

Medical Quality Product Report - COVID-19 issues

Issue 12. Data from June & July 2021

Part A: COVID-19 vaccines

Part B: Other COVID-19 related medical products:

- Diagnostics
- Personal Protective Equipment
- Sanitisers & disinfectants
- Medicines
- Ventilation & oxygenation equipment and consumables

MORU 
Tropical Health Network



IDDO 
INFECTIOUS DISEASES DATA OBSERVATORY

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Summary of findings

Since the beginning of the pandemic we have identified 845 relevant articles on quality problems with COVID-19 medical products in the English lay press. In this issue we report on 104 reported incidents during the months of June and July 2021. All concern incidents with products that were reported as substandard, falsified, diverted, unregistered or of unclear quality that are present in the Medicine Quality Monitoring (MQM) Globe.

Part A of the report covers incidents with COVID-19 vaccines. Between 12th March 2020 and 31st July 2021 we found, excluding duplicates, 150 reports of incidents on quality issues with COVID-19 vaccines linked to 41 different countries and/or online. In June and July 2021, 27 new incidents were reported. The number of incidents reported per month remains stable compared to April and May. For the first time quality issues were reported in Iran, Lebanon, Russia, Thailand, Uganda and Canada. Ten incidents involved falsified COVID-19 vaccines including products labelled as made by Pfizer/BioNTech (3), Covishield (3), Oxford-AstraZeneca, Moderna, Sinopharm, and Sinovac. Seven incidents were related to diversion of COVID-19 vaccines out of the regular supply chain. Finally, 5 incidents involved substandard vaccines and for 5 incidents the type of quality issue was unclear.

Part B of the report covers incidents with other COVID-19 medical products including diagnostics, Personal Protective Equipment, sanitisers & disinfectants, medicines, and ventilation & oxygenation equipment and consumables. The overall number of incidents decreased in May and June. This was linked to fewer reports on diverted, substandard or falsified remdesivir in India and to a smaller extent due to less reports on ventilation & oxygenation equipment and consumables. In mid-May Operation Pangea XIV, involved 92 countries, resulted in 277 arrests and seizures of large volumes of medical products. This Interpol led international effort tries to disrupt the illegal online sale of medicines and medical products. As was the case for last year's operation, this operation showed that criminals are continuing to cash in on the demand for test kits, personal protection and hygiene products generated by the COVID-19 pandemic. Falsified and unauthorized COVID-19 testing kits accounted for more than half of all medical devices seized.

We remain very concerned about the global risk of substandard or falsified COVID-19 medical products, especially vaccines and medicines. We continue to share data from the MQM Globe, that can serve as early warning system for potential SF quality issues.

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 diverted, 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 report aims to collate information and reports in the public domain on the quality of medical 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.

The current report consists of two parts. Part A contains the information related to COVID-19 vaccines. Part B contains information related to the other COVID-19 medical product categories including diagnostics, personal protective equipment (PPE), sanitisers & disinfectants, medicines, and ventilation & oxygenation equipment and consumables. The report aims to aid national medicine regulators, international organizations, manufacturers and distributors, and civil society by summarising the current public domain literature, to inform action and policy.

The reports presented here were mostly extracted from the Medicines Quality Monitoring Globe ([the MQM Globe is accessible on the IDDO website](#)¹), a system that scrapes online newspapers (referenced in Google News) for early warnings of SF medical products. This report also includes scientific literature and policy documents related to COVID-19 medical product quality identified by manual searches in PubMed (Central) and Google Scholar. 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 twelfth issue of the 'Medical Product Quality Report – COVID-19 Issues' covers information published during the months of June and July 2021. Previous issues covered publications from January 1st 2020 onwards and are available on the IDDO² and MORU³ websites.

We have recently released a system to easily access regulatory authority and international organisation websites for alerts – see the 'Regulatory & alert webpages'

¹Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe. Web Page. Published 2020. Accessed July 22, 2021. <https://www.iddo.org/medicine-quality-monitoring-globe>

²Infectious Diseases Data Observatory. Medical Product Quality Reports. Medical Product Quality Reports. Published 2020. Accessed July 22, 2021. <https://www.iddo.org/mq/research/medical-product-quality-reports>

³MORU Tropical Health Network. Medical Product Quality Report - Covid-19 issues. Medicine Quality. Published 2020. Accessed July 22, 2021. <https://www.tropmedres.ac/research-areas/medicine-quality/covid-19-pandemic>

section on our [MQM Globe](#). Any remarks or additions to content are greatly appreciated (please write to medicinequality@iddo.org).

1. Key terminology

In this report we refer to the terminology for different types of poor quality medical products as defined by the World Health Organisation (WHO, 2017)⁴. When coming across quality issues in the lay press we first try to categorise the products as 'falsified', 'substandard' and 'unregistered/unlicensed'. However, when dealing with lay press articles, it is sometimes hard to judge and difficult to classify the quality issues for products discussed in the different articles, very often because not enough detail is known or described in the report. Therefore when not clearly belonging to one of the above groups, we further use the concepts of 'substandard or falsified' (SorF), 'diverted', or 'unclear'. Please see Table 1 for our working definitions.

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'⁵ and 'pirated copyright goods'⁶ as used in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement.

When the concept of 'black market' is used in lay press articles, we notice that the use depends on the personal interpretation of the author: it might refer to products that are illegal in themselves, it might be people trying to avoid taxes, or avoiding government price controls. The products involved can be good quality, substandard, falsified, or of unknown quality. We nevertheless report on them. We argue that products sold on the black market are a problem for the following reasons. Firstly, they are taken from people that are supposed to receive the product. Secondly, products on the black market, such as vaccines and medicines, risk degradation due to improper handling and storage. Currently, articles do not provide evidence on degradation of products on the black market since it is not something that is investigated at the moment. In this report, we will classify black market sales as products for which the quality is 'unclear' when it is not specified in the article or report as falsified, substandard, or a genuine products.

⁴Source: 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

⁵*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

⁶*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 July 22, 2021. https://www.wto.org/english/docs_e/legal_e/27-trips_05_e.htm#fnt-14

Table 1. Key terminology for quality issues used in this Medical Product Quality Report

Falsified	<p>‘Falsified’ refers to products that ‘deliberately/fraudulently misrepresent their identity, composition or source’ (WHO, 2017). In this report, ‘fake’, ‘counterfeit’, ‘spurious’ and ‘falsely labelled’ medicines are regarded as synonyms or part of the group of falsified products.</p>
Substandard	<p>‘Substandard’ also called ‘out of specification’, are authorised medical products that ‘fail to meet either their quality standards or their specifications, or both’ (WHO, 2017). This may result from negligence or errors during the manufacturing process by authorised manufacturers, or degradation through deterioration because of inappropriate storage/transport in the supply chain. Information is usually insufficient to distinguish errors within factories from those in the supply chain, a key evidence gap as the solutions for the two differ.</p>
Unregistered or Unlicensed	<p>‘Unregistered/unlicensed’ medical products 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 (WHO, 2017).</p>
When the above concepts are not applicable	
Substandard or Falsified	<p>‘Substandard or Falsified’ (SorF) was suggested by Saraswati et al. 2019⁷ because it is not possible to reliably classify a medicine as substandard or falsified without packaging analysis. It is used for products that failed at least one quality test without information on packaging authenticity, and falling outside the acceptance range of the specifications chosen as reference by the authors (either specific pharmacopoeia monograph or in-house specifications). In lay press articles the concepts of substandard and falsified products might be wrongly used, as a cautionary approach SorF is used when the information is not sufficient to make the distinction.</p>
Diverted	<p>‘Diverted’ medical products in this report are viewed as legitimate products that have been diverted outside the controlled supply chain. Theft is only one example of diversion. Due to loss of custody, diverted products are generally considered as poor quality medical products as, aside from harming the intended recipients, the products risk degradation due to inappropriate storage and transport.</p>
Unclear	<p>‘Unclear’ quality of medical products is a concept used in this report when there is insufficient information available to judge in which of the previously described category the product falls. These medical products can be good quality, substandard or falsified or of unknown quality. For example some reports discuss about suspicious online offers on the surface or dark web. Often the quality of the products is not known and from the article it is not clear if the product is for example diverted or counterfeit, though the origin and criminal intent of these products slightly differ.</p>

⁷ Saraswati K, Sichanh C, Newton PN, Caillet C. Quality of medical products for diabetes management: a systematic review. *BMJ Glob Heal.* 2019;4(5):1-14. doi:10.1136/BMJGH-2019-001636

2. Methodology for reporting on the lay literature

The reports presented in the sections on 'Articles of incidents in the lay literature' were extracted from the 'Medicine Quality Monitoring Globe'⁸ ([MQM Globe](#)). The MQM Globe contains publicly available information on the quality of medical products from non-peer-reviewed lay literature and serves as early warning system. Any article describing recalls, seizures, degradation, adulteration or contamination of COVID-19 medical products, cases of patients suffering adverse effects/lack of efficacy after using a COVID-19 medical product suspected to be substandard and falsified (SF) will be included. For the category of COVID-19 vaccines we also include scams and diversions (including theft).

2.1. MQM Globe database

The MQM Globe database uses a search system 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 mainly extracts newspaper articles from journals referenced in Google News, articles that are not referenced in Google News will not be captured. [Please consult the IDDO website for full methodology](#)⁹. On the 20th of March 2020, the search terms were adapted to capture more reports on 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 product alerts. In the future, we will extend this feature for the US FDA and to other regulatory authorities.

2.2. Six MQM Globe-reports

Since the COVID-19 pandemic, the MQM Globe enables quick access to automatically created MQM-Globe reports, grouping articles by product categories that are linked to COVID-19. The six summary MQM Globe-reports are generated with pre-defined search terms and cover the following product categories: (a) COVID vaccines, (b) COVID diagnostics, (c) Personal Protective Equipment (PPE), (d) Sanitisers & disinfectants, (e) COVID medicines, and (f) Ventilation & oxygenation equipment and consumables. At the beginning of each MQM Globe-report the pre-defined search terms are displayed. Only the relevant articles included in the summary MQM Globe-reports are selected for the current COVID-19 report. When discussing an article the report ID (six or seven digit code) is mentioned. The original source article can be found using the report ID in the summary MQM Globe-reports in this report's annexes, or on the online MQM Globe.

2.3. Inclusion of a report ID

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 that are being trialled for COVID-19 treatment and/or prevention. In theory there is a distinction

⁸Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe. Web Page. Published 2020. Accessed October 1, 2021. <https://www.iddo.org/medicine-quality-monitoring-globe>

⁹Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe methodology. Web Page. Published 2020. Accessed September 15, 2021. <https://www.iddo.org/medicine-quality-monitoring-globe-methodology>

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 articles cited in this report are not directly linked to the prevention or 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 treatment¹⁰, 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.

With the information provided in the articles, it is not always possible to make the distinction between cases of financial scams, diverted, substandard or falsified products. We aim at including incidents in which it is likely that a physical product is involved. When the article clearly states that the offers are pure financial scams (without a physical purported product), we do not include the article: for example, criminals offering COVID-19 vaccines through a fake website¹¹ or COVID-19 vaccines sold over the phone¹² for which it is clearly established that it concerns a scam in which criminals are after personal details and money. In case of doubt and the possibility of a physical product behind the offer, we include the article: for example, vaccines are offered online or by phone but we cannot exclude that there is a physical product behind the offer because it is not mentioned in the article or no investigation has been done.

For this report, we only included report IDs that were published in English. For articles in French, Spanish, Mandarin, and Vietnamese; please consult the online MQM Globe. Only in part A dedicated to COVID-19 vaccines, do we include incidents reported in other languages if the incident was not reported in English.

2.4. Defining articles and incidents

In this report we define ‘articles’ as the number of unique report ID’s, corresponding to unique articles, that appear on our database. The same article (same report ID) can discuss incidents of different product categories. Therefore the same article might be discussed in different sections of the report.

An incident is a unique event with a specific location and timing with a specific product involved. Sometimes one article is describing several incidents. When summarizing the article, we will cite the different incidents in the text. However, for the overall number of incidents happened during a certain period, we are not

¹⁰Hashemian 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 September 15, 2020. <https://en.irct.ir/trial/48534>

¹¹ For example: CBS Baltimore. 3 Maryland Men Charged With Creating Fraudulent Website To Sell COVID-19 Vaccines . CBS Baltimore. <https://baltimore.cbslocal.com/2021/02/11/3-maryland-men-face-federal-charges-for-fraud-scheme-to-sell-covid-19-vaccine/>. Published February 11, 2021. Accessed March 11, 2021.

¹² For example: Lenahan I. COVID-19 vaccine phone scam: Rye police alert residents of bogus calls. Seacoastonline. <https://eu.seacoastonline.com/story/news/local/2021/02/15/covid-19-vaccine-phone-scam-rye-police-alert-residents-bogus-calls/4488304001/>. Published February 15, 2021. Accessed March 11, 2021.

counting the number of separate incidents that are described in an article. For the purpose of this report we define ‘incidents’ as the number of unique report IDs per product category (i.e. vaccines, diagnostics, PPE, sanitisers & disinfectants, medicines, ventilation & oxygenation).

2.5. Reporting on incidents from the lay press.

The current report consists of two parts. Part A contains the information related to COVID-19 vaccines. Part B contains information related to the other COVID-19 medical product categories including diagnostics, personal protective equipment (PPE), sanitisers & disinfectants, medicines, and ventilation & oxygenation equipment and consumables. In Part B the lay press literature is discussed by product category. However, some articles summarize or describe multiple product categories used during the COVID-19 pandemic. When an article discusses more than 2 product categories, we describe the content of those articles in the section on ‘Overview of all categories’ and do not report on them in the sections for the different product categories.

Within the section of each product category we try to group the information in subheadings by product (e.g. by active pharmaceutical ingredient) that is involved and by quality issue (see Table 1 with key terminology for quality issues). Some articles discuss several products or several types of quality issues and are therefore not straight forward to classify; thus the subdivision might be arbitrary. We only discuss the articles once, even if they could be classified under different subheadings.

The MQM Globe displays one article per incident, the primary article. There are many other articles that describe the same incident, those are considered duplicate articles, and are not displayed on the MQM Globe unless they provide additional relevant information on the extend of the incident (e.g. additional quantities, additional batch numbers etc.). The information available in the lay press articles is often not very detailed which makes it sometimes difficult to separate out incidents on which we have (duplicate articles) or have not (primary articles) previously reported. To the best of our knowledge we try to only discuss primary articles, i.e. articles discussing new incidents on which we have not reported previously.

2.6. Changes in methodology since the first report

There were some minor changes in methodology since the last ‘Medical Product Quality Report – COVID-19 issues’¹³ with data from April and May 2021. For the summary MQM globe-report on ‘Ventilation & Oxygenation equipment and consumables’, the search term “pulse oximeter” was replaced by “oximeter” to ensure all relevant articles are included.

Please read more about the changes in methodology since the first report that was published in July 2020 in Annex A.

¹³Infectious Diseases Data Observatory. Medical Product Quality Reports. Medical Product Quality Reports. Published 2020. Accessed October 1, 2021. <https://www.iddo.org/mq/research/medical-product-quality-reports>

3. Disclaimer and caveats

We include abstracts and extracts from reports and articles that are subject to a takedown 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.

For the scientific publications we include preprints 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.

For the lay press articles 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](#)¹⁴.

¹⁴Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe disclaimer and caveats. Web Page. Published 2020. Accessed October 1, 2021. <https://www.iddo.org/medicine-quality-monitoring-globe-disclaimer-and-caveats>

Part A.

COVID-19 vaccines

A.1. Introduction

It is hoped that the deployment of COVID-19 vaccines, combined with other public health interventions, will further reduce the incidence of COVID-19 infections and help end the pandemic. The storage and distribution of these vaccines is a major logistical challenge. Additional but continued neglected issues are substandard, falsified, and diverted COVID-19 vaccines, a high risk globally.

There have been numerous reports over the last two decades of vaccine falsification, for example, rabies, cholera, meningitis, yellow fever and hepatitis B vaccines and degradation due to storage and transport at inappropriate temperatures. These risk impairing the effectiveness of vaccination programs, increasing mortality, morbidity and economic harm, engendering further viral mutants, confuse and alarm communities, and damage public confidence in immunization programs, reducing vaccine uptake. Major current risks for the implementation of COVID-19 vaccines include falsification and diversion fuelled by impaired access and the vital need for them globally, especially in the face of inequitable distribution. Vaccine degradation (included in the term substandard by WHO¹⁵) is also a major risk without robust regulated supply chains.

The data in this and previous reports suggest that we need a global joined up discussion with the many stakeholders as to how we can reduce the risk of these neglected problems negating, especially in vulnerable communities, the amazing promise that vaccine development, manufacture and implementation has yielded for us all.

A.2. Articles of incidents in the lay literature

Here, we summarise articles in the public domain, on substandard, falsified or unregistered COVID-19 vaccines, since the start of the pandemic. We also include reports of diversion (including theft) of COVID-19 vaccines from legitimate supply chains. 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. The incidents highlighted in this report are not exhaustive but it serves as early warning system of quality issues with COVID-19 vaccines.

¹⁵ 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 April 8, 2021. https://www.who.int/medicines/regulation/ssffc/A70_23-en1.pdf?ua=1

A.2.1. Incidents since the beginning of the pandemic

Between 12th March 2020 and 31st July 2021 we found, excluding duplicates, 150 reports of incidents on quality issues with COVID-19 vaccines linked to 41 different countries and/or online (see Figure 2). Out of these reports 22 reports were published in 2020, 128 reports were published in 2021 (see Figure 1).

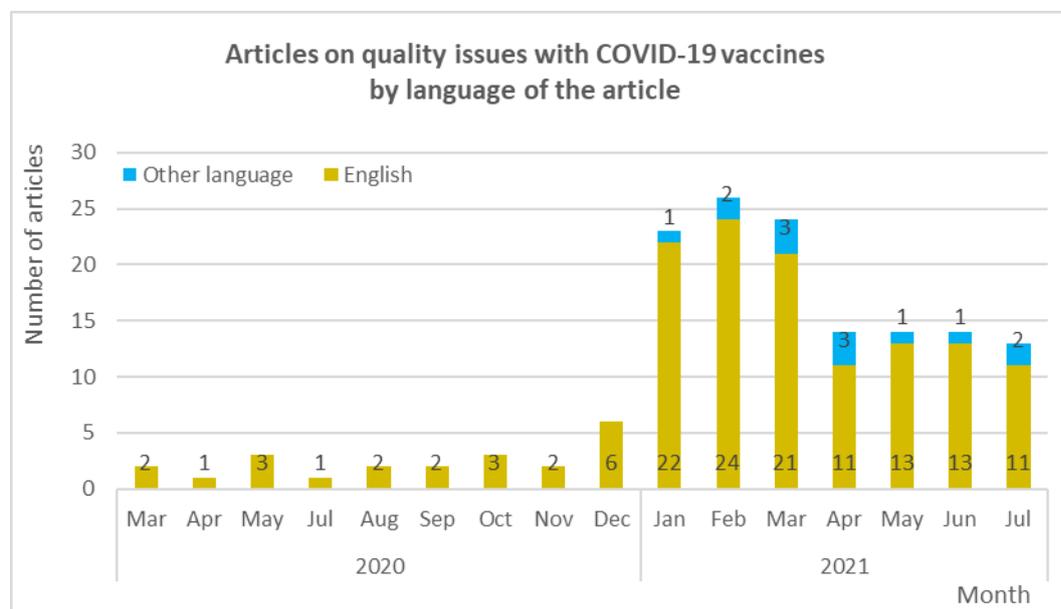


Figure 1. Number of articles on the Medicine Quality Monitoring Globe reporting quality issues with COVID-19 vaccines.

