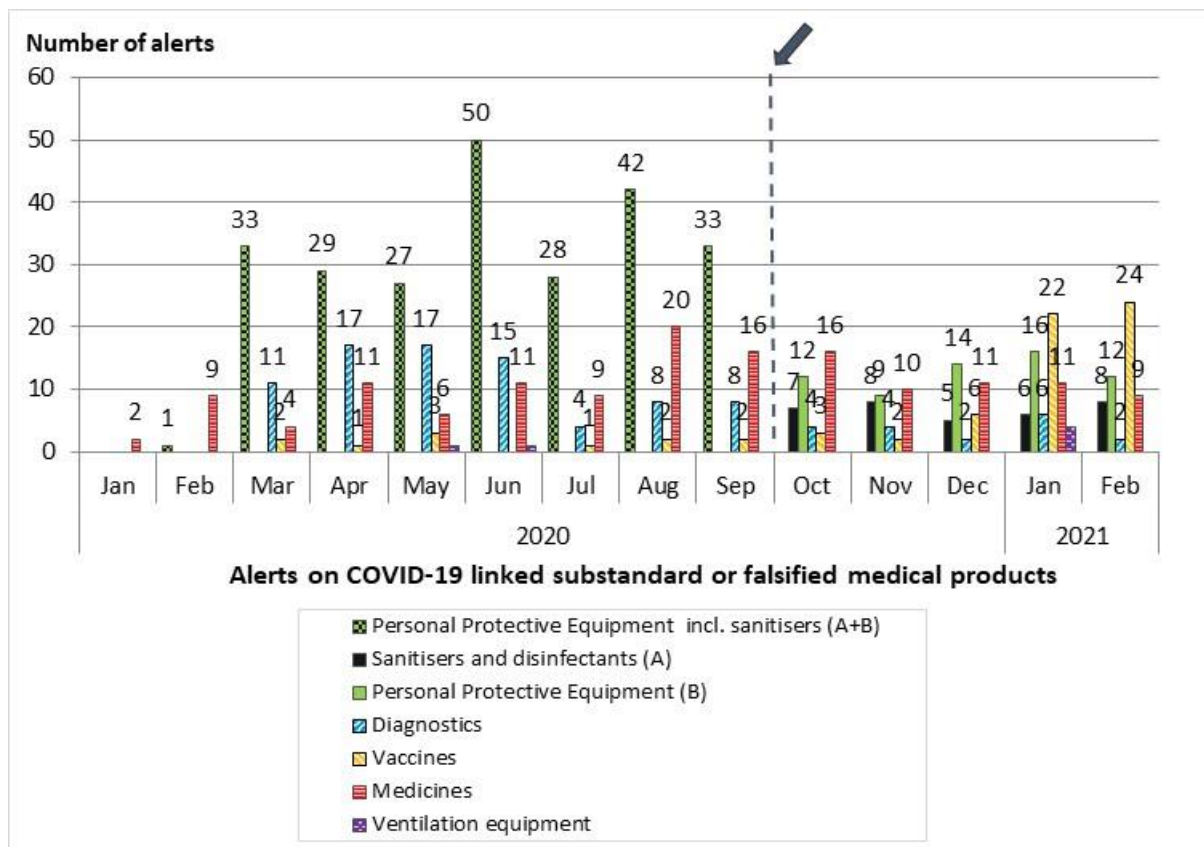


**Figure 1. Number of articles on the Medicines Quality Monitoring Globe linked to substandard or falsified COVID-19 supplies by month.**

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.



