Medical Product Quality Report – COVID-19 Issues Issue 3. August 2020

The document has been produced by the Medicine Quality Research Group, Centre of Tropical Medicine & Global Health, Nuffield Department of Medicine, University of Oxford







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This document is open access but we would be grateful if you could cite it as: Medicine Quality Research Group, University of Oxford. Medical Product Quality Report – COVID-19 Issues. Issue 3, August 2020.

The work is kindly supported by the Bill&Melinda Gates Foundation, the University of Oxford and the Wellcome Trust.

September 2020

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1 Summary of findings

While in some countries COVID-19 cases are still increasing, the number of cases are dropping in others. Countries that successfully slowed down the spread before summer, are seeing a resurgence now. From January to August 2020¹, over 300 articles reported on problems of substandard or falsified (SF) COVID supplies including diagnostic tests, medicines, vaccines, ventilators and personal protective equipment. Each month reports are identified in countries where we did not find reports previously. Including the first, second and the current issues, we identified alerts in 56 different countries.

In this issue, problems with hand sanitizers are prominent. After a wave of methanol containing hand sanitizers starting in June, the United States Food & Drug Administration expanded hand sanitizer warnings to include 1-propanol contaminations on the 12th of August. Several alerts for SF hand sanitizers were found in India. In other countries there are few or no reported problems with hand sanitizers reaching the general public. In many countries hand sanitizers do not fall under the medicinal product regulations and thus are not controlled or regulated like medicines^{2,3,4}. It is likely that there is an underreporting of SF hand sanitizers. So far during the pandemic, there are no confirmed cases of SF remdesivir in the public domain. In the previous issues⁵ there have only been two reports on SF dexamethasone, one substandard product in India⁶ and a falsified product in Nigeria⁷. Both remdesivir and dexamethasone are at high risk for SF versions in the future. As we, hopefully, move closer to having COVID-19 vaccine(s) available, urgent discussion is needed for optimizing risk based surveillance to prevent, detect and respond to the inevitable SF vaccines.

¹This third issue of the monthly report 'Medical Product Quality Report – COVID-19 Issues' covers information published during the month of August. Previous issues cover the period from January to July 2020 and are available on the IDDO website:

Medicine Quality Research Group, University of Oxford. **Medical Product Quality Report-COVID-19 Issues**, viewed 16 September 2020. Available from <u>https://www.iddo.org/mq/research/medical-product-quality-reports</u>

² European Commission. Guidance on the applicable legislation for leave-on hand cleaners and hand disinfectants (gel, solution, etc.), viewed 21 September 2020. Available from https://ec.europa.eu/growth/sectors/cosmetics/products/borderline-products en

³ Asia actual. **Thailand to regulate hand sanitizer as a medical device**, viewed 21 September 2020. Available from <u>https://asiaactual.com/blog/thailand-to-regulate-hand-sanitizer-as-a-medical-device/</u>

⁴Health Canada. Licensing approach to produce and distribute alcohol-based hand sanitizers: guidance document. viewed 21 September 2020. Available from <u>https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/covid-19-expediated-licensing-alcohol-hand-sanitizer.html</u>

⁵ Medicine Quality Research Group, University of Oxford. **Medical Product Quality Report-COVID-19 Issues**, viewed 16 September 2020. Available from <u>https://www.iddo.org/mq/research/medical-product-quality-reports</u>

⁶ Medical Dialogues. **Drug Alert: CDSCP Flags 25 Drugs As Not Of Standard Quality.** Farhat Nasim, viewed 22 September 2020. Available from <u>https://medicaldialogues.in/news/industry/pharma/drug-alert-cdsco-flags-25-drugs-as-not-of-standard-quality-66594</u>

⁷ BBC News. **Fake pharmaceutical industry thrives in West Africa,** viewed 16 August 2020. Available from <u>https://www.bbc.com/news/world-africa-53387216</u>

2 Introduction

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

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

We use the terminology for different types of poor quality medical products as defined by the World Health Organisation (WHO 2017)⁸:

Substandard medical products:

Also called "out of specification", these are authorized medical products that fail to meet either their quality standards or their specifications, or both.