Reports date from 12 March 2020 until 31 July 2021. We count here only one article per incident– there are many other articles describing the same incidents. From 2021 on, we report not only on incidents covered in the English lay press but also in Chinese, French, Spanish and Vietnamese language.

Table 2 gives more detail on the 101 reports that were published from January up to May 2021 and were discussed in previous [Medical Product Quality Reports on COVID-19 vaccines](#) issued by the Medicine Quality Research Group. For further details on the incidents reported during 2020 please consult Annex B.

In this issue we discuss in more detail the 27 incidents that were reported during the months of June (14) and July (13) 2021 (see Table 3). We report for the first time on incidents in Iran, Lebanon, Russia, Thailand, Uganda and Canada. Ten incidents involved falsified COVID-19 vaccines including those labelled as manufactured by Pfizer/BioNTech (3), Covishield (3), Oxford-AstraZeneca, Moderna, Sinopharm, and Sinovac. Seven incidents were related to diversion of COVID-19 vaccines out of the regular supply chain. Finally, 5 incidents involved substandard vaccines and for 5 incidents the quality issue was unclear. After a peak in reported incidents during the months of January, February and March, a lower number of incidents have been reported in recent months. Further analysis is needed to determine if there were fewer incidents or if there are other reasons behind the drop in reported incidents such as the phenomena of media fatigue.

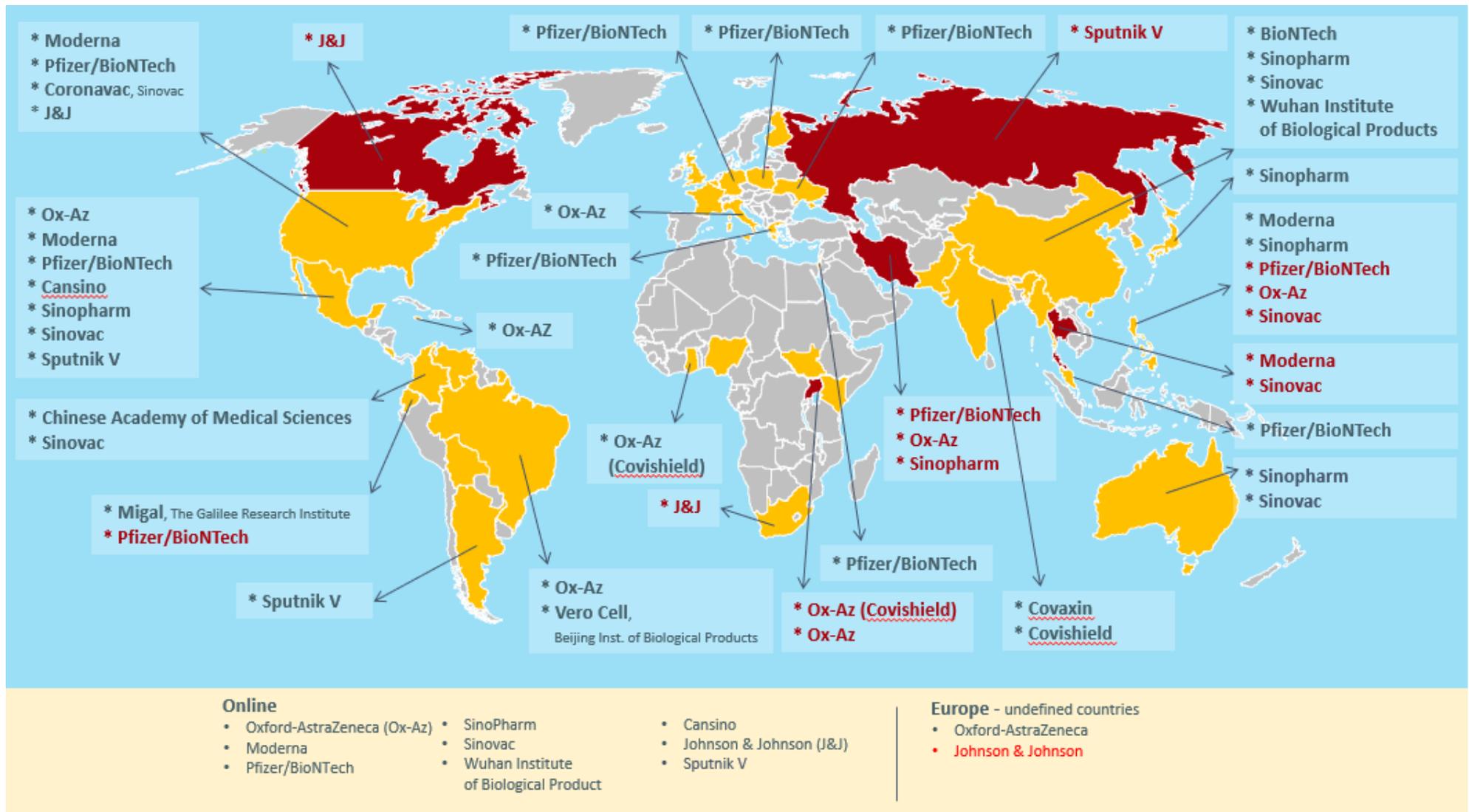


Figure 2. Countries with public reports on COVID-19 vaccine quality issues on the Medicine Quality Monitoring Globe.

Countries linked to incidents are indicated in orange. If a public report mentions a product name or a company, these details are indicated on the map, with in red the information that was added since the last issue. Ox-Az: Oxford-AstraZeneca, and J&J: Johnson & Johnson.

Table 2. COVID-19 vaccine quality issues reported in articles published from January to May 2021.

Each article is available in the Medicine Quality Monitoring (MQM) Globe linked to a report ID. Reports date from 1 January 2021 until 31 May 2021. In the next report we plan to retrospectively categorise prior reports in the same way as in Table 3 with reports from June and July 2021. We included articles from the Spanish, French, Chinese and/or Vietnamese press if the incident was not reported in the English lay press. We list here only one report per incident – there are many other reports describing these issues but we have not included them unless they provide additional relevant information. In the table we only refer to primary incidents described in the report, if a report repeats information on incidents that we already reported on, we do not name it again.

2021						
Publication date	Location	Product/ Organization	Additional information	Title	MQM Globe report ID	URL ¹⁶
JANUARY						
05 January 2021	Online	* Wuhan Institute of Science * Moderna * Pfizer/BioNTech * Oxford-AstraZeneca	-	A COVID-19 shot for \$150? Online scams surge as slow vaccine rollout frustrates	877299	https://in.reuters.com/article/us-health-coronavirus-vaccine-scams/a-covid-19-shot-for-150-online-scams-surge-as-slow-vaccine-rollout-frustrates-idINKBN29A19Z
05 January 2021	Argentina	Sputnik V	degraded	Coronavirus: en Olavarria tuvieron que tirar 400 vacunas que perdieron la cadena de frio ('Due to a cold-chain breakdown 400 doses had to be thrown away')	877565	https://www.rosario3.com/informaciongeneral/Coronavirus-en-Olavarria-tuvieron-que-tirar-400-vacunas-que-perdieron-la-cadena-de-frio-20210105-0001.html
07 January 2021	UK	-	-	Elderly woman, 92, tricked into paying £160 to get fake Covid jab in her own home	881071	https://www.dailystar.co.uk/news/elderly-woman-92-tricked-paying-23282075
13 January 2021	Online, Australia	* Moderna * Pfizer/BioNTech	-	The dark net is being flooded with fraudulent COVID-19 vaccines	890850	https://www.crikey.com.au/2021/01/14/dark-web-covid-19-vaccine-black-market/
14 January 2021	Mexico, online	Pfizer/BioNTech	-	Organized crime in Mexico selling fake Covid-19 vaccines	892039	https://www.laprensalatina.com/organized-crime-in-mexico-selling-fake-covid-19-vaccines/ <u>Original message:</u> https://www.gob.mx/cms/uploads/attachment/file/604366/Comunicado_Vacuna_Covid_050121.pdf
14 January 2021	USA	Moderna	diverted	Two vials of Moderna COVID-19 vaccine stolen from Florida State Hospital in Chattahoochee	936933	https://eu.tallahassee.com/story/news/local/state/2021/01/14/two-vials-moderna-covid-19-vaccine-stolen-florida-state-hospital-chattahoochee/4156644001/

¹⁶ Over time some URLs might not work anymore, and in that case one can find a summary/extract of the article on the online MQM Globe using 'reportID:XXXXXX' in the search box.

15 January 2021	UK	-	-	Shameless fraudster tries to sell 61-year-old woman fake Covid-19 vaccine for £170 in Worksop area	893684	https://www.worksopguardian.co.uk/news/crime/shameless-fraudster-tries-sell-61-year-old-woman-fake-covid-19-vaccine-ps170-worksop-area-3102846
15 January 2021	Nigeria	-	-	Fake COVID-19 vaccines in circulation, NAFDAC warns	892876	https://www.vanguardngr.com/2021/01/updated-fake-covid-19-vaccines-in-circulation-nafdac-warns/
18 January 2021	Costa Rica	-	-	Fake Black market COVID-19 Vaccines in Costa Rica	922769	https://news.co.cr/fake-blackmarket-covid-19-vaccines-in-costa-rica/82725/
18 January 2021	USA	Moderna	uncertain aetiology	Coronavirus: California calls for pause, investigation after allergic reactions to Moderna vaccine batch	897789	https://www.mercurynews.com/2021/01/18/coronavirus-california-calls-for-pause-investigation-after-allergic-reactions-to-moderna-vaccine-batch
18 January 2021	Mexico	-	-	Liquid Gold - False COVID-19 Vaccines Emerge in Latin America	897295	https://www.insightcrime.org/news/analysis/false-covid-vaccines-emerge/
19 January 2021	Mexico	Pfizer/BioNTech	diverted	4 vaccine doses stolen in Mexico, oxygen tanks spark appeal	943497	https://kstp.com/news/4-vaccine-doses-stolen-in-mexico-oxygen-tanks-spark-appeal/5983681/
20 January 2021	USA	Moderna	degraded	Thousands of Moderna Covid vaccine doses spoil in Maine & Michigan due to temperature control issues	900582	https://www.rt.com/usa/513082-michigan-maine-moderna-vaccine-ruined/
21 January 2021	Online, USA	CoronaVac, (Sinovac)	-	Leading Indicators Foreshadow COVID-19 Vaccine Scams	902346	https://securityboulevard.com/2021/01/leading-indicators-foreshadow-covid-19-vaccine-scams/
21 January 2021	Online	-	-	Sale of Fake COVID-19 Vaccines Grew 400% on the Dark Web	902237	https://www.entrepreneur.com/article/363880
22 January 2021	USA	-	-	Seller of fake vaccine arrested in Seattle	904241	https://www.myclallamcounty.com/2021/01/22/seller-of-fake-vaccine-arrested-in-seattle/
22 January 2021	USA	Moderna	diverted	Texas doctor fired, charged with stealing COVID-19 vaccine to give to his friends, family	903988	https://www.foxnews.com/us/texas-doctor-charged-coronavirus-vaccine-theft-case Articles bringing other elements to the event were published in February: *) Doctors says he was wrongly fired for giving expiring Covid vaccine to his wife : https://www.independent.co.uk/news/world/americas/covid-vaccine-expiring-houston-texas-b1801122.html *) Texas doctor fired for giving away expiring vaccines: https://www.webmd.com/vaccines/covid-19-vaccine/news/20210214/texas-doctor-fired-for-giving-expiring-vaccines
25 January 2021	Mexico, online	Moderna	-	Mexico Warns Citizens of Fake COVID-19 Vaccines	907667	https://www.occrp.org/en/27-ccwatch/cc-watch-briefs/13715-mexico-warns-citizens-of-fake-covid-19-vaccines Original message: https://www.gob.mx/cms/uploads/attachment/file/608294/Comunicado_Vacuna_Covid_Moderna_220121.pdf
26 January 2021	UK	-	-	Sick fraudsters inject Scots with fake Covid vaccine for cash in cruel scam	909286	https://www.dailyrecord.co.uk/news/scottish-news/sick-fraudsters-inject-scots-fake-23389274
26 January 2021	USA	Moderna	diverted	Polk County 'Paramedic of the Year' arrested in theft of COVID vaccines	936949	https://www.wfla.com/news/polk-county/judd-polk-county-paramedic-arrested-for-stealing-coronavirus-vaccines/
27 January 2021	Ecuador	-	-	Ecuador Health Centre 'Gives Fake Covid Jab to 70,000 People'	910241	https://www.euroweeklynews.com/2021/01/27/ecuador-health-centre-gave-fake-covid-jab-to-70000-people/
29 January 2021	Online	-	-	Covid-19 medicines, PPE, tests and vaccines are being sold on the dark web	913513	https://www.dailymail.co.uk/sciencetech/article-9198535/Covid-19-medicines-PPE-tests-vaccines-sold-dark-web.html

31 January 2021	Finland	-	-	Woman suspected of peddling fake vaccine in southeast Finland	917132	https://yle.fi/uutiset/osasto/news/woman_suspected_of_peddling_fake_vaccine_in_southeast_finland/11765320
FEBRUARY						
01 February 2021	China	-	-	80 held in China over fake Covid-19 vaccines	918486	https://www.scmp.com/news/china/politics/article/3120083/chinese-police-detain-80-selling-fake-covid-19-vaccines
04 February 2021	Mexico, online	Oxford-AstraZeneca	-	Cofepris alerts about the illicit sale of the AstraZeneca vaccine	924171	https://www.explica.co/cofepris-alerts-about-the-illicit-sale-of-the-astrazeneca-vaccine/ <u>Original message:</u> https://www.gob.mx/cms/uploads/attachment/file/613986/COFEPRIS03022021.pdf
04 February 2021	USA	-	diverted	COVID-19 vaccine doses stolen in Florida after car keys left in ignition	936924	https://www.clickorlando.com/news/local/2021/02/04/video-shows-person-of-interest-in-stolen-covid-19-vaccine-investigation-police-say/
04 February 2021	USA	-	diverted	St. Pete City Council left in the dark on theft of COVID-19 vaccine vials, investigation into fire department employee	936941	https://www.abcactionnews.com/news/region-pinellas/st-pete-city-council-left-in-the-dark-on-theft-of-covid-19-vaccine-vials-investigation-into-fire-department-employee
08 February 2021	Philippines	-	-	Avoid COVID-19 vaccines from black market, doctors warn	930157	https://newsinfo.inquirer.net/1393684/avoid-vaccines-from-black-market-doctors-warn
08 February 2021	Online	-	-	Bogus COVID-19 Vaccine Offers Flooding The 'Dark Web'	929197	https://chicago.cbslocal.com/2021/02/07/dark-web-covid-vaccine-scams/
10 February 2021	China	-	-	Over 58,000 Fake COVID-19 Vaccine Doses Busted in China, 600 Doses Sent Overseas	932609	https://www.urdupoint.com/en/world/over-58000-fake-covid-19-vaccine-doses-buste-1164592.html
10 February 2021	UK, Italy, Japan	Sinopharm (in Japan)	diverted & other issues	黑市疫苗，为何屡禁不止？ ('Black market vaccines, why do they persist?') --> reports on several incidents')	932480	https://www.yicai.com/news/100947924.html
11 February 2021	Greece	Pfizer/BioNTech	diverted	Greek Police Probe Theft of COVID-19 Vaccine Vial Holding Six Doses	948981	https://www.thenationalherald.com/archive_general_news_greece/arthro/greek_police_probe_theft_of_covid_19_vaccine_vial_holding_six_doses-1776428/
11 February 2021	USA	Pfizer/BioNTech	degraded	About 6,000 COVID Vaccine Doses Potentially Spoiled In OC Due To Refrigerator Malfunction	933403	https://news.yahoo.com/6-000-covid-vaccine-doses-003325113.html
14 February 2021	India	-	-	Woman injects fake COVID-19 vaccine to elderly couple, flees with 8 tola jewellery	940683	https://www.timesnownews.com/hyderabad/article/woman-injects-fake-covid-19-vaccine-to-elderly-couple-flees-with-8-tola-jewellery-hyderabad/720332
14 February 2021	USA	Pfizer/BioNTech	diverted	1,000 COVID-19 Vaccine Doses Stolen From Under Nose of Mayor Kane	943453	https://bleedingcool.com/tv/1000-covid-19-vaccine-doses-stolen-from-under-nose-of-mayor-kane/
14 February 2021	Philippines	Moderna	-	Rumoured Moderna vaccine shipment likely fake, says FDA	939722	https://www.sunstar.com.ph/article/1885882/Manila/Local-News/Rumored-Moderna-vaccine-shipment-likely-fake-says-FDA
15 February 2021	Europe	-	-	EU's anti-fraud agency warns against fake COVID vaccines	941124	https://www.swissinfo.ch/eng/eu-s-anti-fraud-agency-warns-against-fake-covid-vaccines/46371790
16 February 2021	Belgium	-	-	Belgium warns against fake Russian vaccines	942342	https://www.brusselstimes.com/news/belgium-all-news/155115/belgium-warns-against-fake-russian-vaccines-vaccination-taskforce-info-campaign-herd-immunity/