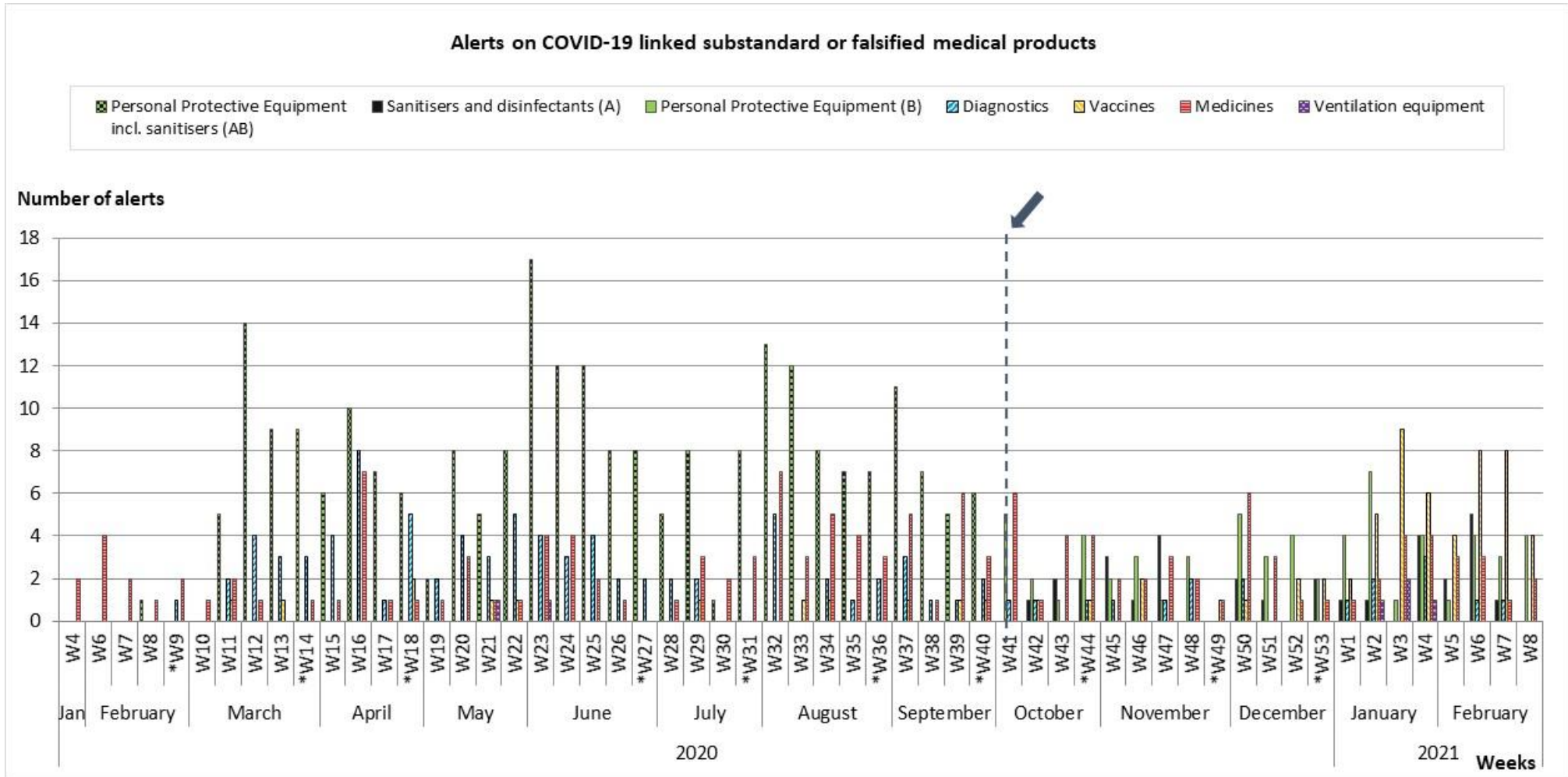
**Figure 2. Number of alerts on the Medicines Quality Monitoring Globe by category of products and by month.**

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.





**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. THE FIGURE STARTS IN WEEK 4, MONDAY 20<sup>TH</sup> OF JANUARY, 2020 AND ENDS ON WEEK 8, SUNDAY 28<sup>TH</sup> OF FEBRUARY, 2021. 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

Two articles reported on potentially degraded vaccines in the USA. One article reports on the number of COVID-19 vaccine doses that were lost in Pima County (report ID 956586). Amongst those vaccines, 20 doses were lost due to “*failure to store properly*” and 100 doses due to a problem with a temperature sensor. In California there was a problem with the refrigeration overnight due to an apparent human error (report ID 933403). Officials did not confirm the quantity of doses affected but it may have been up to 6,000 Pfizer doses. The help of the manufacturer was sought to determine if the vaccine could still be used. We have not seen information on the outcome of the investigation.