Unregistered/unlicensed medical products:

Medical products that have not undergone evaluation and/or approval by the national or regional regulatory authority for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.

Falsified medical products:

Medical products that deliberately/fraudulently misrepresent their identity, composition or source.

We emphasise the difference between the use of the terms 'falsified' and 'counterfeit' medical products. 'Falsified' is a broad term including all the various types of deliberate misrepresentation of a medical product from a public health perspective. The term 'counterfeit' is specifically linked to intellectual property rights, 'trademark counterfeit goods'⁹ and 'pirated copyright goods'¹⁰ as used in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement.

⁸ Source: **Appendix 3 to Annex, World Health Assembly document A70/23**, 2017, viewed 14 August 2020. Available from <u>https://www.who.int/medicines/regulation/ssffc/A70_23-en1.pdf?ua=1</u>

⁹ '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, viewed 14 August 2020. Available from <u>https://www.wto.org/english/docs_e/legal_e/27-trips_05_e.htm#fnt-14</u>.

¹⁰ 'Pirated copyright goods': any goods that are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production, and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation.

The reports presented were mostly extracted from the Medicines Quality Monitoring Globe (MQM Globe)¹¹, a system that scrapes online newspapers (referenced in Google News) for early warnings of substandard and falsified medical products. In addition, alerts and reports by national and international organisations are included when captured by the members of the team or shared by colleagues. This report also includes scientific literature and policy documents related to COVID-19 medical products quality identified by manual searches in Pubmed and Google Scholar. These will be displayed on the Medicine Quality COVID-19 Surveyor to be released in the coming months. We also include preprint of articles. Please note that preprints should be viewed with additional caution as they have not been peer-reviewed. They should not be relied on to guide clinical practice or health-related behaviour and should not be reported in news media as established information.

Please note the caveats for the lay literature (<u>MQM Globe disclaimer and caveats</u>¹²); we include abstracts and extracts from articles that are subject to a take down policy. If we are contacted by a potential rights-holder who objects to the presence of material, we will remove the material in question from the report and Globe until we have been able to assess the case. Where material is removed for valid reasons of copyright, its removal will be considered as lasting until copyright in the material expires, or until the rights-holder agrees that the material can be reinstated.

This third issue of the monthly report **Medical Product Quality Report – COVID-19 Issues** covers information published during the month of August. The <u>previous issues</u> covered publications from January 1st to July 31th 2020 and are available on the IDDO website¹³. We also include publications and reports published prior to August 2020 that were missed in the previous issues of the report. We are developing a system for scraping regulatory authority and international organisation websites for alerts. Any remarks or additions to content are greatly appreciated (please write to <u>medicinequality@iddo.org</u>).

3 Scientific literature

3.1 General

Dawoud D, Chen AMH, Rossing CV, Garcia-Cardenas V, Law A V., Aslani P, et al. **Pharmacy practice research priorities during the COVID-19 pandemic: Recommendations of a panel of experts convened by FIP Pharmacy Practice Research Special Interest Group.** Res Soc Adm Pharm. 2020 Aug 26; Available from <u>https://linkinghub.elsevier.com/retrieve/pii/S1551741120310445</u>

Abstract. "Across the globe, pharmacists on the frontline continue to fight COVID-19 and its continuously evolving physical, mental, and economic consequences armed by their knowledge,

Source: World Trade Organization, viewed 14 August 2020. Available from <u>https://www.wto.org/english/docs_e/legal_e/27-trips_05_e.htm#fnt-14</u>.