17 February 2021	South Africa	-	-	Fake Covid-19 vaccines discovered in Gauteng	945211	https://www.jacarandafm.com/news/news/fake-covid-19-vaccines-discovered-gauteng/ (This incident might be related to the one described in report ID 865724 on 28 December 2020, but not clear if this article mentions an additional warehouse or if it is referring to the same event)
17 February 2021	Brazil	-	air vaccines	'Shots of air': Brazilian health workers accused of giving fake COVID vaccinations with empty syringes	944701	https://nationalpost.com/news/world/brazil-police-probe-reports-of-coronavirus-vaccine-shots-of-air
17 February 2021	Mexico	Pfizer/BioNTech	-	Mexico Arrests 6 for Trafficking False Coronavirus Vaccines	944948	https://www.nbcdfw.com/news/local/mexico-arrests-6-for-trafficking-false-coronavirus-vaccines/2555781/
19 February 2021	Colombia	Chinese Academy of Medical Sciences (Vero Cell)	-	COVID-19 vaccine counterfeits set off alarms across the globe	947830	https://www.bioworld.com/articles/503830-covid-19-vaccine-counterfeits-set-off-alarms-across-the-globe
19 February 2021	Italy, online	* Pfizer/BioNTech * Oxford-AstraZeneca	-	Italy probes vaccine scams even as officials court offers	947669	https://www.theridgefieldpress.com/news/article/Italy-probes-vaccine-scams-even-as-officials-15963865.php
21 February 2021	Ukraine	Pfizer/BioNTech	-	Covid-19 vaccines hit the black market	950068	https://www.aspistrategist.org.au/covid-19-vaccines-hit-the-black-market/
22 February 2021	Trinidad and Tobago	-	-	Fake COVID vaccines being offered to Trinidad	951551	https://www.stabroeknews.com/2021/02/22/news/regional/trinidad/fake-covid-vaccines-being-offered-to-trinidad-pm/
23 February 2021	France	-	-	Il se fait passer pour un infirmier et administre un faux vaccin ('He pretends to be a nurse and administers a fake vaccine')	951944	https://www.alouette.fr/news/bretagne-il-se-fait-passer-pour-un-infirmier-et-administre-un-faux-vaccin-10676
25 February 2021	USA	-	degraded	COVID-19 vaccine doses tossed around state, low amounts in Pima County	956586	https://www.kold.com/2021/02/26/covid-vaccine-doses-tossed-around-state-low-amounts-pima-county/
25 February 2021	Europe	Oxford-AstraZeneca	-	Fraudsters offer 400 million 'ghost' COVID vaccines in EU: officials	955619	https://www.reuters.com/article/us-health-coronavirus-eu-vaccines/fraudsters-offer-400-million-ghost-covid-vaccines-in-eu-officials-idUSKBN2AP1GN
26 February 2021	USA	-	-	Vaccine doses may have been stolen at Pipkin Building in early February, Tennessee health department says	957718	https://www.commercialappeal.com/story/news/local/coronavirus/2021/02/26/covid-19-vaccines-stolen-in-memphis-shelby-county-health-department/6822867002/
MARCH						
01 March 2021	Europe	Oxford-AstraZeneca	-	Europe Probes Attempted Vaccine Scams of More Than \$15 Billion	961495	https://www.bloomberg.com/news/articles/2021-03-01/europe-probes-attempted-vaccine-scams-of-more-than-15-billion
02 March 2021	South Sudan	-	-	Thai Army doctor sold fake Covid-19 vaccines to UN peacekeepers	962520	https://www.straitstimes.com/asia/se-asia/thai-army-doctor-sold-fake-covid-19-vaccines-to-un-peacekeepers
02 March 2021	USA	-	-	National Consumer Protection Week: FDA Is Vigilant in Protecting Consumers Against COVID-19 Vaccine Scams - 2021-03-02	962956	http://www.fda.gov/news-events/fda-voices/national-consumer-protection-week-fda-vigilant-protecting-consumers-against-covid-19-vaccine-scams
03 March 2021	Israel	Pfizer/BioNTech	empty vials: diverted	2 Israelis detained on suspicion of selling used COVID vaccine vials	975656	https://www.timesofisrael.com/2-israelis-detained-on-suspicion-of-selling-used-covid-vaccine-vials/

03 March 2021	USA	Pfizer/BioNTech	diverted	Decatur pharmacist fired after taking COVID-19 vaccines home to family	992152	https://www.chicagotribune.com/coronavirus/vaccine/ct-coronavirus-vaccine-decatur-hospital-pharmacist-20210303-t6nnwtc2vvad5jr4dmtlxvf7mq-story.html
04 March 2021	Malaysia, Online	Pfizer/BioNTech	-	Police Investigate Fake COVID-19 Vaccines Sold Online, Losses Amounting Up To RM285,499	966743	https://worldofbuzz.com/police-investigate-fake-covid-19-vaccines-sold-online-losses-amounting-up-to-rm285499/ Additional information: https://www.sinchew.com.my/content/content_2437445.html
04 March 2021	Online, France, Germany, UK, USA	-	-	Scammers are Selling Fake COVID-19 Vaccines for up to \$1,200	965729	https://www.itnewsafrika.com/2021/03/scammers-are-selling-fake-covid-19-vaccines-for-up-to-1200/
09 March 2021	Online	-	-	Some people turning to black market to get COVID-19 vaccine	973480	https://www.azfamily.com/news/continuing_coverage/coronavirus_coverage/vaccine_headquarters/some-people-turning-to-black-market-to-get-covid-19-vaccine/article_af7de3d2-8144-11eb-bf11-a7a9c31ca1c6.html
10 March 2021	Mexico, online	* Cansino Biologics * Sinopharm Group Co. Ltd * Sinovac	-	Alerta por falsificación de vacunas contra el covid-19 en México que estarían en venta ('Alert for falsified vaccines against covid-19 in Mexico that would be for sale')	976281	https://www.larepublica.co/globoeconomia/alerta-por-falsificacion-de-vacunas-contra-el-covid-19-en-mexico-que-estarian-en-venta-3137336 <u>Original message:</u> https://www.gob.mx/cms/uploads/attachment/file/619020/Alerta_Sanitaria_Cansino_Sinopharm_Sinovac.pdf
13 March 2021	India	-	-	Woman administers fake COVID-19 vaccine to aunt, her family & escapes with gold	978169	https://www.timesnownews.com/chennai/article/woman-administers-fake-covid-19-vaccine-to-aunt-her-family-escapes-with-gold/732152
15 March 2021	Colombia	Sinovac	air vaccines	El video del engaño: enfermera vacuna contra el Covid-19 con una jeringa vacía ('The video of the deception: nurse vaccinates against COVID-19 with an empty syringe')	987387	https://www.clarin.com/internacional/video-engano-enfermera-vacuna-covid-19-jeringa-vacia_0_5bj7mXUTK.html
16 March 2021	USA	-	diverted	Nurse arrested for allegedly stealing COVID-19 vaccine at TCF Center in Detroit	981668	https://www.wxyz.com/news/coronavirus/covid-19-vaccine/nurse-arrested-for-allegedly-stealing-covid-19-vaccine-at-tcf-center-in-detroit
16 March 2021	Jamaica	Oxford-AstraZeneca	diverted (under investigation)	Ten doses of COVID vaccine missing from Cornwall Regional Hospital	1003286	https://jamaica-gleaner.com/article/lead-stories/20210316/ten-doses-covid-vaccine-missing-cornwall-regional-hospital
18 March 2021	Mexico	Sputnik V	-	Mexico authorities seize fake batch of Russian Sputnik V vaccine: RDIF	984176	https://www.reuters.com/article/us-health-coronavirus-russia-vaccine-mex-idUSKBN2BA1RD <u>Original message:</u> https://www.gob.mx/cofepris/es/articulos/nota-informativa-sobre-vacunacion-ilegal-en-campeche?idiom=es
22 March 2021	Ghana	Oxford-AstraZeneca 'Covidshield' [sic]	diverted	Ghana Health Service start dey investigate 3 health officials who 'dey sell Covid-19 vaccines'	988608	https://www.bbc.com/pidgin/tori-56481793 <u>Additional information:</u> '4 accused of stealing and selling Covid-19 vaccines granted bail': https://www.myjoyonline.com/4-accused-of-stealing-and-selling-covid-19-vaccines-granted-bail/
23 March 2021	Online	* Johnson & Johnson * Oxford-AstraZeneca	-	Covid-19 vaccines and counterfeit vaccine cards are for sale on the dark web	989053	https://www.cnn.com/2021/03/23/tech/covid-vaccines-dark-web/index.html

23 March 2021	UK	-	diverted	Man charged after Covid vial stolen from Edinburgh vaccination centre	990549	https://www.bbc.com/news/uk-scotland-edinburgh-east-fife-56505041
24 March 2021	Mexico	Sputnik V	-	México investiga supuesta aplicación de vacuna anticovid "falsa" a un millar de personas ('Mexico investigates alleged application of falsified COVID-19 vaccine to thousand people')	990553	https://www.clarin.com/agencias/afp-mexico-investiga-supuesta-aplicacion-vacuna-anticovid-falsa-millar-personas_0_klvqCFjVO.html Original message: https://www.gob.mx/cofepris/es/articulos/cofepris-informa-sobre-la-vacuna-falsa-presuntamente-aplicada-en-campeche-y-las-acciones-en-curso?idiom=es
24 March 2021	Kenya	Sputnik V	diverted	Kenya: Distributors 'Sneaked' Russian Vaccine Into Kenya for Sale at Sh11,000 Per Jab	990984	https://allafrica.com/stories/202103240210.html
24 March 2021	Macau - China	BioNTech	-	Hong Kong, Macau suspend Pfizer COVID-19 vaccine over packaging flaw	1021092	https://www.arabnews.com/node/1830936/world
26 March 2021	Mexico	Pfizer/BioNTech	-	Medical Product Alert N°2/2021: Falsified COVID-19 Vaccine BNT162b2	994973	https://www.who.int/news/item/26-03-2021-medical-product-alert-n-2-2021-falsified-covid-19-vaccine-bnt162b2
30 March 2021	Philippines	-	-	Galvez says gov't probing 3 firms offering fake COVID-19 vaccines	998393	https://newsinfo.inquirer.net/1413018/galvez-says-govt-probing-3-companies-offering-fake-covid-19-vaccines
31 March 2021	USA	Johnson & Johnson	-	Johnson & Johnson COVID-19 vaccine batch fails quality check	1000915	https://www.thetelegraph.com/news/article/Johnson-Johnson-COVID-19-vaccine-batch-fails-16068073.php
31 March 2021	Pakistan	-	degraded & diverted	Corona vaccine stolen in Services, wasted in Mozang hospital	1001109	https://www.thenews.com.pk/print/813092-corona-vaccine-stolen-in-services-wasted-in-mozang-hospital
APRIL						
04 April 2021	Europe	-	-	Descubren contenedores de vacunas falsificadas que iban a distribuir en Europa ('They discover containers of falsified vaccines that were going to be distributed in Europe')	1005914	https://espanadiario.net/salud/descubren-contenedores-vacunas-falsas-distribucion-europa
07 April 2021	USA	Johnson & Johnson	-	Another 62million Covid vaccines 'contaminated' at scandal-hit factory	1011051	https://metro.co.uk/2021/04/07/another-62million-covid-vaccines-contaminated-at-scandal-hit-factory-14373004/
07 April 2021	Brazil	-	-	Au Brésil, une fausse infirmière s'est fait plus de 5000 euros en administrant de faux vaccins à plus de 50 hommes d'affaires ('In Brazil, a fake nurse made more than 5,000 euros injecting falsified vaccines to over 50 businessmen')	1010975	https://www.sudinfo.be/id385891/article/2021-04-07/au-bresil-une-fausse-infirmiere-sest-fait-plus-de-5000-euros-en-administrant-de
08 April 2021	USA	Johnson & Johnson	diverted	Capel Coral Police investigating stolen vials of Johnson & Johnson Covid-19 vaccine	1013423	https://www.fox4now.com/news/local-news/capel-coral-police-investigating-stolen-vials-of-johnson-johnson-covid-19-vaccine
13 April 2021	USA	Pfizer/BioNTech	degraded	Thousands need to be revaccinated after state finds substandard vaccine storage, handling at El Paso County clinic	1021500	https://www.msn.com/en-us/health/medical/thousands-need-to-be-revaccinated-after-state-finds-substandard-vaccine-storage-handling-at-el-paso-county-clinic/ar-BB1fCWLL <u>Additional information:</u> 3,000 vaccine doses seized from Colorado Springs medical spa due to storage problems: https://coloradosun.com/2021/04/12/moma-health-and-wellness-coronavirus-vaccine-seized/

14 April 2021	India	Covaxin	diverted	Rajasthan: 320 doses of COVID-19 vaccine stolen from Jaipur hospital, FIR filed	1020922	https://www.timesnownews.com/india/article/rajasthan-320-doses-of-covid-19-vaccine-stolen-from-jaipur-hospital-fir-filed/745043 Additional information: Over 300 Covaxin Covid-19 doses go missing from Rajasthan govt hospital https://www.livemint.com/news/india/over-300-mn-covaxin-covid-19-doses-go-missing-from-rajasthan-govt-hospital-11618395901531.html
15 April 2021	Online, Venezuela	-	-	Venezuela: arrestation de vendeurs de vaccins au noir ('Venezuela: illegal vaccine sellers arrested')	1023308	https://www.tvanouvelles.ca/2021/04/15/venezuela-arrestation-de-vendeurs-de-vaccins-au-noir
16 April 2021	Republic of Korea	-	syringes: substandard	Korea gives 500,000 AstraZeneca shots with potentially faulty syringes	1025296	http://www.koreaherald.com/view.php?ud=20210416000870
21 April 2021	Poland	Pfizer/BioNTech	-	Pfizer Identifies Fake Covid-19 Shots Abroad as Criminals Exploit Vaccine Demand	1030129	https://www.wsj.com/articles/pfizer-identifies-fake-covid-19-shots-abroad-as-criminals-exploit-vaccine-demand-11619006403
21 April 2021	Online, Argentina (Brazil, Mexico)	-	-	PAHO warns of fake Covid-19 vaccines in Argentina, Brazil and Mexico	1030705	https://batimes.com.ar/news/latin-america/paho-warns-of-fake-covid-19-vaccines-in-argentina-brazil-and-mexico.phtml
22 April 2021	India	* Covishield * Covaxin	diverted	1,710 doses of Covid-19 vaccine stolen from civil hospital in Haryana	1031435	https://www.livemint.com/news/india/1710-doses-of-covid-19-vaccine-stolen-from-civil-hospital-in-haryana-11619069095866.html
23 April 2021	Bolivia (Mexico, Colombia)	-	-	PAHO warns against acquiring vaccines from unofficial sources	1034582	https://www.nycaribnews.com/articles/paho-warns-latin-america-about-counterfeit-unauthorized-vaccines/
27 April 2021	Germany	Pfizer/BioNTech	-	Nurse 'gave people fake Covid vaccines to cover up for dropping vial'	1038395	https://metro.co.uk/2021/04/27/nurse-gave-people-fake-covid-vaccines-to-cover-up-for-dropping-vial-14478894/
30 April 2021	USA, online	* Moderna * Pfizer/BioNTech	empty vials	CBS 2 Investigators Go Undercover And Find Pharmacist Selling 'Empty' COVID Vaccine Vials Online: 'I Did Not Think It Was A Big Deal'	1043609	https://chicago.cbslocal.com/2021/04/30/pharmacist-selling-empty-covid-vaccine-vials-online-cbs-2-investigators-dorothy-tucker/
MAY						
01 May 2021	USA	Johnson & Johnson	diverted	COVID-19 vaccines, medical equipment stolen from Purdy dentist's office	1043734	https://www.kiro7.com/news/local/covid-19-vaccines-medical-equipment-stolen-purdy-dentists-office/VHTYI6WRHFETBDPQEAMYCE46HA/
05 May 2021	Online	* Sputnik V * Pfizer/BioNTech	-	Dubious Covid-19 Shots, Fake Vaccination Certificates Proliferate on Dark Web	1048306	https://www.wsj.com/articles/dubious-covid-19-shots-fake-vaccination-certificates-proliferate-on-dark-web-11620207001
10 May 2021	Online	Pfizer/BioNTech	-	Surgical masks, vaccines among counterfeit goods on the rise online	1095520	https://www.tnp.sg/news/singapore/surgical-masks-vaccines-among-counterfeit-goods-rise-online
11 May 2021	India	* Covishield * Covaxin	diverted	Exclusive: Black marketing of vaccine in Silchar Civil, unauthorised centre running inside a chamber	1086365	https://www.barakbulletin.com/en_US/exclusive-black-marketing-of-vaccine-in-silchar-civil-unauthorised-centre-running-inside-a-chamber/
12 May 2021	USA	Pfizer/BioNTech	diverted	Police Investigating Man Suspected Of Stealing COVID-19 Vaccines	1057163	http://ktoe.com/2021/05/12/police-investigating-man-suspected-of-stealing-covid-19-vaccines/
17 May 2021	India	Covishield	diverted	40 doses of Covid-19 vaccine missing; Andhra police files case	1063860	https://www.newindianexpress.com/states/andhra-pradesh/2021/may/18/40-doses-of-covid-19vaccine-missing-andhra-police-filescase-2303946.html

18 May 2021	USA	Pfizer/BioNTech	substandard preparation	Exclusive: Whistleblower Alleges Queens Company Ordered Health Clinic Workers To Over Dilute Doses Of COVID Vaccine	1067060	https://newyork.cbslocal.com/2021/05/18/whistleblower-lawsuit-over-diluted-covid-vaccine-new-york-city/
19 May 2021	USA	Johnson & Johnson	-	100 million doses of Johnson & Johnson's vaccine need to be checked for contamination and may need to be thrown out	1071640	https://www.yahoo.com/news/100-million-doses-johnson-johnsons-200345343.html
20 May 2021	India	-	diverted	Three Bengaluru doctors held for blackmarketing of COVID-19 vaccines and drugs	1068658	https://www.thenewsminute.com/article/three-bengaluru-doctors-held-blackmarketing-covid-19-vaccines-and-drugs-149243
21 May 2021	Online	* Moderna * Pfizer/BioNTech	-	COVID-19 vaccine scam warning	1069276	https://mybroadband.co.za/news/trending/398181-covid-19-vaccine-scam-warning.html
25 May 2021	India	-	non-injected doses	UP govt order probe after 29 syringes filled with Covid vaccine was found in dustbin in Aligarh	1074206	http://www.uniindia.com/~up-govt-order-probe-after-29-syringes-filled-with-covid-vaccine-was-found-in-dustbin-in-aligarh/States/news/2404840.html
28 May 2021	India	-	-	Thieves steal 300 vials of children's vaccines thinking they were Covid doses in Maharashtra's Ulhasnagar	1078285	https://www.indiatoday.in/coronavirus-outbreak/story/thieves-steal-300-vials-children-vaccines-thinking-they-were-covid-doses-maharashtra-ulhasnagar-1808077-2021-05-28
28 May 2021	South Africa	(Chinese COVID-19 vaccines)	-	国外竟有人收高价， 骗人接种假的“国产疫苗”.....中国驻南非使馆发布重要通知！ ('Some people abroad charge high prices to trick people into inoculating fake "domestic vaccines"... The Chinese Embassy in South Africa issued an important notice!')	1077654	https://baijiahao.baidu.com/s?id=1700952799193001379&wfr=spider&for=pc
28 May 2021	India	-	diverted/unregistered	Dr Reddy's takes action against bogus entities offering Sputnik V Covid vaccine	1078624	https://www.livemint.com/news/india/dr-reddy-s-takes-action-against-bogus-entities-offering-sputnik-v-covid-vaccine-11622211977442.html

Table 3. Quality issues with COVID-19 vaccines in articles published in June and July 2021.

Each article is available in the Medicine Quality Monitoring (MQM) Globe linked to a report ID. Reports date from 1 June 2021 until 31 July 2021. Each type of quality issue has an attributed colour in this table. For the definition of the different terms of quality issues, please consult Table 1. In the next report we plan to retrospectively categorise prior reports. We included articles from the Spanish, French, Chinese and/or Vietnamese press if the incident was not reported in the English lay press. We list here only one report per incident– there are many other reports describing the same incidents. In the table we only refer to primary incidents described in the report, if a report repeats information on incidents that we already reported on, we do not name it again.