### Thefts

In February 2021 5 cases of stolen COVID-19 vaccines were reported. In a medical centre in Greece, police are investigating a case where a vial containing six doses of the COVID-19 Pfizer/BioNTech vaccine disappeared (report ID 948981). Four alleged cases were in the USA. In the first case, on the 3th of February, a car containing 30 vials<sup>13</sup> of COVID-19 vaccines was stolen in Plant City (report ID 936924). The second occurred in St-Petersburg, where a firefighter was under investigation for the theft of COVID-19 vaccine vials (report ID 936941). The third is a case in Knox County where approximately 1,000 Pfizer/BioNTech doses went missing; but according to the mayor of the county the missing box might have never been shipped by Pfizer (report ID 943453). Pfizer claims having shipped the vaccine and allegedly upon delivery the box was signed off. Finally, an article reports on vaccine management issues in Shelby County (report ID 957718). The state of Tennessee is investigating the case and allegedly COVID-19 vaccine doses might have been stolen.

### Seizures of falsified COVID-19 vaccine

On the 3th of March Interpol published a press alert on two investigations that were supported and facilitated by Interpol and for which we found articles, published in February, in the MQM Globe<sup>14</sup>. First, in South Africa, law enforcement agencies raided two warehouses in Gauteng and found COVID-19 vaccines without the necessary approval (report ID 945211). This incident might be related to the one described in the December issue of the report (report ID 865724) but with the available information in the articles it is not clear if this article mentions an additional warehouse or if it is referring to the same event. Approximately 2,400 falsified COVID-19 vaccine doses, in around 400 vials, were seized. Secondly, in China 80 people were arrested and accused of selling falsified COVID-19 vaccines in Beijing, Jiangsu and Shandong (report ID 918486). Three thousand pre-filled saline syringes

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<sup>13</sup> Report ID 936924 states “30 doses”, however several other articles in the lay press reporting on the same incident mention “30 vials”.

<sup>14</sup> Interpol. Fake COVID vaccine distribution network dismantled after INTERPOL alert. News. Published March 3, 2021. Accessed March 3, 2021. <https://www.interpol.int/en/News-and-Events/News/2021/Fake-COVID-vaccine-distribution-network-dismantled-after-INTERPOL-alert>

were seized. Interpol stated that they believed that it is only the tip of the iceberg of COVID-19 vaccine crime.

In November 2020, the Chinese police were reported to have detained several suspects linked to production and distribution of approximately 58,000 doses of falsified COVID-19 vaccines (report ID 932609). The falsified vaccines consisted of saline solution and allegedly several doses were transferred to Hong Kong. A first batch of 600 doses arrived on the 11<sup>th</sup> of November 2020 and were allegedly shipped overseas. A second shipment with 1,200 doses arrived on November 12<sup>th</sup> in Hong Kong but were subsequently destroyed.

On February 11, a shipment of vaccines labelled as the Moderna COVID-19 vaccine arrived in the Philippines (report ID 939722). The Philippine FDA started an investigation since they believed that the products were falsified, since Moderna did not commit to send a shipment and the company previously said it was not able to supply until June or July 2021. In Colombia, a Chinese couple was arrested upon arrival at the Colombia's El Dorado International Airport and a cooler box with 70 vials of COVID-19 vaccines was seized (report ID 947830). The vials were labelled as "*manufactured by the Chinese Academy of Medical Sciences, from Kunming, China*", which developed the Vero cell COVID-19 vaccine. It is unclear if the vaccines were genuine or falsified products but the couple were fined for importing an unregistered product.

### **Injection of purported COVID-19 vaccines**

In India a nursing student injected an elderly couple with an unknown chemical at their home and stole their jewellery (report ID 940683). The nursing student told the couple she was able to obtain the vaccine because she worked as a nurse. In Brazil, health care workers allegedly inoculated elderly people with fake COVID-19 vaccine doses, using empty syringes (report ID 944701). At least three cases have been reported of "*shots of air*" instead of genuine vaccine doses and police started an investigation. Several senior officials in Ukraine have allegedly paid 4,700 USD to receive a COVID-19 vaccine (report ID 950068). It is thought to have been the Pfizer/BioNTech vaccine that might have been imported by Israeli organised crime groups.