¹¹ Infectious Disease and Data Observatory. **Medicine Quality Monitoring Globe**, viewed 22 September 2020. Available from <u>https://www.iddo.org/mqmglobe/</u>

¹² Infectious Disease and Data Observatory. **Medicine Quality Monitoring Globe disclaimer and caveats**, viewed 17 August 2020. Available from <u>https://www.iddo.org/medicine-quality-monitoring-globe-disclaimer-and-caveats</u>

¹³ Medicine Quality Research Group, University of Oxford. **Medical Product Quality Report -COVID-19 Issues**, viewed 22 September 2020. Available from <u>https://www.iddo.org/mq/research/medical-product-quality-reports</u>

professionalism, and dedication. Their need for credible scientific evidence to inform their practice has never been more urgent. Despite the exponentially increasing number of publications since the start of the pandemic, questions remain unanswered, and more are created, than have been resolved by the increasing number of publications. A panel of leading journal editors was convened by the International Pharmaceutical Federation (FIP) Pharmacy Practice Research Special Interest Group to discuss the current status of COVID-19 related research, provide their recommendations, and identify focal points for pharmacy practice, social pharmacy, and education research moving forward. Key priorities identified spanned a wide range of topics, reflecting the need for good quality research to inform practice and education. The panel insisted that a foundation in theory and use of rigorous methods should continue forming the basis of inquiry and its resultant papers, regardless of topic area. From assessing the clinical and cost effectiveness of COVID-19 therapies and vaccines to assessing different models of pharmaceutical services and education delivery, these priorities will ensure that our practice is informed by the best quality scientific evidence at this very challenging time."

Tesfaye W, Abrha S, Sinnollareddy M, Arnold B, Brown A, Matthew C, et al. **How Do We Combat Bogus Medicines in the Age of the COVID-19 Pandemic?** Am J Trop Med Hyg. 2020 Aug 18;tpmd200903. Available from <u>https://www.ajtmh.org/content/journals/10.4269/ajtmh.20-0903</u>

Abstract. "The COVID-19 pandemic has brought concurrent challenges. The increased incidence of fake and falsified product distribution is one of these problems with tremendous impact, especially in lowand middle-income countries. Up to a tenth of medicines including antibiotics and antimalarial drugs in the African market are considered falsified. Pandemics make this worse by creating an ecosystem of confusion, distraction, and vulnerability stemming from the pandemic as health systems become more stressed and the workload of individuals increased. These environments create opportunities for substandard and falsified medicines to be more easily introduced into the marketplace by unscrupulous operators. In this work, we discussed some of the challenges with fake or falsified product distribution in the context of COVID-19 and proposed strategies to best manage this problem."

Wallace LJ, Nouvet E, Bortolussi R, Arthur JA, Amporfu E, Arthur E, et al. **COVID-19 in sub-Saharan Africa: impacts on vulnerable populations and sustaining home-grown solutions.** Can J Public Health. 2020 Aug 26 Online ahead of print;19:1–5. Available from http://www.ncbi.nlm.nih.gov/pubmed/32845460

Abstract. "This commentary draws on sub-Saharan African health researchers' accounts of their countries' responses to control the spread of COVID-19, including social and health impacts, homegrown solutions, and gaps in knowledge. Limited human and material resources for infection control and lack of understanding or appreciation by the government of the realities of vulnerable populations have contributed to failed interventions to curb transmission, and further deepened inequalities. Some governments have adapted or limited lockdowns due to the negative impacts on livelihoods and taken specific measures to minimize the impact on the most vulnerable citizens. However, these measures may not reach the majority of the poor. Yet, African countries' responses to COVID-19 have also included a range of innovations, including diversification of local businesses to produce personal protective equipment, disinfectants, test kits, etc., which may expand domestic manufacturing capabilities and deepen self-reliance. African and high-income governments, donors, nongovernmental organizations, and businesses should work to strengthen existing health system capacity and back African-led business. Social scientific understandings of public perceptions, their interactions with COVID-19 control measures, and studies on promising clinical interventions are needed. However, a decolonizing response to COVID-19 must include explicit and meaningful commitments to sharing the power-the authority and resources-to study and endorse solutions."

Additional publications prior to August 2020

Sharma A, Gupta P, Jha R. COVID-19: Impact on Health Supply Chain and Lessons to Be Learnt. J Health Manag. 2020 Jun 11;22(2):248–61.