Publication date	Probable quality issue	Location	Product/Organisation	Title	MQM Globe report ID ¹⁷	Quantities involved	Constituent
03 June 2021	Unclear	Kenya	-	DCI probes facilities illegally giving Covid jabs at a fee	1086161	-	unknown
04 June 2021	Diverted	India	Bharat Biotech (Covaxin), Serum Institute	Will inquire matter myself: Punjab Health Minister on allegations of vaccine diversion to private hospitals	1086967	40,000 doses	-
11 June 2021	Substandard	USA, Europe	Johnson&Johnson	EU regulator flags contamination in some J&J COVID-19 vaccines	1095771	unknown	-
11 June 2021	Substandard	USA, Canada	Johnson&Johnson	First batch of J&J COVID vaccines won't be released in Canada	1096549	300,000 doses	-
12 June 2021	Substandard	USA, South-Africa	Johnson&Johnson	2 million doses of J&J vaccine in South Africa possibly contaminated Citypress	1097627	2 million doses	-
14 June 2021	Diverted	Uganda	Oxford-AstraZeneca	Police names suspects arrested over stolen Covid-19 vaccines	1129380	unknown	-
15 June 2021	Falsified	Ecuador	Pfizer/BioNTech	Five fraudsters are arrested in Ecuador for selling fake Pfizer vaccines	1100787	43 syringes seized	unknown, sea water?
16 June 2021	Falsified	India	Covishield	Mumbai Society Residents Allege Vaccination Scam, Suspect They Received Fake COVID-19 Vaccine; Probe	1101158	around 390 people vaccinated	unknown
23 June 2021	Falsified	India	Covishield	TMC MP Mimi Chakraborty falls for fake Covid-19 vaccination drive, gets accused arrested	1110971	200-250 people vaccinated	amikacin
24 June 2021	Substandard	Russia	Sputnik V	WHO uncovers problems at Sputnik V Covid-19 vaccine at Russia's Ufa plant	1131615	unknown	-

¹⁷ Each report ID contains the link to the original article. Over time some URLs might not work anymore, and in that case one can find a summary/extract of the article [on the online MQM Globe](#) using 'reportID:XXXXXXX' in the search box

25 June 2021	Falsified	India	-	Escroquerie aux faux vaccins en Inde: 2500 personnes vaccinées avec de l'eau saline (India's fake vaccine scam: 2,500 people vaccinated with saline water)	1114048	2,000 people	saline
29 June 2021	Substandard	Thailand	Sinovac	Gel-like substance found in 110 bottles of Sinovac's COVID-19 vaccine	1173183	110 vials	-
30 June 2021	Falsified	Uganda	Oxford-AstraZeneca - Serum Institute of India	Uganda: State House Says Over 800 People Vaccinated With Fake COVID-19 Jabs	1119681	> 800 people vaccinated	(bottled) water
30 June 2021	Falsified - incident 1 Substandard (after diversion) - incident 2	Venezuela, online	-	Venezuela's Thriving Black Market for COVID-19 Vaccines	1120499	> 2,000 people affected (incident 1)	boiling water, painkillers and antibiotics (incident 1)
01 July 2021	Unclear	Online	Oxford-AstraZeneca, Pfizer/BioNTech, Johnson & Johnson, Moderna, Sputnik V	Fake Covid Certificates, Stolen Vaccines Sold on Darkweb for Bitcoin	1122035	-	-
03 July 2021	Unclear	Online, Italy	-	Website accepting cryptocurrency for selling fake coronavirus vaccines and certificates in Italy	1123690	-	-
07 July 2021	Falsified, Unclear	Iran	Sinopharm, Oxford-AstraZeneca, Pfizer/BioNTech	Iran Cracks Fake COVID Vaccine Ring, Seizing Large Shipment	1216975	unknown	unknown
07 July 2021	Unclear	Philippines	Oxford-AstraZeneca, Pfizer/BioNTech, Sinovac	Pasay City police arrest fake nurse, cohort for illegal sale of COVID vaccines	1129126	unknown	-
08 July 2021	Diverted	Philippines	Sinovac Biotech	Sinovac shots confiscated in QC 'unsafe,' had dirty packaging – FDA	1130843	300 doses	unknown
13 July 2021	Falsified	Lebanon	-	Scandale à l'Hôpital de Batroun, un employé accusé d'avoir falsifié les vaccins Pfizer (Scandal at Batroun Hospital, employee accused of falsifying Pfizer vaccines)	1135850	-	unknown
13 July 2021	Unclear	Mexico	-	Alertan por hallazgo de vacunas falsas contra Covid-19 en Ciudad Juárez (Alert for the discovery of false vaccines against Covid-19 in Ciudad Juárez)	1157058	unknown	unknown
14 July 2021	Falsified	Thailand	Moderna	Thai clinic shut down for selling fake Moderna vaccine: cops	1136434	unknown	unknown

15 July 2021	Diverted	South Africa	-	'Covid-19 vaccines and scheduled medicines now in the hands of looters'	1138581	unknown	-
18 July 2021	Diverted	India	Covishield	COVID-19 in Chhattisgarh: 70 doses of Covishield vaccine stolen in Durg's Ahirwara	1143378	70 doses	-
24 July 2021	Diverted	India	Covishield	Covid: Pharmacist held for vaccine fraud in Diamond Harbour	1151752	at least 40 people vaccinated	-
26 July 2021	Diverted	Pakistan	-	Man held, former army officer booked on charges of 'illegal' Covid vaccination in Karachi	1153392	unknown	-
26 July 2021	Falsified	Mexico	-	Police arrest man for administering fake Covid vaccine for 1,000 pesos	1153776	unknown	unknown, sodium chloride?

A.2.2. Incidents published in June and July 2021

A.2.2.1. *Falsified COVID-19 vaccines*

During an operation to seize a large shipment of falsified and smuggled COVID-19 vaccines, the Ministry of Intelligence of Iran (VAJA), arrested multiple individuals (report ID 1216975). The confiscated products included vaccines labelled to be from Sinopharm, AstraZeneca and Pfizer. The VAJA report did not specify how many vaccines were falsified products.

AstraZeneca

On the 30th of June the first lay press article reporting on the case of falsified COVID-19 vaccines in Uganda was loaded into our database (report ID 1119681). That report was followed by almost 50 other articles related to this incident, please go to our annexes to consult the related stories. The State House Health Monitoring Unit in Uganda revealed that over 800 people received falsified COVID-19 vaccines over May and June. Several private companies that made arrangements to have their staff privately vaccinated became victims, paying high prices for the falsified products. The vaccines were sold as 'AstraZeneca' COVID-19 vaccines (additional information report ID 1155700)¹⁸. Analytical results from the Government Analytical Laboratory and the National Drug Authority, showed that the vials were filled with - most likely bottled water. Serum Institute of India said that they did not produce the concerned batch number and the vials were not from them. The article mentions that the labels on the vials seemed locally printed. Several people have been arrested and charged in relation to the falsified vaccines, including two nurses.

Covishield

Two articles report on incidents with falsified Covishield vaccines in India. In the first incident residents of Hiranandani Estate Society in Mumbai, Maharashtra state of India, suspect they were administered falsified COVID-19 vaccines (report ID 1101158). On May 30 a vaccination camp was organised during which around 390 people received their alleged first dose of Covishield vaccine, paying Rs 1,260 for a dose (approximately 17 USD). The organiser of the vaccination camp claimed to be a representative of the Kokilaben Ambani Hospital. The residents had no symptoms or side effects and got suspicious when they did not receive vaccination certificates for nearly two weeks. Upon receipt of the certificates, they mentioned an incorrect place and date of vaccination.

In the second incident, a man was arrested for allegedly impersonating an Indian Administrative Service officer and conducting a Covid-19 vaccination camp in the name of Kolkata Municipal Corporation (report ID 1110971). A member of parliament (MP) of Trinamool Congress was present and was vaccinated along with 200 to 250 people with the alleged Covishield vaccine. The MP became suspicious as registration was not as per usual, no SMS was sent and nobody received a vaccine certificate. An article published some days later suggests the people might have been injected with amikacin, as a large number of amikacin vials and falsified labels

¹⁸ Source: The Independent. 800 fake Covid-19 vaccine doses were 99% water. The Independent. <https://www.independent.co.uk/800-fake-covid-19-vaccine-doses-were-99-water-monitoring-unit/>. Published July 20, 2021. Accessed September 6, 2021.

of Covishield were recovered at the suspects office (report ID 1112828)¹⁹. Another article that reports amongst others on the above two cases, summarizes that at least 2,500 people have been victims of fake COVID-19 scams in two major Indian cities, Mumbai and Kolkata (French report ID 1114048). According to the Mumbai police around 2,000 people were administered saline instead of a genuine COVID-19 vaccine dose.

Moderna

In Thailand in Prachinburi Province, a clinic was ordered to close after allegedly selling falsified Moderna vaccines (report ID 1136434). Patients had to pay 46 USD per dose, they were not shown the packaging of the vaccine, and allegedly they did not suffer any of the expected side effects. The COVID-19 Moderna vaccine was not officially available in Thailand and during a raid of the clinic no actual Moderna vaccine was found.

Pfizer/BioNTech

Ecuadorian authorities arrested five people for allegedly selling jars filled with sea water that they claimed were Pfizer/BioNTech COVID-19 vaccines for 25 USD per shot (report ID 1100787). Authorities did not say whether any of the residents in Manta were injected with the product. The individuals were charged with the “*alleged production, manufacturing, marketing and distribution of adulterated drugs*”. A total of 43 syringes filled with liquid as well as an unknown number of small glass jars that contained ocean water were seized.

In Lebanon, an employee of the government hospital in Batroun was fired for giving false doses of Pfizer vaccines (French report ID 1135850). No further details were given in the article.

Unknown ‘COVID-19 vaccines’

A man posing as a doctor was arrested in Tapachula, Mexico, for selling falsified Covid-19 vaccines for 1,000 to 1,500 pesos per dose (approximately 50 to 75 USD; report ID 1153776). The police found a plastic bag with empty syringe cases, two empty bottles of sodium chloride, fake vaccination certificates and a list of people who had received the shots.

An article reports on 2 separate cases in Venezuela (report ID 1120499). The first incident involves the sale of falsified COVID-19 vaccines. On June 26, authorities detained an employee of the health department in western Lara state for allegedly filling vials with boiling water, painkillers and antibiotics and sell them as COVID-19 vaccines. A total of four individuals were accused of scamming nearly 2,000 people, who paid 50 to 150 USD per dose. The second incident involves diversion of COVID-19 vaccines. In April, authorities dismantled a gang selling vaccines via WhatsApp for 280 USD. The article reports the doses were stolen from a health centre in Caracas and had expired after not complying with the appropriate storage conditions.

¹⁹ Hindustan Times Correspondent. People may have got antibiotics at fake jab camp in Kolkata: Cops. Hindustan Times. <https://www.hindustantimes.com/india-news/people-may-have-got-antibiotics-at-fake-jab-camp-in-kolkata-cops-101624561190596-amp.html>. Published June 25, 2021. Accessed September 6, 2021.

A.2.2.2. *Substandard COVID-19 vaccines*

Johnson & Johnson

In previous reports we reported on the quality issues discovered at the manufacturing plant Emergent BioSolutions, a subcontractor producing both the Johnson & Johnson (J&J) and the Oxford-AstraZeneca COVID-19 vaccine in Baltimore, USA. The United States Food and Drug Administration (US FDA) conducted a thorough review to decide on release or destruction of the potentially affected batches, estimated to cover 100 million doses. Additional information was shared in an article published on June 11th²⁰ mentioning that the US FDA allegedly had decided to release 10 million doses and discard at least 60 million doses of J&J vaccine made at the Emergent BioSolutions plant. The European Union regulator said some of the affected batches under review are not going to be used in Europe (report ID 1095771). The article did not mention any quantities. Furthermore, 300,000 doses of the J&J COVID-19 vaccine will not be released for use in Canada (report ID 1096549). The vaccines were quarantined in April before they were distributed to provinces because Health Canada was informed that those vaccines were produced at the Emergent BioSolutions facility. Similarly, in South Africa, two million doses of the J&J vaccine, that were awaiting distribution from the Aspen Pharma plant in Gqeberha, will not be used due to suspicions that a core component of the vaccine was contaminated in the US factory (report ID 1097627).

Sinovac

In a Thai vaccination site, 110 vials of Sinovac COVID-19 vaccine have been found to contain a lump of transparent gel (report ID 1173183). The Thai FDA have called for the suspension of the administration of any bottles of Sinovac's CoronaVac vaccine which are found to contain lumps and the notification of such discoveries. In addition they shared the concerned batch number (Sinovac vaccine, batch C202105079, manufacturing date May 10th, expiry date November 9th the substance.). They believe the gel is likely formed due to the vaccine being stored at a too low temperature, and/or its pH level that has changed. Allegedly, the vaccine is not dangerous but its efficacy would be reduced.

Sputnik V

An article reports that the World Health Organization (WHO) inspected several Sputnik V manufacturing sites in Russia and that they found non-compliance with good manufacturing practices at the Pharmstandard Ufa Vitamin Plant (report ID 1131615). In the summary report with preliminary findings, the WHO inspectors reportedly highlight six issues found. They identified issues with the traceability and identification of vaccine batches. There were also concerns over the filling lines, sterility assurance, sterile filtration validation and the risks of cross-contamination. The Russian government said that the shortcomings identified by the WHO inspectors have been addressed.

²⁰ Additional information in report ID 1095788. Source: McGinley L, Rowland C, Stanley-Becker I. FDA has decided at least 60 million doses of Johnson & Johnson's coronavirus vaccine must be discarded; 10 million can be released. The Washington Post. <https://www.washingtonpost.com/health/2021/06/11/fda-releases-johnson-johnson-vaccine-from-emergent-plant/>. Published June 11, 2021. Accessed September 8, 2021.

A.2.2.3. *Diverted COVID-19 vaccines*

The Punjab government, India, has been accused of procuring COVID-19 vaccines from manufacturing companies Bharat Biotech (Covaxin) and Serum Institute at Rs 400 (approximately 5.5 USD) and earning profits by selling them to private hospitals at Rs 1060 (approximately 14.5 USD; report ID 1086967). Allegedly the private hospitals are further charging people Rs 1,560 for each dose. A government official replied that a total of 40,000 doses were given to private hospitals, and that it was a one-time measure.

AstraZeneca

In Uganda, COVID-19 vaccines were stolen from the Ministry of Health store and sold on the black market to the public (report ID 1129380). The police arrested twelve suspects from two city pharmacies in connection with the stolen COVID-19 vaccines. During the raids, more than 600 doses of AstraZeneca coronavirus vaccine were recovered. The article reported that investigations and operations were still ongoing.

Covishield

Two articles report on incidents with diverted Covishield vaccines in India. In the first incident in Ahirwara, Chhattisgarh state, 70 vials of Covishield vaccine were stolen from a COVID vaccination centre (report ID 1143378). According to the article the attendant came with 150 vials of Covishield in two carriers. When one carrier with 80 vials was exhausted, the second carrier was opened but appeared to be empty. The police filed a case against unidentified men for theft.

In the second incident, the police arrested a man, allegedly a pharmacist attached with a primary health centre, for procuring vaccines and organising small vaccination camps in people's homes in Sonarpur, in West Bengal state (report ID 1151752). The police seized two vials with Covishield labels from him. A sample was sent for forensic examination to ascertain the composition of the liquid. The police suspects that the accused could be stealing vials from the official stocks he received for vaccination at the primary health centre. The serial number on the vials could be used to check if it matches with the vials in the stock. Allegedly the suspect vaccinated at least 40 people and was charging Rs 300 or Rs 400 per dose (approximately 4 to 5.5 USD).

Sinovac

In Quezon City, Philippines, 300 doses of COVID-19 vaccine stated as manufactured by China's Sinovac Biotech were confiscated (report ID 1130843). The article reported the vaccines look authentic and were sold on the black market at very high price. The vaccine bottles were slightly opened and the packaging was slightly dirty. The FDA chief said investigators are now tracing where the confiscated vaccines were sourced. Furthermore he said: *"Once vaccines get out of the system, they are unsafe for us because there is no way of knowing how they were handled and these probably did not go through the correct cold handling facilities"*

COVID-19 vaccines for which the brand was not specified

In South Africa a wave of looting and vandalism started as protests against former president Jacob Zuma's imprisonment for contempt of court (report ID 1138581).

More than 90 pharmacies, amongst other establishments, in KwaZulu-Natal and Gauteng were targeted. Among the looted items were COVID-19 vaccines. The South African Pharmacy Council warned residents against buying medicine which could be stolen. They pointed out the danger of using medical products that were not stored properly.

In Pakistan, police have arrested a suspect on charges of illegally administering COVID-19 vaccines in return for payment at homes in Karachi (report ID 1153392). The suspect allegedly stole vaccine doses from a vaccination centre of the Sindh government. During the entrapment, the suspect showed up with a box of syringes, three used vials and two empty vaccination cards with inscription of the Government of Sindh and the health department. The police have registered a first information report against the detained suspect, his alleged employer and some others that might be involved in the activity.

A.2.2.4. COVID-19 vaccines for which the quality is unclear

In Kenya, the Directorate of Criminal Investigations started an investigation into some facilities that have been illegally vaccinating people for Covid-19 and charging them for that vaccination (report ID 1086161). The ministry did not disclose which facilities are on the radar, in order not to compromise the ongoing operations. The Health Ministry said that *“Chances are that you are not even being vaccinated with proper vaccines. There is every possibility that you are even being vaccinated with water and paying for it and therefore I want to warn the country and Kenyans at large first, vaccination in Kenya is free, nobody should be charging you for it”*.

Authorities found an establishment in Juárez, Mexico, where alleged COVID-19 vaccines were administered (Spanish report ID 1157058). During the operation used syringes and empty vials were found. It is unknown whether the contents of the vials were genuine, degraded or falsified. The location where the vaccines were administered did not meet the required conditions for cold chain, storage, distribution and administration.

Online

According to a report from blockchain analytics company Coinfirm, vendors have been selling vaccines (and certificates) in exchange for a range of cryptos on the dark web (report ID 1122035). One particular vendor, known as the ‘COVID-19 Vaccine Shop’, appears to be selling vaccines in bulk stated as from AstraZeneca, Pfizer-BioNTech, Johnson & Johnson, Moderna and Sputnik V.

Italian police have broken up a network that was selling COVID-19 vaccine vials (and falsified European vaccination certificates) online, where purchases and sales could be completed in cryptocurrency (report ID 1123690). They identified ten accounts and channels on Telegram, referring users to anonymous “dark web” accounts, where they can be obtained. The article further reports that *“despite the exorbitant prices and extremely exorbitant health risks”* the police notes thousands of people registered on illegal channels in search of vaccines and certificates.

In the Philippines, two persons, one posing as a nurse, were arrested in an entrapment operation for selling COVID-19 vaccines through social media (report ID 1129126). They were allegedly getting the supply of vaccines from a private hospital in Makati City and a government hospital in Quezon City and were offering

Pfizer/BioNTech, Oxford-AstraZeneca and Sinovac vaccines. The entrapment operation concerned the transaction of 50 vials of COVID-19 vaccine for P120,000 (Philippine pesos, approximately 2400USD) but operatives were not able to recover vaccine vials from the suspects.