### **Illicit sales**

In the previous Medical Product Quality Report we reported on findings of the cyber security company Check Point on the rise of COVID-19 vaccines on the dark web. In February an article provided some examples of what is found on the dark web (report ID: 929197): 300 USD for 14 doses; 30,000 USD for 10,000 vials; one seller is using a picture of a 'sample' vial with an expiration date in December 2020; 1,500 USD for four doses of a 'Chinese vaccine'.

In January, the Mexican medicine regulatory authority, Cofepris, reported on the illicit sales of Pfizer/BioNTech and Moderna vaccines. In February they reported illicit sales of the AstraZeneca vaccine (report ID 924171). Another article in February, reported on six men being arrested in Mexico for allegedly trafficking falsified Pfizer/BioNTech vaccines and selling them for approximately 2,000 USD per dose (report ID 944948). In the Philippines a group of doctors from the Healthcare



Professionals Alliance Against Covid-19 (HPAAC) warned in an article against diverted or falsified medicines (report ID 930157). Allegedly COVID-19 vaccines are illegally sold in “*online chat groups, workplaces, and even in neighbourhoods across Metro Manila*”. Belgian authorities received reports of falsified COVID-19 vaccines offered to the population, allegedly most of them were Russian vaccines (report ID 942342). All the above mentioned authorities warn that people should not buy vaccines through the private sector in shops, on the streets or online and stress the importance of relying on the government distribution systems.

Not only individual patients are lured into buying falsified vaccines. National and regional authorities, responsible for the procurement of vaccines are also targeted. The Ministry of Health of Trinidad and Tobago has been offered falsified and extremely high-priced COVID-19 vaccines (report ID 951551). In mid-February the European Anti-Fraud Office (OLAF) warned against falsified COVID-19 vaccines and said criminals are also approaching national authorities with falsified products (report ID 941124). At the end of February an article reported that criminals have allegedly offered, altogether, 400 million doses of COVID-19 vaccines to European Union countries (report ID 955619). Most of the offers concern vaccines labelled as from AstraZeneca. It remains unclear if the offers concern diverted genuine vaccine doses or falsified non-vaccine solutions. In Italy, the police are investigating several cases of people trying to sell COVID-19 vaccines outside the European Union procurement system (report ID 947669): a regional official was offered 27 million doses of the Pfizer/BioNTech, Russian or Chinese vaccines to buy; someone tried to sell AstraZeneca vaccines to regional officials, claiming to be a representative of the company.

### **Another worrying phenomena: hacking COVID-19 vaccine data**

In addition to the incidents on SF COVID-19 vaccines registered by the MQM Globe, several articles were published in February 2021 on South Korea intelligence officials stating that North Korea tried to steal Pfizer/BioNTech COVID-19 vaccine and treatment technology from Pfizer<sup>15</sup>. We did not find details as to whether the alleged attempt was successful.

## **6.4 COVID-19 diagnostics**

For the month of February we only found 2 reports highlighting SF issues with COVID-19 test kits. In March 2020, OLAF, the European Anti-Fraud Office, opened an investigation on falsified COVID-19 protection products. In the last year OLAF reports seizing over 14 million COVID-19 supplies, including falsified test kits (and masks) (report ID 941124). In Zimbabwe an article reported on substandard COVID-19 test kits being imported from China and entering the market, showing only a 20% accuracy rate (report ID 934414). Normally tests are submitted to an evaluation by

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<sup>15</sup> Denyer S. North Korea tried to steal Pfizer coronavirus vaccine information, South says. The Washington Post. [https://www.washingtonpost.com/world/asia\\_pacific/north-korea-pfizer-coronavirus-vaccine-hack/2021/02/16/c09ec7fc-702e-11eb-8651-6d3091eac63f\\_story.html](https://www.washingtonpost.com/world/asia_pacific/north-korea-pfizer-coronavirus-vaccine-hack/2021/02/16/c09ec7fc-702e-11eb-8651-6d3091eac63f_story.html). Published February 16, 2021. Accessed March 15, 2021.

the Medicines Control Authority of Zimbabwe (MCAZ) and the Medical Laboratory Scientists Council of Zimbabwe (MLSCZ) should also contribute to the evaluation. The COVID-19 tests allegedly bypassed the usual quality-checks. MLSCZ said that the Ministry of Health (MoH) took over the responsibility in the evaluation and validation of COVID-19 supplies without involving the MCAZ, but the MoH contradicted this.