A.3. Reports from scientific literature

Ramakanth D, Singh S, Maji PK, Lee YS, Gaikwad KK. **Advanced packaging for distribution and storage of COVID-19 vaccines: a review.** *Environ Chem Lett.* Published online June 3, 2021:12. doi:10.1007/s10311-021-01256-1

Extract. *"The pharmaceutical industry is more vulnerable to counterfeit medical products. A survey conducted by International Data Corporation (IDC) in June 2020 revealed that approximately 70% of manufacturers agreed on the vulnerability of their supply chain, if COVID-19 continued for a couple of months and approximately 75% of companies agreed to an increase in theft, diversion, or counterfeiting of vaccines, test kits, and antivirals (Forcinio 2021). Vaccine manufacturers should be aware of the fake COVID-19 vaccines entering the market. A study conducted by the Authentication Solution Providers Association of India revealed that counterfeiters do not produce vaccines, they just fool people by duplicating the vaccine packaging while putting harmful or inactive contents inside. A recent Interpol global alert to law enforcement agencies in 194 member countries against organized networks targeting COVID-19 vaccines provides evidence of the severity of the situation (Outlook 2021). [...] In order to curb counterfeiting, laws, and regulations have been formulated by various agencies such as the European Union's Falsified Medicine Directive and the US's Drug Supply Chain Security Act (Forcinio 2021). The WHO also constituted a task force unit in 2006, The International Medical Products Anti-Counterfeiting Taskforce (IMPACT), to fight against the multi-million-dollar illegal trade of counterfeit drugs and vaccines (WHO 2020e)."*

Schneider M, Ho Tu Nam N. **How pharmaceutical companies can prevent falsified medicine and vaccines from entering African markets.** *J Intellect Prop Law Pract.* Published online July 30, 2021. doi:10.1093/JIPLP/JPAB112

Extract. *"As the result of an increase in demand, the value of the African pharmaceutical market is projected to rise to an estimated USD 56–70 billion by 2030. This increase will occur in a context where Africa is already the continent the most at risk of an influx of counterfeit drugs. With a prevalence of 18.7 per cent of falsified and substandard medicine—the highest worldwide—counterfeiters and traffickers will be looking closely at this growing demand. The COVID-19 pandemic, which brought about counterfeit vaccines, medical supplies, and PPE is a stark reminder of the dangers faced by the continent's population when demand is high but supply low."*

Sharma M, Sikka G. **Blockchain based Approaches For Preventing Drug Counterfeit: A Survey.** *Int J Eng Res Technonology.* 2021;7(9):1-6. Accessed September 24, 2021. <https://www.ijert.org/blockchain-based-approaches-for-preventing-drug-counterfeit-a-survey>

Abstract. *"During the current spread of COVID-19 tons of people have suffered critical health issues, which in many cases also lead to death. The death rate in the past few months has been on a spike. News channels are flooded with information regarding fake doses of drugs been injected into people, ultimately leading to the death of many. There has been duplication of the antiviral drug Remdesivir and also the important Pfizers vaccine. The lives of people are at stake with the counterfeit drugs been sold in the market. This generates a sudden need to look upon the matter and define the methods for preventing the counterfeit of drugs to save the lives of people. Through this paper, we review various blockchain-based approaches which can help in preventing drug counterfeit."*

A.4. Reports from international organisations

OECD/EUIPO. **Illicit Trade: Global Trade in Fakes. A Worrying Threat**; 2021. doi:10.1787/74c81154-en

Extract. "Last but not least, the counterfeiting of pharmaceuticals products is a reality. Even though they are not the most infringed products, their trade is a real threat to public health and was documented by the OECD and EUIPO in (OECD/EUIPO, 2020). The findings show that both common medicines as well as more complex drugs (i.e. for cancer or heart disease) are counterfeited. These challenges have become even greater with the COVID-19 pandemic, which has created new opportunities for profits for criminal networks. Supply chains broken by border closures, a strong demand for medicines, protective equipment and tests, and the limited capacity of law enforcement officials all shape the illicit trade in fake pharmaceuticals. Criminals are clearly taking advantage of the global pandemic, and enforcement authorities are reporting a sharp increase in seizures of fake and substandard medicines, test kits and personal protective equipment (PPE), as well as other medical products. In addition, the first instances of counterfeit COVID-19 vaccine have been reported, posing a vital threat to vaccination programmes."

Unicef. **Development of a Global Trust Repository – Solution, Implementation and Operation Services**. United Nations Global Marketplace - Term of reference. Published June 2021. Accessed June 16, 2021.

<https://www.ungm.org/Public/Notice/131648>

Extract. "As COVID-19 vaccines are being distributed, there has been an upsurge in the production and distribution of falsified and sub-standard vaccines and related COVID-19 supplies, particularly those reported in the media as potential therapies for COVID-19. This trend is expected to continue as COVID-19 vaccines and therapeutics become more available. The development of one of the most valuable vaccines in history has driven the proliferation of falsified COVID-19 vaccines, diversions and theft to degrees not seen before. The highest risk is in low- and middle-income countries national supply chains, where governance structures and traceability systems are non-existent or not fully mature, and tools and technical capacity to ensure good practices in manufacturing, quality control and monitoring of distribution chains is limited. To this end, a solution that provides countries with mechanisms to monitor national supply chains of COVID-19 vaccine is imperative to ensure equitable access, safety, and security – and build the foundation for end-to-end traceability for vaccines and medicines."

A.5. Reports from regulatory authorities

U.S. Food & Drug Administration. **FDA Takes Steps to Increase Availability of COVID-19 Vaccine**. Press Announcements. Published June 11, 2021. Accessed June 21, 2021. <https://www.fda.gov/news-events/press-announcements/fda-takes-steps-increase-availability-covid-19-vaccine>

Extract. "The agency is announcing today that it is authorizing for use, under the emergency use authorization (EUA) for the Janssen COVID-19 vaccine, two batches of vaccine drug substance manufactured at the Emergent BioSolutions facility in Baltimore. Before making this decision, the FDA conducted a thorough review of facility records and the results of quality testing performed by the manufacturer. Based on this review and considering the current COVID-19 public health emergency, the FDA concluded these batches are suitable for use. While the FDA is not yet ready to include the Emergent BioSolutions plant in the Janssen EUA as an authorized manufacturing facility, the agency continues to work through issues there with Janssen and Emergent BioSolutions management."

A.6. Miscellaneous

In this section we report on organisations, associations or independent writers who have highlighted the risk or threat of SF COVID-19 vaccines but that are not necessarily covered in the general articles on the MQM Globe database.

Okunola A. **How Can I Spot A Fake COVID-19 Vaccine? – Fight the Fakes. Fight the Fakes.** Published June 24, 2021. Accessed September 28, 2021.

<https://fightthefakes.org/how-can-i-spot-a-fake-covid-19-vaccine/>

Extract. *"In the climate of COVID-19, where some place an even higher significance on the vaccine, international authorities are working even harder to ensure doses are verified. [...] Furthermore, it can take a while to realize a fake vaccine has been administered, which can increase the risk of someone with asymptomatic COVID spreading the virus. Fake vaccines also erode trust in legitimate vaccines and vaccination programmes, and place an additional burden on health systems which are already stretched by the pandemic.[...] Education is the first action towards tackling counterfeit medicines that anyone anywhere in the world can take. When you know what to look out for and how to spot fake medical products, you can teach other people and so on. A good start is the "six Ps" of identifying fake medicine, according to Interpol."*

Part B.

Other medical products linked to COVID-19

B.1. Articles of incidents in the lay literature

B.1.1. Overview of all categories

Since the beginning of the pandemic we have identified 845 relevant articles on quality problems with COVID-19 medical products: (a) vaccines, (b) diagnostics, (c) Personal Protective Equipment (PPE), (d) sanitisers & disinfectants, (e) medicines, and (f) ventilation & oxygenation equipment and consumables. In this issue we report on 96 relevant articles: 60 articles for June 2021 and 35 articles for July 2021 (see Figure 3), including vaccines. We also report on an article that was published in May but that was not included in the previous issue. Therefore the total number of articles published in May is 74 instead of 73. The peak in articles in May was mainly related to the high number of articles related to COVID-19 medicines, more specifically to quality issues with remdesivir, and to some extent to an increased number of articles related to incidents with ventilation & oxygenation equipment and consumables. The lower number of articles in July compared to June was mainly linked to fewer articles on COVID-19 related medicines.

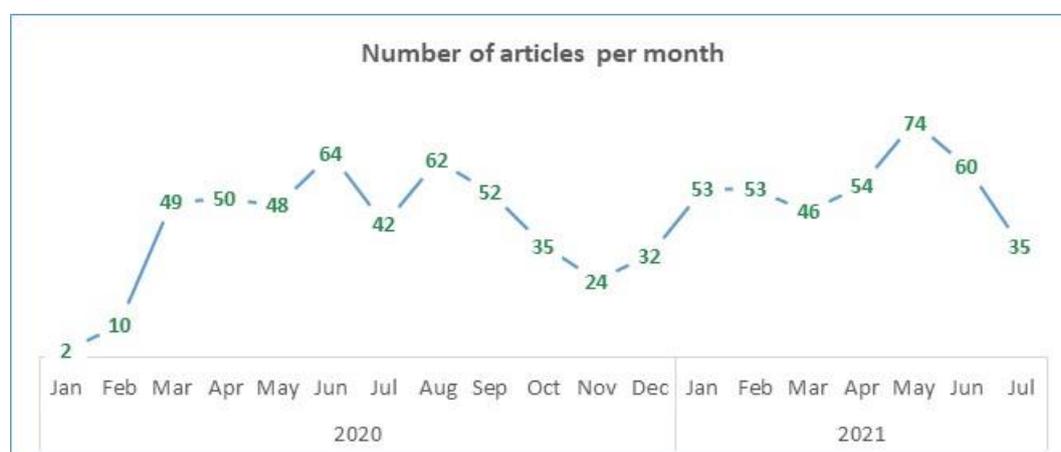


Figure 3. Number of articles on the Medicines Quality Monitoring Globe on quality issues of COVID-19 supplies by month.

As some articles describe more than one category of products, the sum of incidents per month as shown in Figure 4 may exceed the sum of articles per month of Figure 3. Note (i) since November '20, non-COVID-19 medicines containing hidden active pharmaceutical ingredients (API) that are used or trialled for COVID-19 are no longer included. Only medicines for which the stated API is used or trialled for COVID-19 treatment are included in this report. The observed decrease of the number of articles can be at least partially due to this change. Note (ii) 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.

The articles we discuss for June and July include 104 incidents: 35 (28; 7) on COVID-19 related medicines, 24 (13; 11) on vaccines, 16 (10; 6) on PPE, 12 (8; 4) on sanitisers & disinfectants, 12 (6; 6) on diagnostics, and 5 (3, 2) on ventilation & oxygenation equipment and consumables. Figure 4 shows the number of alerts for each category by month since the beginning of the pandemic. To see the number of incidents for each category by week since the beginning of the pandemic, please consult Annex C.

Some articles summarize or describe multiple product categories used during the COVID-19 pandemic. When an article discusses more than 2 product categories, we describe the content of those articles in this section and do not report on them in the sections for the different product categories.

In mid-May 2021, Operation Pangea XIV was conducted, involving regulatory authorities from 92 countries and resulting in 277 arrests (report ID 1091825 and [see Interpol news](#)²¹). Every year Interpol leads this international effort to disrupt the illegal online sale of medicines and medical products. This year a record number of fake online pharmacies have been shut down. Overall the operation resulted in the seizure of around 9 million medical devices (e.g. COVID-19 test kits, masks etc.) and illicit pharmaceuticals (e.g. erectile dysfunction pills, analgesics/painkillers, antiseptics and germicides, vitamins, etc.). The operation showed that criminals are continuing to cash in on the demand for personal protection and hygiene products generated by COVID-19 pandemic. Falsified and unauthorized COVID-19 testing kits accounted for more than half of all medical devices seized. In Italy, authorities recovered more than 500,000 falsified surgical masks as well as 35 industrial machines used for production and packaging. As part of Operation Pangea XIV, Cypriot police confiscated 600,000 unauthorised or falsified COVID-19 rapid tests and suspended their use (report ID 1095542).

An article reports on SF products in Karnataka State of India. Between March 2020 and May 6, 2021, Bengaluru police seized 17,312 bottles of falsified sanitisers, 18,750 falsified masks and 270 falsified thermometers (report ID 1097480). Furthermore the article reports that since last year Karnataka's Drugs Control Department has red flagged at least 89 poor-quality hand sanitiser products, some of which were sold to government hospitals.

²¹ Interpol. Thousands of fake online pharmacies shut down in INTERPOL operation. News. Published June 8, 2021. Accessed June 9, 2021. <https://www.interpol.int/en/News-and-Events/News/2021/Thousands-of-fake-online-pharmacies-shut-down-in-INTERPOL-operation>

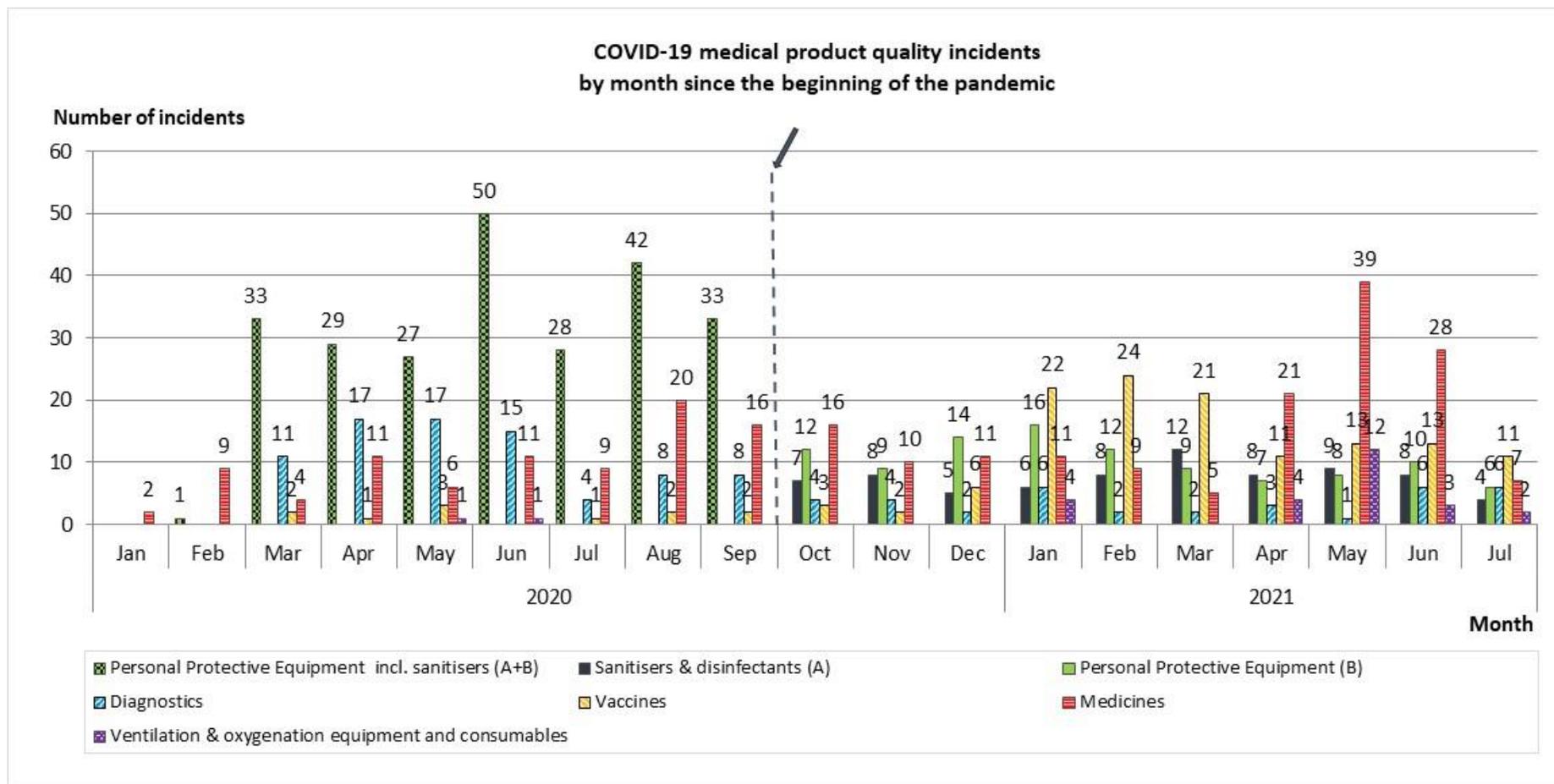


Figure 4. Incidents on the Medicines Quality Monitoring Globe on quality issues with COVID-19 medical products by month.

The arrow indicates the end of September 2020 when the category of ‘Personal Protective Equipment Incl. sanitisers’ was split in two distinct categories: (A) Sanitiser & disinfectants, and (B) Personal Protective Equipment. As some articles describe more than one category of products, the sum of incidents per month may exceed the sum of articles per month reported in Figure 3.

Note (i) since November ‘20, non-COVID-19 medicines containing hidden active pharmaceutical ingredients (API) that are used or trialled for COVID-19 are no longer included. Only medicines for which the stated API is used or trialled for COVID-19 treatment are included in this report. The observed decrease of the number of articles can be at least partially due to this change. Note (ii) 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.

B.1.2. COVID-19 diagnostics

B.1.2.1. Substandard COVID-19 diagnostics

The Nigerian National Agency for Food and Drug Administration and Control (NAFDAC) has cautioned against the importation, distribution and sale of COVID-19 test kits from Peru, more specifically 'Coronavirus Disease 2019 Antibody (IgM/IgG) combined test kit', produced by Chinese Medical System Biotechnology Co. Ltd (report ID 1119145). Pharmacovigilance analysis by NAFDAC showed that the kits are defective, as they did not meet the required IgG specificity and IgM sensitivity standards. Allegedly a recall has been ordered by the Peruvian Directorate of Medicines, Supplies and Drugs (DIGIMED).

In the USA, Quidel recalled Lyra SARS-CoV-2 Assay (M120), a real-time polymerase chain reaction assay, due to a risk of false negative results (report ID 1128626). The US FDA identified it as a Class I recall, use of the device may cause serious injuries or death.

B.1.2.2. Unauthorised COVID-19 diagnostics

There were several warning letters from the US FDA concerning COVID-19 diagnostic tests that were not or no longer authorised for sale in the USA. US FDA inspection of the Innova Medical Group Inc revealed that their SARS-CoV-2 Antigen Rapid Qualitative Test had been distributed in the USA without marketing approval, clearance, or authorization from US FDA (report ID report ID 1094616). The US FDA requested immediate action by Innova Medical Group Inc to cease the sale and distribution of the product and advised consumers to stop purchasing and using the products.

US FDA issued a communication to warn consumers to stop using unauthorized COVID-19 tests produced by Lepu Medical Technology (report ID 1084734, additional information report ID 1172682). The China based company offers COVID-19 test kits for sale without marketing approval, clearance, or authorization from the FDA: a Neutralization Antibody Test kit, a SARS-CoV-2 Antigen Rapid Test Kit and a Saliva Antigen Rapid Test.

The US FDA has sent four warning letter to 3 different USA based companies concerning COVID-19 test kits sold online without marketing approval, clearance, or authorization from the FDA. Two letters were sent to Vivera Pharmaceuticals, Inc. in California (report ID 1172680 for COVx-products & 1172681 for vivera products) and one letter was sent to Biopolygen in California (report ID 1207458 for 'Covigen' and 'Covidex' products) and USH Diagnostics Inc in Missouri (report ID 1207459 for 'Covidinstanttest' products).

B.1.2.3. Diverted COVID-19 diagnostics

In Imphal, Manipur state of India, some pharmacies are allegedly illegally selling 'Standard Q COVID-19 AG Test Kit' (report ID 1134624). The tests have been approved for professional use in health care setting but have not been approved for personal use for at-home testing and therefore should not be sold in pharmacies. It is feared that the results from self-testing have a high probability of being false negatives.

B.1.3. Personal Protective Equipment

B.1.3.1. Falsified masks and gloves

Mask and gloves

In Agra, Uttar Pradesh state of India, a factory allegedly manufactured falsified medical products, including gloves and masks (report ID 1121782). During a raid in early July, the owner was arrested and several raw materials and finished products were seized: 100,000 gloves, 50,000 surgical masks, 26,000 sanitary napkins, 2,000 urine catheters, 1,000 Nebulizer masks, and syringes.

Gloves

The Delhi Police, India, conducted several investigations (report ID 1086629). One case was linked to six people that are suspected of washing, repacking and selling several tonnes of used surgical gloves from hospitals.

Shijiazhuang Hongray Group, a Chinese corporation, filed a demand for jury trial targeting two US corporations, World Trading 23 Inc and World Tech Toys (report ID 1093443). The complaint is linked to the alleged sale of falsified Hongray Nitrile gloves and consists of elements on unfair competition and false advertising.

Masks

Two articles discuss falsified masks in the USA. The first incident is a company in Kentucky, that was allegedly selling falsified 3M N95 respirators, some of which made it to frontline workers in Minnesota (report ID 1094690). The 3M branch based in Minnesota, USA, says it helped stop the sale of more than one million of falsified N95 masks. After an alert through 3M's fraud hotline, 3M worked together with the U.S. Marshals Service which led to seizure of one million falsified N95 masks at the company in Kentucky. The second incident concerns the city of Houston, that spent more than a million dollars on falsified masks (report ID 1110592). Allegedly, the city paid the company 'Med Tech Resource' roughly USD 1.7 million for around 900,000 3M N95 masks. Only after delivery did it come to light that the masks, intended for frontline employees, were falsified.

In Mumbai, Maharashtra state of India, an Indian NGO (Friends of Wadala East) has filed a petition against Amazon Retail India over the sale of falsified medical-grade face masks (report ID 1086265). In May, they had placed an order for 400 masks for health care workers on Amazon but the products they received were "*shoddy and substandard in quality, poorly packaged and nowhere close to what they were described as on the portal*". At the same time the NGO criticized the Union Ministry of Health & Family Welfare and the Union Ministry of Consumers Affairs for failing to check the sale of falsified masks.

The Kerala State Drugs Control Department seized Rs 3 lakh (approximately 4,095 USD) worth of N95 masks (and hand sanitisers) from an unlicensed company in Thiruvananthapuram, India (report ID 1130689). The same article reports on seizures of falsified hand sanitisers and masks from Malappuram, Thrissur, Alappuzha, Palakkad, Ernakulam, and Kannur.

In Saudi Arabia, two people were arrested in relation to violations of the Anti-Commercial Fraud Law and the Anti-Cover-up Law. The duo was producing and

stocking falsified goods and during a raid of their warehouse 4,430,000 masks were seized, together with machines and tools used for their illegal activities.

In Malaysia, the Johor Domestic Trade and Consumer Affairs Ministry has seized 112,350 pieces of suspected falsified 'Neutrovis' face masks in 3 different locations. It is believed that the three premises were used as storage location to manage distribution activities of various types of face masks. The operation was planned following complaints from the 'Neutrovis' trademark owner.

B.1.3.2. Substandard or Falsified masks and gloves

Masks

At the end of May, the Health and Sciences Authority of Singapore shut down an illegal surgical mask manufacturing and repackaging facility (report ID 1095146). A total of 82,500 'Vision Empire Healthcare' surgical masks were seized. Vision Empire International allegedly manufactured the masks in unhygienic conditions and is also suspected to have imported surgical masks from overseas for repackaging and rebranding without a licence.

One article reports on a study published by Plana et al. in BMC Infectious Diseases²² (report ID 1160268). The study suggests that hospitals in the USA still have substandard or falsified (SorF) masks in storage. The study found that over 100 different masks and respirators were available in the surveyed US teaching hospitals. Whereas pre-pandemic, most large hospitals would have 2 to 5 models. Due to the absence of publicly available information on mask suppliers and inconsistent labelling it is difficult to distinguish between genuine and falsified products. Many of the masks studied were from unknown manufacturers, not correctly labelled, and/or did not perform to accepted standards. The study concludes that many of the masks were likely to be falsified.

Mask and gloves

Approximately one hundred individual samples of masks and gloves available on the market in Cyprus were analysed (report ID 1125574). The results of the laboratory tests were released at the beginning of July. A large number of products were found to be non-compliant with personal protective equipment standards including lack of proper labelling, available certifications, and substandard protective qualities. Almost all KN95 masks did not meet the testing criteria. Over 50 percent of the gloves tested were non-compliant with the designated criteria.

B.1.3.3. Unregistered masks

The US FDA has sent warning letters to some companies concerning masks sold online to consumers in the USA without marketing approval, clearance, or authorization from the FDA. Zhejiang Xichen Medical Technology Co. Ltd. based in China offered 'FFP2 NR 5-Layer KN95 Face Mask', 'Medical Face Mask', and 'Sterile Surgical Mask', for which the website contains a number of false or misleading representations (report ID 1207454). Captain's Cloth LLC based in the

²² Plana D, Tian E, Cramer AK, et al. Assessing the filtration efficiency and regulatory status of N95s and nontraditional filtering face-piece respirators available during the COVID-19 pandemic. BMC Infect Dis. 2021;21(1):1-13. doi:10.1186/S12879-021-06008-8

USA, offered KN95 Face Mask, stated as manufactured by “Lianyungang Manai Protective Equipment Co. Ltd.” that are misbranded (report ID 1207457).

B.1.4. Sanitisers & disinfectants

B.1.4.1. Falsified hand sanitisers

In the COVID-19 medical product report covering April and May we reported on several recalls of hand sanitizers by Health Canada. One of the articles published in June mentions that the list of recalls has been further updated (report ID 1111814). The products were recalled due to health risks such as containing ingredients that are not permitted, defective or faulty packaging, undeclared impurities, improper labelling, lack of sufficient product testing, unauthorized for sale in Canada, and falsified products. For the most up to date list please consult the website of Health Canada²³.

In Maharashtra state of India, the Pune FDA found falsified hand sanitisers under both existing and fake brand names, during a raid at chemists, wellness centres and shops (report ID 1155514). Following a tip-off and a complaint a raid was conducted at the premises of ‘Atma Agencies’. The owner was found to be involved in manufacturing and marketing of various falsified sanitisers and selling them for the previous five months in different areas: Chandan Nagar, Vadgaonsheri, Kharadi, Hadapsar, Viman Nagar, Wagholi, Yerwada and more. In premises in Chandan Nagar a stock of sanitisers without labels and over 1,000 sticker labels worth Rs 17,000 (approximately 233 USD) were seized. The products were sold under the names of ‘Happy Hand Advanced Hand Sanitiser, an original existing product manufactured by DDN SFA Ltd, and ‘Jolly Hand Sanitisers’ as per label manufactured by Microgen Hygiene Pvt Ltd. The seized products have been sent to a laboratory for testing.

In India, the Kerala State Drugs Control Department (KSDCD) seized Rs 3 lakh (approximately 4,095 USD) worth of hand sanitisers (and N95 masks) from an unlicensed company in Thiruvananthapuram (report ID 1130689). The hand sanitisers were from a factory in Tamil Nadu state and the product allegedly caused burns on the skin. The same article mentions that 50 cases regarding the sale of low-quality Covid essential sanitisation products were reported across the state of Kerala, including seizures of falsified hand sanitisers and masks from Malappuram, Thrissur, Alappuzha, Palakkad, Ernakulam, and Kannur.

B.1.4.2. Substandard hand sanitisers

In Florida (USA), ‘MPL Laboratories’ launched a voluntary recall of 26 lots of antimicrobial hand sanitizers, manufactured from February up to June 2020, due to microbial contamination concerns caused by *Burkholderia cepacia* complex and *Ralstonia pickettii* (report ID 1093504).

²³ Government of Canada - Health Canada. Recall of certain hand sanitizers that may pose health risks (Part 2 – March 31, 2021 to present) - Recalls and safety alerts. Recalls and safety alerts. Published August 24, 2021. Accessed August 31, 2021. <https://healthykanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/75267a-eng.php>

B.1.4.3. Substandard or Falsified hand sanitisers

The Indian Central Drugs Standard Control Organization (CDSCO) released their results for April, for the monthly random quality tests on a range of pharmaceutical products (report ID 1083074). One hand sanitiser, Isopropyl Alcohol Hand Rub 'Icandy' by Cosmetics Pvt Ltd., was declared as "Not of Standard Quality" after failing the identification test.

B.1.4.4. Unregistered or unlicensed hand sanitisers

During a raid in Rajarhat, West Bengal state of India, the manager of a manufacturing unit producing chemicals was arrested and 500 litres of blue liquid was seized (report ID 1100774). The unit was allegedly producing hand sanitisers without authorisation.

The US FDA addressed warning letters to companies regarding the quality of their hand sanitizers. The companies had allegedly tried to import products into the USA that were adulterated and/or misbranded and/or unapproved. In this paragraph four of the warning letters are described.

In June, the Mexican company 'DMM Vission, S.A. de C.V.' received a warning letter (report ID 1091500). The US FDA previously recommended to remove all their hand sanitizers from the US market. Following an attempt to import DMM hand sanitizer into the United States, the products were detained and refused admission at the border. Two of their hand sanitisers were wrongly labelled to contain 70% v/v ethanol, but the ethanol content was lower and in addition contained traces of methanol. For 'Syp Health Hand Sanitizer Alcohol Gel' FDA laboratory testing showed an average of 31% ethanol and an average of 2.3% methanol v/v, and for 'By Cristalware hand sanitizer' alcohol gel they found an average of 22% ethanol and an average of 10% methanol v/v. The USA based company 'PurePurge Inc', received a warning letter related to its 'Medpure Hand Sanitizer' product line (report ID 1095799). Although the product is unapproved and misbranded, the product was marketed online.

In July, the Turkish company 'Sck Zeta Dis Ticaret, Pazarlama Ltd' received a warning letter (report ID 1154811). Following an attempt to import 'Neutrevo Instant Hand Sanitizer' into the USA, it was detained and refused admission at the border and it has not been given permission to enter the country. Although the product was labelled to contain 70% v/v ethanol, laboratory testing found that it contained on average 63% v/V ethanol and an average of 6% methanol v/v. Also the Turkish company 'Delta Kozmetik Sanayi Ve Ticaret' received a warning letter (report ID 1146050). Following an attempt to import a hand sanitiser listed to be manufactured at their facility', it was detained and refused admission at border. The US FDA found that the product contained an average of only 59% v/v ethanol. This ethanol content is lower than that which is declared on the products labelling and lower than CDC recommendations.

B.1.5. COVID-19 medicines

We have tried to order the incidents by medicine involved and then by the quality issue described. Some articles discuss several medicines or several incidents, and some incidents are not straightforward to classify; thus the subdivision might be arbitrary. We only discuss the articles once, even if they could be classified under different subheadings.

In this section 35 articles related to quality issues with COVID-19 medicines are discussed: 28 articles were published in June and 7 in July. The drop in articles on COVID-19 medical products goes in parallel with the drop of reported incidents in India. Twenty-seven articles (77%) are linked to incidents in India out of which 24 were reported in June and only 3 were reported in July. When quality issues were reported Remdesivir was most commonly reported (13 out of 35 articles) but the proportion is lower compared to April and May (53 out of 60 articles). Some other active pharmaceutical ingredients for which quality issues were reported are favipiravir (6), amphotericin (4) and tocilizumab (3).

B.1.5.1. Remdesivir

Falsified

Articles discussed one case of falsified remdesivir in Mexico, the other four articles discuss cases in India. Authorities in Mexico have found falsified remdesivir offered for sale on the internet and at a private hospital near the US border in the state of Tamaulipas (report ID 1164000). The appearance and lot numbers on the packaging did not match the original and Gilead Sciences confirmed the falsification.

In the previous issue we reported on falsified remdesivir vials that were found dumped in the Bhakra canal near Ropar in India.²⁴ That incident led to investigations in different companies and states. The Punjab police arrested six people of an interstate gang, who used to sell falsified remdesivir and they recovered designs and packaging materials used for making the vials (report ID 1105491).

In Rajasthan state, laboratory analysis confirmed that the remdesivir vials seized in Jaipur were falsified (report ID 1104076). The police suspects that at least 900 vials were sold in the city of Jaipur.

Two articles report on incidents of falsified remdesivir in the National Capital Territory of Delhi. The first article reports on several investigations the Delhi Police conducted (report ID 1086629). One of the described cases was the arrest of a gang that allegedly made and sold falsified remdesivir for up to 40 times the market price. The other article reports on a former hospital employee who was arrested on April 30 for allegedly selling falsified remdesivir, pasting stickers of remdesivir on injections of the antibiotic Monocef (ceftriaxone; report ID 1098779). Two injections were seized during the raid. A co-accused was arrested after 70 stickers of remdesivir injections were recovered from his possession.

²⁴ Report ID 1050572 discussed in Medical Product Quality Report – COVID-19 issues. Issue 11. Source article: Tribune News Service. 621 fake Remdesivir vials found in Bhakra. The Tribune India. Published May 6, 2021. Accessed September 2, 2021. <https://www.tribuneindia.com/news/punjab/621-fake-remdesivir-vials-found-in-bhakra-249186>

Substandard or Falsified (SorF)

In Maharashtra state, the Mumbai FDA laboratory found 6 remdesivir samples to be SorF including products labelled as Jubi R, Covifor, and Remdac (report ID 1156719). Some samples contained a clear colourless solution other a yellow coloured liquid instead of remdesivir. In addition, other medicines used to treat COVID-19 patients allegedly have been found as SorF.

Unregistered

In June an article reported that, in recent months, federal authorities in the USA seized more than a hundred shipments of unauthorized remdesivir destined for Mexico (report ID 1111214). The goods were seized by the US Customs and Border Protection (CBP) at various airports after they arrived by plane from Bangladesh and India. Investigations were started to determine if the products were falsified or genuine.

B.1.5.2. Amphotericin B

Falsified

In Gujarat state of India, a 24-year-old man from Surendranagar was arrested for allegedly selling 42 falsified vials of amphotericin B injections (report ID 1093374). The case came to light when a patient's health deteriorated after administration of the first 20 vials.

In India, Delhi police seized 3,293 vials of falsified liposomal amphotericin B injections (report ID 1107417). They arrested 7 people involved, including 2 doctors, for manufacturing and selling the product.

Diverted

An article describes how in India police are tracking down black marketers of products used in COVID-19 (report ID 1083769). The Rachakonda (Telangana State) police allegedly came across eight cases of illegal selling of amphotericin B and around 50 cases of remdesivir. The police had launched a large investigation and in some cases they have arrested doctors, nurses and some medical representatives. The article further gives several examples of cases of amphotericin B injections that were black marketed and people who were arrested subsequently. The article states that amphotericin B normally does not cost more than Rs 7,858 (approximately 108 USD), but black marketers are selling it for Rs 50,000- Rs 70,000 per injection (approximately 685-960 USD).

In Hyderabad, Telangana state of India, police seized 35 vials of amphotericin B injection and arrested three pharmacists, each owner of a different pharmacy, for their role in the illegal sale of the product (report ID 1109134). The suspects, allegedly bought the vials from a person who's relative only used part of the injection he had purchased for his treatment. Subsequently they tried to sell the vials for Rs 35,000 to Rs 50,000 (approximately 480 to 685 USD) each. The article further reports that Hyderabad police arrested 136 persons for in their involvement in the illegal sale of Remdesivir and Amphotericin B vials and registered 58 cases against them. All the offenders were allegedly linked to hospitals and medical stores.

B.1.5.3. Tocilizumab

Falsified

At the beginning of June, an article reported that Gujarat police tracked down several cases of black-marketing, hoarding and selling of falsified COVID-19 medicines and injections in the previous two to three months (report ID 1086529). The operations resulted in revealing dozens of cases of black-marketing and selling falsified remdesivir and tocilizumab injections. In May, the Surat's Umra police (Gujarat state of India), arrested eight people, including a doctor, for black-marketing of Tocilizumab injection. One person allegedly died after injection with the suspected product. The Forensic Science Laboratory of Gandhinagar analysed two of the seized vials and found that they contained steroids instead of Tocilizumab.

In mid-June, an article reports on the content of falsified tocilizumab and remdesivir injection that were seized in the state of Gujarat, India (report ID 1100945). Some of the cases have been discussed in the previous issue of this report. Sources at the state Directorate of Forensic Sciences (DFS) said that they had received six samples so far. In one of the falsified tocilizumab injections, dexamethasone and theophylline were found²⁵. Another vial contained antibiotics but the label was changed to be sold as a genuine tocilizumab injection.

Diverted

At the beginning of June an article was published that there was still no action taken against the doctor who was allegedly involved in a case at the Medical College Hospital in Kolkata, Indian state of West Bengal, where 26 vials of Tocilizumab were stolen (report ID 1089047). No further details on the incident were mentioned in the article.

B.1.5.4. Favipiravir

Falsified

In Haridwar, Uttarakhand state of India, the owner of 'Life Max Cancer Laboratories' filed a complaint for the sale of falsified favipiravir, sold under the company's logo and brand name (report ID 1100164). The batch number and wrappers of the medicine were tampered with. The police opened a case against unnamed people.

Two articles report on incidents in Cuttack, Odisha state of India, involving falsified favipiravir. Firstly, police seizure of at least 170 boxes containing 17,000 falsified favipiravir tablets in a chemist shop (report ID 1095707). The medicines were intercepted prior to release on the Odisha market and were sent to a laboratory for testing. Secondly, a dealer was found to be allegedly involved in the trade of 40,600 falsified favipiravir tablets (report ID 1096845). The tablets were allegedly brought from Noida (Uttar Pradesh) to Cuttack (Odisha) and subsequently shipped to Gwalior (Madhya Pradesh). According to the packing, the medicine was manufactured by a non-existing manufacturer in Solan, Himachal Pradesh State.

²⁵ The sample with dexamethasone and theophylline might be the same sample as the one mentioned in report ID 1086529 published beginning of June, that was said to contain steroids.

B.1.5.5. *Various active pharmaceutical ingredients*

Falsified

Azithromycin & favipiravir. In Noida, Uttar Pradesh, an illegal medicines manufacturing unit was discovered (report ID 1091779). The police allegedly said that the unit was connected to the larger falsified medicine route with links in Meerut and supply chain in Mumbai. During the raid packed and loose falsified azithromycin and favipiravir medicines worth Rs 25 lakh (approximately 34,200 USD) were found along with packing wrappers and equipment used to make and pack the medicines.

Hydroxychloroquine & Favipiravir. An article published in May and discussed in the eleventh issue of this report, reported on falsified favipiravir sold as 'Favimax-400' and 'Favimax-200' by the company owner of 'Max Relief Healthcare'²⁶. At the beginning of June further information was revealed. Laboratory analysis showed that samples of hydroxychloroquine sulphate tablets allegedly manufactured by 'Max Relief Healthcare' were also falsified (report ID 1086758). According to the article falsified favipiravir and hydroxychloroquine medicines, marketed by 'Covalent Healthcare', were seized by the Maharashtra FDA from three premises in Mumbai that were selling them online. The medicines were distributed in major cities in Maharashtra, Karnataka, Gujarat state. The products were labelled with 'Max Relief Healthcare, Village Anji, Solan, Himachal Pradesh', though no licence was issued by the drug controller on this name. The FDA ordered to stop the sale and launched a recall of all unsold stock, however allegedly thousands of persons had already consumed the medicines. In the wake of the above case, the Mumbai police arrested the owner of a pharmaceutical drug factory in Meerut, Uttar Pradesh, and seized several medicine samples (report ID 1089601). The article does not mention which products were seized and if they were falsified or not.