## 6.5 Personal protective equipment

In March 2020, OLAF opened investigation on falsified COVID-19 protection products. In the last year they have seized over 14 million COVID-19 supplies, including falsified masks (and test kits) (report ID 941124).

One year into the pandemic governments continue having issues with SF personal protective equipment. In June 2020, the Belgian federal government procured 15 million cloth facemasks and had put them at the disposal of its population for free (report ID 956266). The masks were made by the Luxembourg firm Avrox in Asia. In February 2021, more than 8 months after the start of the distribution, health authorities warned the citizens to stop using those masks since they may contain toxic materials such as titanium dioxide and toxic nanoparticles of silver. Further evaluation of the Avrox masks is ongoing.

In Ontario, Canada, the provincial stockpile contained 'potential' falsified 3M N95 masks (report ID 957784). Some of the stock had already been distributed, thus the provincial government sent out a notification with lot numbers for health partners to verify their remaining stocks. The article also reports that according to the president of 3M Canada (Penny Wise): "*the company has been receiving increasing reports of fraud related to respirators in Canada*". In February 2021, 3M Canada allegedly received more complaints on falsified products compared to the first wave in the COVID-19 pandemic.

Throughout the month of February 2021 there were reports of falsified 3M masks in the USA. 3M continues to struggle with criminals targeting 3M products and putting falsified versions on the market. Wee report on six different articles in order of their date of publication. Firstly, 3M sent out a safety alert on several lot numbers used by criminals (report ID 928739). According to the Washington State Hospital Association, dozens of hospitals in Washington state were impacted and the hospitals were asked to put the masks in quarantine, waiting for the results of the 3M investigation.

A second article reported that Tower Health, a regional health system in Pennsylvania, received falsified 3M N95 model 1860 masks and is now recalling them (report ID 930096). Twelve percent of the masks were already distributed through its system to hospitals, outpatient facilities, urgent care centres, physician practices and home care division. The other masks were still in their stock and were removed.

A third article reported on a seizure of 1.7 million falsified 3M N95 masks in a warehouse in New York (report 934549). The masks were repacked with 3M branding and were ready for sale to health care workers; the manager of the warehouse has been arrested.

In mid-February, a fourth article reported on a seizure by Homeland Security agents of falsified 3M N95 masks which involved hundreds of thousands of masks in a warehouse on the US east coast (report ID 944494). Since details of the seizures are not always included, it is difficult to tell which articles are related to 'new' incidents and which articles are related to incidents that were already described in this or previous reports. In this regard, the article reports that the above mentioned seizure on the east coast is part of an investigation into falsified 3M masks that were sold in at least five states to hospitals, medical facilities and government agencies. The investigation led to seizure of approximately 10 million falsified N95 masks, by federal agents in recent weeks. Also the article reports that "*Investigators notified about 6,000 potential victims in at least 12 states including hospitals, medical facilities and others who may have unknowingly purchased knockoffs, urging them to stop using the medical-grade masks*".

A fifth article reports on the US Customs and Border Protection (CBP) seizing 108,000 falsified 3M surgical masks (report ID 969460). The 450 boxes were seized in Cincinnati and were destined for a company in Canada. The masks were allegedly imported from Hong Kong but were labelled as "*Made in the USA*".

At the end of February, a sixth article reported that 460,000 falsified 3M N95 masks were seized in the Seattle area (report ID 957577).

Two other articles on SF masks in the USA report on a different brand or did not mention the affected brand. In New Jersey, Ally Cosmetics Inc has been accused by BMY Global Sourcing for knowingly selling SF masks in April 2020 (report ID 930832). Allegedly the 320,000 medical-grade Chinese KN95 masks did not meet FDA requirements for use against the coronavirus. The state of Maine was affected by a national recall on N95 masks with falsification issues (report ID 937169). The state authorities had distributed approximately 161,000 masks of the affected batch to health care facilities, schools and state employees.

In the UK, an article reported on issues with FFP3 masks and gloves followed by the Department of Health and Social Care (DHSC) (report ID 961203). One week after the first safety alert, 1.2 million masks were withdrawn by the DHSC since the masks "*may not meet the required technical specifications*". The FFP3 masks were branded as 'Fang Tian' model FT-045 and allegedly provided by a distributor Polyco Healthline. The manufacturer Suzhou Fangtian Industries claims it never supplied those masks to Polyco Healthline.

The DHSC issued an alert on 'nitri-hand', non-sterile nitrile examination gloves. Since June 2020, Full Support Group supplied 27 million of these 'nitri-hand' gloves in the UK. When reading the packaging of the gloves, one might think the gloves are not tested for resistance to virus. However, the supplier Full Support Group claimed the gloves had passed the test and recognizes the packaging should have been updated accordingly.

## 6.6 Sanitisers and disinfectants

A factory producing falsified hand sanitizers was raided in Abu Dhabi, the United Arab Emirates (report ID 944290). Products were being allegedly relabelled with labels of “a *big international brand*”. All falsified products were seized and legal action was requested against the owners.

In the beginning of February an article reported that Health Canada was recalling fifteen hand sanitizers because they did not meet Health Canada’s requirements and may hold health risk to the user (report ID 924119). The reasons for recall were multiple, including improper labelling (expiry date placement, directions for use, etc), lack of necessary testing, presence of toxic products or ingredients that do not meet the required quality standards, or that some of the products are not authorised for sale in Canada or are falsified. Since June 2020 Health Canada has updated a list with affected products ‘Recall of certain hand sanitizers that may pose health risks’. By the end of February 2021, the list contained 147 entries providing detailed information on the affected product and reasons for recall<sup>16</sup>.

The US FDA sent warning letters to 1 Chinese and 5 Mexican companies concerning the quality of their hand sanitizers. The goods were detained and refused admission at the USA border because they were adulterated and not approved by the US FDA. Hand sanitisers from three companies (Mexico: Grupo Ycana Mexico, Precision Analitica Integral, and Botanicals International) had lower ethanol contents than stated and were contaminated with methanol: 70 to 75% stated ethanol but analysis showed the ethanol content ranged from 0,04% to only 40% v/v and the methanol from 28% to more than 75% v/v (report ID 920598, 931281 and 931284). The AAA Cosmetica (Mexico) product did not contain any ethanol but instead an average of 78-81% methanol v/v (report ID 931283). For two companies the hand sanitizers strength was below that stated: for Simex Logistics (Mexico) it contained 51% instead of 70% ethanol v/v, and for ShangRao Chungyu Technology (China) 58% instead of 75% (report ID 931286 and 931282). By the end of February 2021, the US FDA Do-Not-Use-List for hand sanitizers contained 230 entries with detailed information on the affected hand sanitizers.<sup>17</sup>

## 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 types of products even if for certain treatments the efficacy is not proven in the prevention or treatment of COVID-19 patients.

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<sup>16</sup> Health Canada. Recall of certain hand sanitizers that may pose health risks. Recalls and safety alerts. Published June 17, 2020. Accessed March 24, 2021. <https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2020/73385a-eng.php>

<sup>17</sup> United States Food and Drug Administration. FDA updates on hand sanitizers consumers should not use. Drug Safety and Availability. Published June 19, 2020. Accessed March 24, 2021. <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-consumers-should-not-use>

In the USA, a physician, serving as state representative of Missouri state, was charged with marketing of a falsified stem cell treatment allegedly useful in the treatment of various diseases, including COVID-19 (report ID 926267). She administered amniotic fluid that did not contain any type of stem cells to patients but the physician claimed it was a “*stem cell shot*” containing “*mesenchymal stem cells*”. The US FDA sent a warning letter to Dr. Paul’s Lab, a company offering ‘COVID-Aid Tincture’ online and claiming that it has activity against COVID-19 (report ID: 944261). The FDA said that the product is misbranded and not approved in the USA.