Piperacillin/tazobactam. Following a tip-off, Pakistani authorities seized Rs 1 million (approximately 6000 USD) worth of falsified medicines during a raid in a private house in Multan (report ID 1137809). The falsified medicines included falsified 'Tanzon', piperacillin/tazobactam injections, that are used for the treatment of COVID-19 patients.

Substandard

Atorvastatin. In May, the USA based Dr Reddy's Laboratories Inc initiated a nationwide recall of 2,980 bottles of atorvastatin calcium tablets (500-count; report ID 1090519). The products were manufactured at Dr Reddy's Indian plant in Bachupally, Telangana state. The voluntary recall was initiated after quality issues were detected related to "failed impurities degradation specifications". Previously, in March Dr Reddy had recalled 10,440 (90-count) and 2,24,710 (500-count) bottles of atorvastatin calcium tablets in the US market.

²⁶ Report ID 1082548 discussed in Medical Product Quality Report – COVID-19 issues. Issue 11. Source article: The Times of India. India's first spurious favipiravir racket busted. The Times of India - Ahmedabad News. Published May 31, 2021. Accessed September 3, 2021. <https://timesofindia.indiatimes.com/city/ahmedabad/countrys-first-spurious-favipiravir-racket-busted/articleshow/83127677.cms>

Ivermectin. In Malaysia, a coalition of doctors and medical professional groups called for action against the off-label use and black market of ivermectin (report ID 1146006). The Malaysian Health Coalition said ivermectin from veterinary supplies and unknown sources are sold at very high prices with false or misleading claims for the treatment of COVID-19 patients.

Losartan & valsartan. In Aruba, there was a recall of some batches of losartan and valsartan (and ibesartan) from the company Menafn due to contamination with azidomethyl-biphenyl-tetrazole (AZBT), which may increase the risk of developing cancer (report ID 1145242).

Metformin. In the USA, Viona Pharmaceuticals Inc voluntarily recalled 21,240 bottles of metformin hydrochloride extended-release tablets (report ID 1131542). The products were manufactured at a Cadila Healthcare factory in Ahmedabad, India. The US FDA had detected levels of n-nitrosodimethylamine that were higher than the acceptable daily intake limit.

Unregistered

Sildenafil. The US Customs and Border Protection (CBP) seized almost 24,000 tablets of illegal sildenafil in Cincinnati (report ID 1160270). It is not yet known whether the blisters with the name 'Signaforce' were falsified or genuine products. The shipment originated from an apartment in India and were headed to an apartment in Georgia, USA.

Substandard or falsified

Two articles described the results of the monthly random quality tests performed by the Indian Central Drugs Standard Control Organization (CDSCO). We only highlight the medicines that were declared as "Not of Standard Quality" that are used or trialed in the treatment for COVID-19. For April (report ID 1083074), the list contained 22 medicines that were not of standard quality, including metformin (Glucorid by Ridley Life Science Pvt Ltd), telmisartan (TLM-80 by Shine Pharmaceuticals Ltd, and Telmisartan Tablets IP 40mg by Caremax Formulations), atorvastatin (Orvastin-20 by Morepen Laboratories Ltd), paracetamol (Mepicar 650 Tablets by Sotac Pharmaceuticals Pvt Ltd), and zinc (Zinc Sulphate Dispersible Tablets IP 20mg by Hindustan Laboratories). Reasons why the samples were defined as not of standard quality included abnormalities in dissolution, uniformity of weight, and disintegration tests.

For June (report ID 1159752), the list contained 39 medicines that were defined as not of standard quality, including remdesivir (Covipri injection 100mg/vial), ivermectin (Iverpil-12 by Psychotropics India Ltd, and Ivermectin Tablets USP 6mg by Maan Pharmaceuticals Ltd), dexamethasone (Sandexa injection 30ml by Jpee Drugs), Coldbest-PC syrup (containing paracetamol, phenylephrine, hydrochloride and chlorphenamine, and manufactured by Mis. Digital Vision), acetylsalicylic acid (Dilsprin 75 by Jackson Laboratories Pvt), atorvastatin (Atorvastatin Tablets IP 20mg by Unicure India Ltd), ibuprofen and paracetamol tablets (by Tulip Formulations Pvt Ltd). Reasons why the samples were defined as not of standard quality included abnormalities in identification or assay of the active pharmaceutical ingredient, total aerobic microbial count, description, assay & particulate matter, and dissolution. The

Coldbest-PC syrup failed the assay of phenylephrine hydrochloride and showed the presence of diethylene glycol at 1.27% w/w and 7.71% w/w.

B.1.5.6. Unspecified 'COVID-19 medicines'

Falsified

In Jharsuguda, Odisha state of India, allegedly falsified COVID-19 medicines were seized from Amit Medical Agency (report ID 1097696). During the raid three types of medicines were seized and sent for laboratory tests but the report does not mention which medicines.

Anandaiah's herbal concoction is a herbal medicine that purportedly cures COVID-19. An article reports that falsified versions of Anandaiah's product are flooding the market in Andhra Pradesh state of India (report ID 1106884). So far, eight cases have been registered in connection with the sale of falsified herbal concoctions. In mid-June police arrested a person selling 'Anandaiah's Covid medicine' and seized 150 packets of the alleged medicine. The accused is said to have sold 750 packets of the concoction for Rs 200 each (approximately 2,75 USD).

In Uttar Pradesh state of India, a huge racket of manufacturing and packaging of falsified medicines, mostly branded painkillers and antibiotics, was found (report ID 1117967). The 'business' started during the peak of the second wave of the COVID-19 pandemic in India. The medicines were made in Muzaffarnagar and packed in Baghpat. Subsequently they were sold in rural and sub rural medical stores of Meerut, Baghpat, Shamli, Muzaffarnagar and other district. The alleged mastermind of the racket was arrested during a raid of the manufacturing premises. During a raid in the packaging unit in Baghpat, falsified medicines, packaging machines and printed wrappers were seized and the owner of the house was arrested.

Unregistered

An article reports that in Ireland in 2020, more than 1.6 million illegal medicines were detained, including 56,876 doses of COVID-19 medicines (report ID 1091505). The article does not specify which active pharmaceutical ingredients were involved.

In Surajpur, Himachal Pradesh state of India, health authorities raided a pharma unit for manufacturing and selling medicines without approval under the 'Tulip' brand (report ID 1104799). They seized 171,000 tablets of illegally made painkiller, a combination of ibuprofen and paracetamol that was in demand during the spike in COVID-19 cases in India. Laboratory test were requested to see if the product contained the active ingredients and whether was falsified. The current incident is linked to an ongoing investigation regarding an incident in April in Madhya Pradesh²⁷, in which a person was arrested for selling falsified remdesivir injections and 400 vials of remdesivir were seized. The vials were allegedly sourced by the accused in the Surajpur based pharma unit.

²⁷ Incident might be linked to an article with reported ID 1066516 that was discussed in the previous Medical Product Quality Report (issue 11). Source article: Outlook. 85 pc seized Remdesivir injections suspected to be fake: Cops. Outlook India. Published May 19, 2021. Accessed September 2, 2021. <https://www.outlookindia.com/newscroll/85-pc-seized-remdesivir-injections-suspected-to-be-fake-cops/2086189>

B.1.6. Ventilation & oxygenation equipment and consumables

B.1.6.1. Falsified oxygen cylinders

In Jakarta, Indonesia, there was a case of suspected falsified oxygen cylinders (report ID 1154953). The cylinders were seized and the accused were arrested. Earlier, the police uncovered the smuggling of imported oxygen cylinders and confiscated 166 one-meter cubic sized cylinders with falsified goods. After they were examined by the Health Ministry, around 138 oxygen cylinders were found to be in a usable condition.

B.1.6.2. Falsified oximeters

In Kathmandu, Nepal, the police arrested a group of people allegedly involved in the selling of falsified oximeters²⁸. The police seized 738 falsified oximeters. The article reporting on this was published in May. It was not picked up in the eleventh issue of this report therefore we report on the article in this issue. However, in Figures 3 and 4 that discuss the number of articles and incidents reported per month, the article is included in the numbers for May.

An article published in July reports on a case in Taiwan, where police investigated six people over the alleged sale of falsified oximeters (report ID 1132521). The suspect allegedly imported the oximeters from China using forged paperwork. Subsequently they sold more than 7,000 pieces to a distributor who resold them to clinics and pharmacies. The police raided nine sites in Taipei, Taoyuan and Kaohsiung and confiscated 856 falsified oximeters.

B.1.6.3. Substandard ventilation equipment

Philips Respironics issued a recall on thousands of its products sold in the USA (report ID 1120503). The recalled products include Bi-Level Positive Airway Pressure (Bi-Level PAP), Continuous Positive Airway Pressure (CPAP) and mechanical ventilator devices. The issue stems from potential health risks related to the polyester-based polyurethane sound abatement foam component in these devices.

B.1.6.4. Substandard oxygen cylinders

In Pakistan, in Khyber Teaching Hospital, one of the doctors wrote a letter to the hospital's administration concerning patients becoming infected with mucormycosis (report ID 1085977). Fungus was found 'at the bottom of the oxygen cylinders' due to lack of cleanliness. Mucormycosis is allegedly spreading among several COVID-19 patients as they were using substandard and used old oxygen cylinders.

²⁸ Report ID 1055649 published in May. Source article: Republica. Police bust racket selling fake Oximeter in Kathmandu. myRepublica. <https://myrepublica.nagariknetwork.com/news/police-bust-racket-selling-fake-oximeter-in-kathmandu/>. Published May 11, 2021. Accessed September 6, 2021.

In the main section of this report report ID 1086685 is discussed as it summarizes interventions conducted by the police in Nepal involving several product categories, some of the numbers included in that summary may be linked to report ID 1055649.

B.2. Reports from scientific literature

B.2.1. General

Amanyi-Enegela JA, Burn N, Dirisu O, et al. **Lessons from the field: delivering trachoma mass drug administration safely in a COVID-19 context.** *Trans R Soc Trop Med Hyg.* 2021;0:1-4. doi:10.1093/TRSTMH/TRAB102

Extract. "A number of factors contributed to low compliance during the MDA. Discomfort with the masks was one factor, as it was during the training. While it is possible to be completely compliant with a poor-quality mask, compliance might be more difficult to achieve if the masks are uncomfortable to wear and pointless if the masks do not adequately filter. This needs to be considered when procuring training supplies."

Assefa D, Melaku T. **Commercial Hand Sanitizers use amid COVID-19 Pandemic: the Concerns of Antimicrobial Resistance.** *Infect Drug Resist.* 2021;14:2183-2185. doi:10.2147/IDR.S317767

Abstract. "Following the outbreak of novel coronavirus disease, the rising concerns about the prevalence of alcohol-based hand sanitizers' inappropriate use and substandard products in the market create an ongoing safety concern. They can cause frequent exposure of microorganisms to below the alcohol concentrations to the range recommended for infection prevention and development of mutations. Thus, it is invaluable to sensitize the scientific community for further researches to provide additional evidence. Additionally, regulation of quality and proper use of alcohol-based hand sanitizers should be effectively promoted. This commentary justifies the impact of COVID-19 on the current and future use of alcohol-based hand sanitizers."

Banerjee A, Paul B, Dasgupta A, Bhattacharyya M, Bandyopadhyay L, Ghosh P. **Anxiety Levels of Doctors Working in Kolkata during COVID-19 Pandemic: A Cross-sectional Study.** *J Compr Heal.* 2021;9(1):23-31. doi:10.53553/JCH.V09I01.006

Extract. "PPE forms a vital component of doctors as it serves as a protective shield for our 'COVID-19 warriors'. Participants who perceived that the PPE available to them was of poor quality had significantly higher odds of high anxiety levels than those having access to good quality PPE. Although a significant association of perceived inadequate PPE availability with higher anxiety levels was noted in the univariate logistic regression model, no such significant association was noted in the final multivariable model. Therefore, the supply of good quality and adequate quantity of PPE should be given prime importance by the administrative authorities. Lack of proper protection will in turn lead to mental stress thus compromising the working capacity of an individual."

Dutta R, Kucchal T. **India's pain: beyond COVID-19 case numbers and mortality rates.** *Lancet.* 2021;397(10293):2463. doi:10.1016/S0140-6736(21)01248-4

Extract. "The scarcity of resources has created a market that exploits suffering. COVID-related cyber scams have risen by 86%. Medical resources being sold on the black market have increased the cost of oxygen cylinders by 15 times and counterfeit medications circulate at 17 times the official genuine price cap. Well-intentioned but poorly executed government attempts to regulate this price increase by controlling the release of these resources only aggravates the scarcity. Ambulances now charge an exorbitant INR 30 000 (US\$400) to travel to the nearest hospital, and crematoriums demand service fees 53 times the base price, just to observe the last rights of a loved one."

Miller R, Wafula F, Onoka CA, et al. **When technology precedes regulation: the challenges and opportunities of e-pharmacy in low-income and middle-income countries.** *BMJ Glob Heal.* 2021;6(5):5405. doi:10.1136/BMJGH-2021-005405

Abstract. "The recent growth of medicine sales online represents a major disruption to pharmacy markets, with COVID-19 encouraging this trend further. While e-pharmacy

businesses were initially the preserve of high-income countries, in the past decade they have been growing rapidly in low-income and middle-income countries (LMICs). Public health concerns associated with e-pharmacy include the sale of prescription-only medicines without a prescription and the sale of substandard and falsified medicines. [...] Key regulatory challenges included the lack of consensus on regulatory models, lack of regulatory capacity, regulating sales across borders and risks of over-regulation. However, e-pharmacy also presents opportunities to enhance medicine regulation—through consolidation in the sector, and the traceability and transparency that online records offer. The regulatory process needs to be adapted to keep pace with this dynamic landscape and exploit these possibilities. This will require exploration of a range of innovative regulatory options, collaboration with larger, more compliant businesses, and engagement with global regulatory bodies. A key first step must be ensuring that national regulators are equipped with the necessary awareness and technical expertise to actively oversee this e-pharmacy activity."

Najmi, Kaore S, Sadasivam B, Ray A. **Letter to editor: Role of materiovigilance in COVID era: An update.** *J Fam Med Prim Care.* 2021;10(7):2723.

doi:10.4103/JFMPC.JFMPC_2499_20

Extract. "In the ongoing COVID-19 pandemic, various medical devices are being used for prevention or treatment of the disease. These include masks, respirators, ventilators, personal protective equipment (PPE) kits, in-vitro diagnostic (IVD) kits, sanitizers and many more. As per various media reports, counterfeit and substandard quality medical devices are freely available in the Indian market which can lead to serious risk to the health of both the patients and the healthcare providers. Hence, strict vigilance of medical devices is required to eliminate the use of such medical devices which do not meet the minimum quality requirements. Batches of such medical devices can also be recalled from market by the manufacturers or authorised agents, if needed. Recall means any action taken by its manufacturer or supplier to remove or withdraw the medical device from the market or to retrieve the medical device from any person to whom it has been supplied, because the device is hazardous to health."

Osuagwu UL, Nwaeze O, Ovenseri-Ogbomo G, et al. **Opinion and uptake of chloroquine for treatment of COVID-19 during the mandatory lockdown in the sub-Saharan African region.** *African J Prim Heal Care Fam Med.* 2021;13(1):1-8.

doi:10.4102/PHCFM.V13I1.2795

Extract. "The indiscriminate promotion of this medication by those in authority and widespread use of CQ [chloroquine] in Africa have led to extensive shortages, self-treatment and fatal overdoses. The shortages and increased market prices of this medication left the already weak health systems in Africa vulnerable to substandard and falsified medical products. Governments in sub-Saharan African countries are 'strongly considering' putting prescription monitoring programs in place to ensure that off-label use of CQ and HCQ [hydroxychloroquine] is appropriate and beneficial for COVID-19 patients."

Ritchie CS, Gallopyn N, Sheehan OC, et al. **COVID Challenges and Adaptations Among Home-Based Primary Care Practices: Lessons for an Ongoing Pandemic from a National Survey.** *J Am Med Dir Assoc.* 2021;22(7):1344.

doi:10.1016/J.JAMDA.2021.05.016

One of the challenges that were mentioned for the supply chain were concerns about falsified or poor-quality supplies. Extract. "Providers reported difficulty accessing supplies of all kinds, including PPE and sanitation products, because of supply chain issues. One practice reported: "We had to put all home visits on hold due to lack of proper PPE and training. For now, we have all the PPE we need, but are starting to save N95's again for potential re-use. We are also likely to have to start making our own wipes. The face shields we first got were awful—fell apart and were cloudy—what we have now is better. It has and continues to be a learning curve."

B.2.2. Seizures/Surveys/Case reports/Reviews

[Preprint] Matatiele, Southon B, Dabula B, Marageni T, Poongavanum P, Kgarebe B. **Monitoring Quality of Alcohol-Based Hand Sanitizers Used in Johannesburg Area During the Covid-19 Pandemic.** *Res Sq.* Published online June 18, 2021:1-10. doi:10.21203/RS.3.RS-612413/V1

Abstract. "Since the outbreak of the Coronavirus Disease 2019, the World Health Organization has recommended that, in the absence of soap and water, alcohol-based hand sanitizer can be used to prevent the transmission of coronaviruses. Unfortunately, many media reports indicate that majority of current alcohol-based hand sanitizers are substandard and some contain potentially toxic ingredients. The study aimed to identify sanitizers used in the Johannesburg area that do not contain the WHO-recommended alcohol concentration of at least 70% propanol or 60% ethanol, and contain traces of toxic ingredients. Hand sanitizers were randomly collected from various traders around Johannesburg. The samples were analyzed using Agilent Auto sampler coupled to a gas chromatograph utilizing flame ionisation detection. Of the 94 different hand sanitizers collected, three preparations were found to contain no alcohol, whereas the rest contained either ethanol or 2-propanol or a combination of the two. Of the alcohol-containing sanitizers, 37 (41%) contained less than 60% v/v alcohol. Ethyl acetate, isobutanol and other non-recommended alcohols (methanol, 1-propanol and 3-methyl-butanol) were also identified. Consumers are therefore warned that among the many brands of hand sanitizer found around Johannesburg, there are some substandard preparations and some that contain traces of toxic ingredients."

Plana D, Tian E, Cramer AK, et al. **Assessing the filtration efficiency and regulatory status of N95s and nontraditional filtering face-piece respirators available during the COVID-19 pandemic.** *BMC Infect Dis.* 2021;21(1):1-13. doi:10.1186/S12879-021-06008-8

Extract. "Results: Over 100 different makes and models of traditional and non-traditional filtering facepiece respirators (N95-type masks) were in the inventory of surveyed U.S. teaching hospitals as opposed to 2–5 models under normal circumstances. A substantial number of unfamiliar masks are from unknown manufacturers. Many are not correctly labelled and do not perform to accepted standards and a subset are obviously dangerous; many of these masks are likely to be counterfeit. Due to the absence of publicly available information on mask suppliers and inconsistent labeling of KN95 masks, it is difficult to distinguish between legitimate and counterfeit products."