In two Indian states, falsified antibiotics that are being trailed for their use in COVID-19 were found. In Gujarat state, the Food and Drugs Control Administration (FDCA), raided a pharmaceutical company and found several violations (report ID 951239). The company was manufacturing falsified medicines and exporting them to Nigeria. They labelled the products with brands of other pharmaceutical companies such as ‘Exaclav-625 Co-Amoxiclav Tablet B.P’. Furthermore, they altered the manufacturing date. In Andhra Pradesh, drug inspectors found SF azithromycin 500mg tablets (report 953850). At least 10% of the samples did not contain any active ingredient. Some of the medicines were found to be manufactured by a company based in Uttarakhand. Following this finding, the Department of Drug Control started an investigation to determine how many shops in the state are selling falsified medicines.

A court in the United Arab Emirates found a pharmacist guilty for distributing falsified Viagra (sildenafil) tablets to several pharmacies (report ID 921825). The case came to light after a pharmaceutical company notified the Ministry of Health and Prevention. In the province of Gia Lai in Vietnam, two men were arrested for importing 20,000 falsified Viagra tablets from China into the country (report ID 958638). The men bought the tablets through Chinese social media and were planning to sell them on the local Vietnam market.

On two occasions, the US CBP seized sildenafil tablets that were illegally imported, although it is not allowed to bring in prescription medication that has been bought outside the USA. At the Chicago O’Hare International Airport, a man tried to bring in tablets from India claiming them to be for his friends (report ID 928775). The 3,200 tablets of Vigore representing a street value of approximately 100,000 USD were seized, but the man was not arrested. In Cincinnati, 17,400 falsified Viagra tablets were seized from a shipment of ‘herbal pasta’ coming from Istanbul, Turkey (report ID 936346). A South Korean man was found guilty of importing bulk sildenafil and tadalafil from China into the USA (report ID 931627). The man produced falsified erectile dysfunction drugs and distributed them through an illegal supply chain in liquor, gas and convenience stores. The products were mislabelled as medicines that need no prescription.

## 7. Annexes

### Annex A: Methodology changes for searches in the lay literature.

In section 6 ‘Lay literature’, we report on incidents that were reported in the lay press. In section 6.1 we briefly describe the methodology we apply to collect the lay press articles. Changes in methodology since the first ‘Medical Product Quality Report – Covid-19 issues’ are listed here below.<sup>18</sup>

#### Since the October 2020 issue

- Personal protective equipment (PPE), and sanitisers and disinfectants: alerts from January to September 2020 in the PPE category included sanitisers and disinfectants. From October 2020 onwards, we created two distinct categories: sanitizers/disinfectants and other PPE.
- Key terms used to generate the Globe-reports: key 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.

#### Since the November 2020 issue

- COVID-19 medicines: 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/alerts over time may at least partially be due to this change.

#### Since the January 2021 issue

- COVID-19 vaccines:
  - Search terms used for Google News scraping: 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.
  - Inclusion of reports: scams and fraudulent claims are included in the 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 fraudulent claims of efficacy.
- Ventilation equipment: We include incidents related to ventilation equipment in the overall article count. In the first Medical Product Quality Report, we

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<sup>18</sup>Infectious 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>

reported on two incidents with ventilators (one in May and one in June 2020) but they were not included into the overall count in subsequent reports. From the January 2021 issue onwards the figures for ventilation equipment are included, including those incidents in May and June 2020).

## **Annex B: Medicine Quality Monitoring Globe reports containing report ID**

Annex B contains the reports generated by the Medicine Quality Monitoring Globe (MQM Globe) using pre-defined search terms for each of the product categories. 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<sup>19</sup>, containing the annexes, and/or consult the online MQM Globe<sup>20</sup>, introducing "reportID:XXXXXX" in the search box.

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<sup>19</sup>Infectious 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>

<sup>20</sup>Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe. Web Page. Published 2020. Accessed March 3, 2021. <https://www.iddo.org/medicine-quality-monitoring-globe>