B.3. Reports from international organisations

European Anti-Fraud Office. **OLAF in 2020: stopping fraud, keeping Europeans safe. Press Release No 12/2021.** Published June 10, 2021. Accessed June 11, 2021. https://ec.europa.eu/anti-fraud/media-corner/news/10-06-2021/olaf-2020-stopping-fraud-keeping-europeans-safe_en

Extract. "Counterfeiters saw major business opportunities as the COVID-19 pandemic led to a sudden and massive increase in demand for personal protective equipment. OLAF has been on their trail since March 2020, and so far has identified over 1,000 suspicious operators and helped seize millions of substandard or counterfeit items related to the pandemic – in particular face masks but also hand sanitisers and testing kits."

Interpol. **Thousands of fake online pharmacies shut down in INTERPOL operation. News.** Published June 8, 2021. Accessed June 9, 2021. <https://www.interpol.int/en/News-and-Events/News/2021/Thousands-of-fake-online-pharmacies-shut-down-in-INTERPOL-operation>

Extract. "A record number of fake online pharmacies have been shut down under Operation Pangea XIV targeting the sale of counterfeit and illicit medicines and medical products. The operation coordinated by INTERPOL involved police, customs and health regulatory

authorities from 92 countries. It resulted in 113,020 web links including websites and online marketplaces being closed down or removed, the highest number since the first Operation Pangea in 2008.[...] Operation Pangea XIV also showed that criminals are continuing to cash in on the demand for personal protection and hygiene products generated by the COVID-19 pandemic. Fake and unauthorized COVID-19 testing kits accounted for more than half of all medical devices seized during the week of action (18 – 25 May) which resulted in 277 arrests worldwide and the seizure of potentially dangerous pharmaceuticals worth more than USD 23 million. In Italy, authorities recovered more than 500,000 fake surgical masks as well as 35 industrial machines used for production and packaging. Operation Pangea XIV also showed that criminals are continuing to cash in on the demand for personal protection and hygiene products generated by the COVID-19 pandemic."

B.4. Miscellaneous

In this section we report on organisations, associations or independent writers who have highlighted the risk or threat of SF COVID-19 medical products but that are not necessarily covered in the general articles on the MQM Globe database.

Bown CP. **How COVID-19 Medical Supply Shortages Led to Extraordinary Trade and Industrial Policy**; 2021. Accessed September 24, 2021.

<https://www.piie.com/sites/default/files/documents/wp21-11.pdf>

Extract. "PPE [Personal Protective Equipment] scarcity and exploding prices generated a separate problem: counterfeit products. On April 10 the Chinese government responded by establishing a new system of quality controls for exports of various medical supplies, including nine PPE products.¹⁰ One governmental concern was that a few bad actors could create large, negative reputational spillovers impacting the important Chinese PPE exporting industry."

Den Boer H, Nash K. **Regional Responses to COVID-19: The Role of Intergovernmental Organisations in Latin America, Africa, and the Middle East**; 2021. Accessed September 27, 2021. <https://www.politicalsettlements.org/wp-content/uploads/2021/07/Covid-Report-DIGITAL.pdf>

Extract. "The 'Integrated Response of the OAS [Organisation of American States] General Secretary to COVID-19 in Support of Member States, Based on its Four Pillars' was released in April 2020. [...] The Multidimensional Security Pillar unites the Department of Public Security (DPS), the Department against Transnational Organised Crime (DTCO), and the InterAmerican Drug Abuse Control Commission (CICAD) to develop guides and tools to address risks as a result of the pandemic in the context of criminality and public health emergencies. Topics addressed include COVID-19-related internet fraud; counterfeit masks and substandard disinfectants; corruption in the management of health emergency funds; and care for people with substance use disorder. The DSP furthermore facilitated the creation of a virtual community for the security and emergency systems of member states which will enable access to information on emergency response tools."

Fight the Fakes. Watch our WHA74 event: Old Problem, New Foes – Time to act against falsified medicines and vaccines for COVID-19. Fight the Fakes.

Published June 1, 2021. Accessed September 28, 2021.

Extract. "The World Health Organisation is celebrating the 74th World Health Assembly this week (24 May – 1 June) which will have a decisive impact on the global health agenda ahead of us. Fight The Fakes used this important occasion to put the spotlight on the dangers that the proliferation of substandard and falsified Covid-19 medicines and treatments is causing all over the globe."

Forcinio HB. **Countering Counterfeiters and Diverters.** *Pharm Technol.* Published online February 2, 2021:43-45. Accessed August 13, 2021.

<https://www.pharmtech.com/view/countering-counterfeiters-and-diverters>

Extract. *"Anticounterfeiting laws and regulations, such as the European Union's Falsified Medicine Directive and the US's Drug Supply Chain Security Act (DSCSA), safeguard prescription drugs available from pharmacies. "However, pharmaceutical manufacturers should be aware that these measures alone will not guarantee a product's integrity and authenticity," says Gene Dul, president of Schreiner MediPharm US. He says, "Only additional counterfeit-proof authenticity features can provide a comprehensive approach against fraud, misuse, and tampering." Unfortunately, the coronavirus pandemic has increased the opportunities for counterfeiting. "In a survey issued by IDC in June 2020, 70% of companies agreed that their supply chain is 'very vulnerable' to suffering more problems if the COVID-19 crisis lasted more than a couple of months longer, and 75% of companies agreed that the COVID-19 pandemic has 'greatly increased/will greatly increase' problems with diversion, theft, and counterfeiting of critical products such as test kits, vaccines, and antivirals," reports Aimee Genzler, vice-president, Corporate & Brand Communications at TraceLink, the study sponsor."*

Annexes

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

We report on incidents that were reported in the lay press. In the introduction (2. Methodology for reporting on the lay literature) 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' that was published in July 2020 are listed below.²⁹

Since the October 2020 issue

- Personal protective equipment (PPE), and sanitisers & 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.
- Search terms used to generate the summary MQM 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.

²⁹Infectious 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>

- Ventilation & Oxygenation equipment and consumables: We 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 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).

Since the March 2021 issue

- PPE: 'face shield' was added to the search terms used to generate the summary MQM Globe-reports for PPE. Therefore caution is required when interpreting the number of alerts or articles over time.
- COVID-19 medicines:
'Amphotericin' was added to the search terms used to generate the summary MQM Globe-reports for COVID-19 medicine. Although the product is not used as direct treatment for COVID-19 it has been included in the search terms. Amphotericin is used to treat mucormycosis, a fungal infection increasingly reported in patient that previously suffered from COVID-19. Adding Amphotericin to the search terms does not generate bias in the previous reports since the Globe database did not hold any incidents with amphotericin from 1st of January 2020 to 31st of March 2021.

Since the April-May 2021 issue

- Ventilation & Oxygenation equipment and consumables: In the search terms used to generate the summary MQM Globe-reports "pulse oximeter" was replaced by "oximeter" to ensure all relevant articles are included.

Annex B. Table - Articles in lay literature on COVID-19 vaccine quality incidents published in 2020

Between 12th March 2020 and 31st December 2020 we found, excluding duplicates, 22 reports of quality incidents with COVID-19 vaccines. We only report on articles published in the English lay press and present in the online [Medicine Quality Monitoring Globe](#) (MQM Globe) and exclude articles that discuss the same incident (i.e. ‘duplicates’).

Table 4. Articles from 2020 on quality issues with COVID-19 vaccines available in the Medicine Quality Monitoring (MQM) Globe, in chronological order.

Reports date from 12 March 2020 until 31 December 2020. We list here only one report per incident– there are many other reports describing these issues but we have not included them unless they provide additional relevant information. We only included in this table articles from the English lay press.

2020					
Publication date	Location	Product/ organization	Title	MQM Globe report ID	URL ³⁰
12 March 2020	India	-	Maharashtra: Three held for administering fake coronavirus vaccines	487568	https://www.deccanherald.com/national/west/maharashtra-three-held-for-administering-fake-coronavirus-vaccines-812962.html
23 March 2020	USA	-	US Court Blocks Website Selling Fake #COVID19 Vaccine	497263	https://www.infosecurity-magazine.com/news/us-court-blocks-fake-covid-19/
30 April 2020	USA	-	Man busted for selling fake coronavirus vaccine in Washington	549794	https://mynorthwest.com/1847021/coronavirus-vaccine-scam-washington/
01 May 2020	Online	-	Blood of coronavirus survivors sold on the dark web as ‘makeshift vaccine’	550753	https://www.thescottishsun.co.uk/news/5550884/coronavirus-vaccine-blood-dark-web/
23 May 2020	USA	-	US FDA issues warning letters to two groups for selling fake COVID-19 vaccines	578176	https://www.republicworld.com/world-news/us-news/us-fda-issues-warning-to-two-groups-for-selling-fake-covid-19-vaccines.html
27 May 2020	Ecuador	Migal, The Galilee Research Inst.	Fake Israeli coronavirus vaccine being sold in South America	582392	https://www.jpost.com/health-science/fake-coronavirus-vaccine-with-hebrew-label-being-sold-in-south-america-629416
13 July 2020	USA	-	US attorney shuts down Louisville man's website advertising fake coronavirus vaccine	646267	https://www.courier-journal.com/story/news/local/2020/07/13/louisville-man-advertised-fake-coronavirus-vaccine/5431942002/
13 August 2020	Online, China	* Sinovac * Wuhan Inst. of Biological Products	Fake pre-orders for coronavirus vaccines found in China	688388	https://www.taiwannews.com.tw/en/news/3987217

³⁰ Over time some URLs might not work anymore, and in that case one can find a summary/extract of the article [on the online MQM Globe](#) using ‘reportID:XXXXXX’ in the search box.

21 August 2020	Online, China	* Sinopharm * Sinovac	Authorities warn against illegal COVID-19 vaccines and medication sold online	723320	https://www.abc.net.au/news/2020-08-22/border-force-warn-against-importing-coronavirus-vaccines/12581996
11 September 2020	Online	-	Darknet Dealers are Selling COVID-19 Test Kits for Thousands of Dollars	723812	https://www.vice.com/en_us/article/akzpv5/covid-19-rapid-test-kits-for-sale-dark-web
26 September 2020	India	-	Fake COVID-19 Vaccine Manufacturing Unit Busted In Bargarh	742841	https://odishatv.in/odisha-news/fake-covid-19-vaccine-manufacturing-unit-busted-in-bargarh-478473
02 October 2020	Myanmar	-	Myanmar Health Chiefs Warn Against Fake COVID-19 Vaccines	750450	https://www.irrawaddy.com/specials/myanmar-covid-19/myanmar-health-chiefs-warn-fake-covid-19-vaccines.html
13 October 2020	Brazil	Oxford- AstraZeneca	Sales of fake Covid-19 vaccine in Brazil reported	764662	https://www.plenglish.com/index.php?o=rm&id=60698&SEO=sales-of-fake-covid-19-vaccine-in-brazil-reported Accessible duplicate article https://riotimesonline.com/brazil-news/miscellaneous/covid-19/fake-covid-19-vaccine-sold-in-brazils-city-of-niteroi-regulatory-body-alerts/
30 October 2020	Online	-	FDA Warns Of Bogus Coronavirus Vaccines And Treatments Being Sold Online	787356	https://pittsburgh.cbslocal.com/2020/10/30/fda-warns-of-bogus-coronavirus-vaccines-and-treatments-being-sold-online/
11 November 2020	Online	-	Dark Web Has Become a Market place for 'Vaccines' and Other Pandemic Scams	835199	https://www.bloomberg.com/news/articles/2020-11-11/dark-web-has-become-a-marketplace-for-vaccines-and-other-pandemic-scams?sref=Pqfp0AgC
13 November 2020	Online, Australia	* Sinopharm * Sinovac	COVID-19 vaccines selling for \$24k on black market	803482	https://www.noosanews.com.au/news/covid-19-vaccines-selling-for-24k-on-black-market/4139565/
04 December 2020	Online	Pfizer/BioNTech	Darknet Drug Dealers Are Now Selling 'Pfizer COVID Vaccines'	830853	https://www.vice.com/en/article/akdkkg/darknet-drug-dealers-are-now-selling-pfizer-covid-vaccines
11 December 2020	Online	Pfizer/BioNTech	Covid vaccine: Scammers are flogging fake coronavirus jabs on the dark web for £230	841777	https://www.mirror.co.uk/tech/covid-vaccine-scammers-flogging-fake-23151276
21 December 2020	Philippines	Sinopharm	Locsin says reported COVID-19 vaccine in Binondo could be fake, just 'dextrose'	855225	https://www.gmanetwork.com/news/news/nation/768836/locsin-says-reported-covid-19-vaccine-in-binondo-could-be-fake-just-dextrose/story/
23 December 2020	Brazil	Vero Cell, Beijing Institute of Biological Products	Creative Professional Says He Saw Street Vendor Selling a False Vaccine in Rio for \$R50	890939	https://www1.folha.uol.com.br/internacional/en/scienceandhealth/2020/12/street-vendors-sell-fake-vaccine-against-covid-19-for-r-50-in-rio.shtml
28 December 2020	South Africa	-	Interpol notes fake Covid-19 vaccine bust in SA	865724	https://citizen.co.za/news/south-africa/crime/2413293/interpol-notes-fake-covid-19-vaccine-bust-in-sa/
31 December 2020	USA	Moderna	Pharmacist Arrested, Accused Of Destroying More Than 500 Moderna Vaccine Doses	895651	https://www.npr.org/2020/12/31/952536531/pharmacist-arrested-accused-of-destroying-more-than-500-moderna-vaccine-doses?t=1614099235033

Annex C. Figure - Incidents in lay literature on quality issues with COVID-19 medical products by week

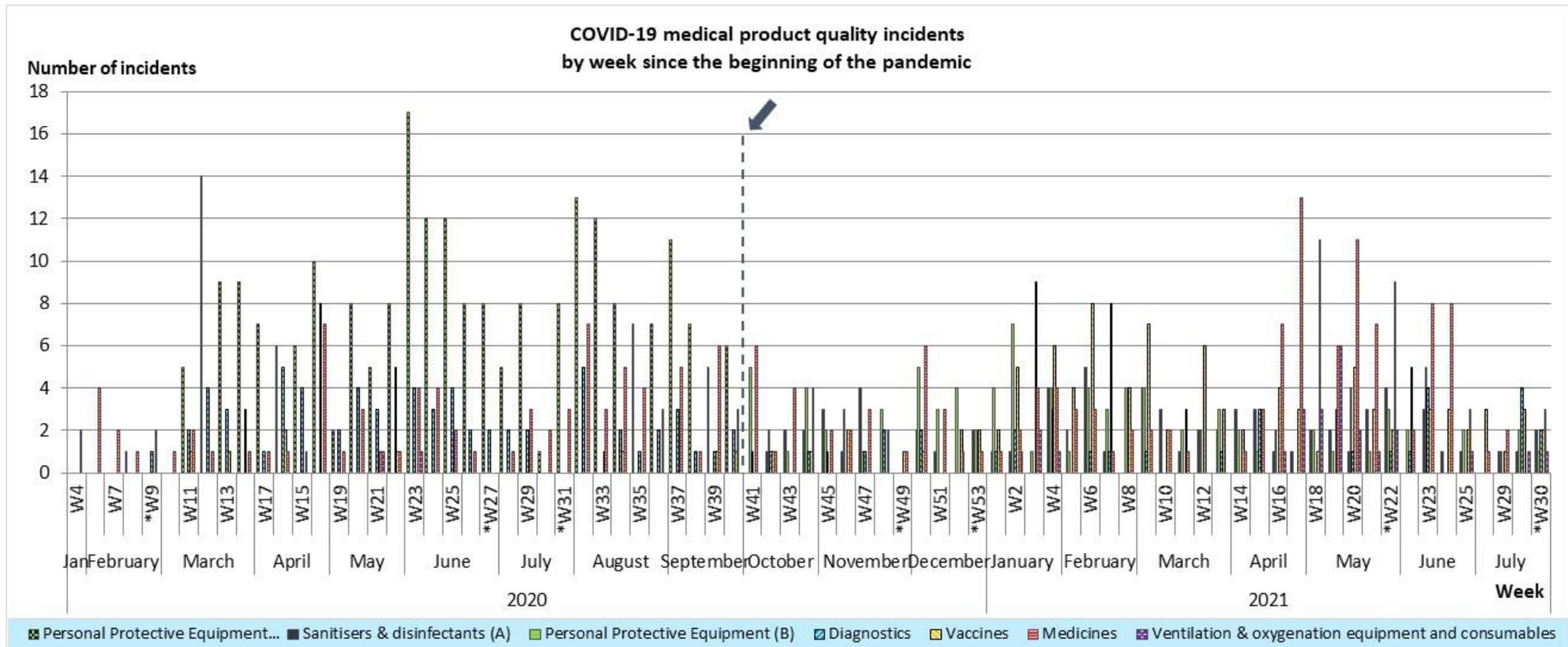


Figure 5. Incidents on the Medicines Quality Monitoring Globe on quality issues with COVID-19 medical products by week since the beginning of the pandemic.

The figure starts in week 4, Monday 20th of January, 2020 and Ends on week 30, Saturday 31st of July, 2021. Weeks with an asterisk (*) are overlapping 2 months, each time the week is attributed to the earliest month. The arrow indicates the end of September 2020 when the category of 'Personal Protective Equipment Incl. sanitisers' was split in two distinct categories: (A) Sanitiser & disinfectants, and (B) Personal Protective Equipment. As some articles describe more than one category of products, the sum of incidents per month may exceed the sum of articles per month reported in Figure 3.

Note (i) since November '20, non-COVID-19 medicines containing hidden active pharmaceutical ingredients (API) that are used or trialled for COVID-19 are no longer included. Only medicines for which the stated API is used or trialled for COVID-19 treatment are included in this report. The observed decrease of the number of articles can be at least partially due to this change. Note (ii) 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.

Annex D. Report ID information and source articles

This annex contains the reports generated by the Medicine Quality Monitoring Globe (MQM Globe) using pre-defined search terms for each of the six product categories. At the beginning of each MQM Globe-report the pre-defined search terms used to generate the report are displayed.

Only the relevant articles in the MQM Globe-reports were selected for the current COVID-19 report. For each of the report IDs (six or seven digit code) discussed in the sections on 'Articles of incidents in the lay literature', additional information (including the source article) can be found in the MQM Globe reports in Annexes D.1 to D.6 or they are available on the online [MQM Globe](#)³¹, when introducing "reportID:XXXXXXX" in the search box.

As the file size of annexes D.1 up to D.6 is too large to include in this file, please consult the Medical Product Quality Report page on the [IDDO](#) or [MORU](#) webpage to access the MQM Globe reports by product category.

Annex D.1. Vaccines

Annex D.2. COVID-19 diagnostics

Annex D.3. Personal Protective Equipment

Annex D.4 Sanitisers & disinfectants

Annex D.5 COVID-19 medicines

Annex D.6 Ventilation & oxygenation equipment and consumables

³¹Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe. Web Page. Published 2020. Accessed October 1, 2021. <https://www.iddo.org/medicine-quality-monitoring-globe>