Available from http://journals.sagepub.com/doi/10.1177/0972063420935653

Abstract. "Before the imposition of the strict lockdowns and the spread of COVID-19, the disruptions in China caused a ripple effect on the global supply chains. Emphasis has been laid on minimisation of costs and timely delivery of essential products. In India, as the situation worsens due to the outbreak, we have seen disruptions in the logistics supply chain. There are several reasons attributed to the increase in demand and slowing of the supply. There are several workable solutions available to look into this situation. We should work towards promoting Indian markets and amend policies to help the local workforce lessen the interdependencies of imports on other countries. This will help in strengthening the logistics supply chain in India. This will create employment opportunities and increase the GDP growth."

Udwadia Z, Raju R. The N-95 mask: invaluable ally in the battle against the COVID-19 pandemic.LungIndia.2020Jul1;37(4):323-328.Availablehttp://www.lungindia.com/preprintarticle.asp?id=284492;type=0

Abstract. "The present COVID-19 pandemic, caused by the airborne SARS-CoV-2 virus, has highlighted the vital importance of appropriate personal protective equipment for all exposed health care workers. The single most important part of this armor is the N-95 mask. With the awareness that the virus is spread by both droplets and through the aerosolized route, the N-95 provides protection that a surgical mask cannot match. This timely review looks at the special advantages that an N-95 offers over a surgical mask with specific reference to the COVID-19 epidemic. It also emphasizes the crucial importance of ensuring quality masks with a proper fit. Finally, with acute scarcities of N-95 masks being reported from hospitals globally, it reviews recent literature which attempts to prolong the life of these masks with extended use, reuse and decontamination of used masks."

3.2 Seizures/Surveys/Case Reports/Reviews

Brun D, Curti C, Mekideche T, Benech A, Hounliasso I, Lamy E, et al. **Stockpiled N95** respirator/surgical mask release beyond manufacturer-designated shelf-life: a French experience. J Hosp Infect. 2020 Aug 1;106(2). Available from <u>https://pubmed.ncbi.nlm.nih.gov/32745593/</u>

Abstract. "Background: To reduce the shortage of N95 respirators and surgical masks during the COVID-19 pandemic, stockpiled equipment beyond its expiry date could be released.

Aim: Centralized testing of batches of expired surgical masks and N95 for safe distribution to hospital departments saving users time.

Methods: Tests of compliance with health authority directives were developed and carried out on 175 batches of N95 masks and 31 batches of surgical masks from 12th March 2020 to 16 April 2020. Five quality-control tests were performed on batch samples to check: packaging integrity, mask appearance, breaking strength of elastic ties and strength of nose clip test, and face-fit.

Findings: Forty-nine per cent of FFP2 mask batches were compliant with directives, 32% of batches were compliant but with some concerns and 19% of batches were non-compliant. For surgical masks, 58% of batches were compliant, 39% of batches compliant but with concerns and 3% of batches were non-compliant.

Conclusion: The main areas of non-compliance were the breaking strength of the elastic ties and the nose clip but these alone were not considered to make the masks unacceptable. Only mask appearance and face-fit results were decisive non-compliance criteria."

Mackey TK, Li J, Purushothaman V, Nali M, Shah N, Bardier C, et al. **Big Data, Natural Language Processing, and Deep Learning to Detect and Characterize Illicit COVID-19 Product Sales: Infoveillance Study on Twitter and Instagram.** JMIR Public Heal Surveill. 2020 Aug 25;6(3):e20794. Available from <u>http://publichealth.jmir.org/2020/3/e20794/</u> Abstract. "Background: The coronavirus disease (COVID-19) pandemic is perhaps the greatest global health challenge of the last century. Accompanying this pandemic is a parallel "infodemic," including the online marketing and sale of unapproved, illegal, and counterfeit COVID-19 health products including testing kits, treatments, and other questionable "cures." Enabling the proliferation of this content is the growing ubiquity of internet-based technologies, including popular social media platforms that now have billions of global users.

Objective: This study aims to collect, analyze, identify, and enable reporting of suspected fake, counterfeit, and unapproved COVID-19-related health care products from Twitter and Instagram. Methods: This study is conducted in two phases beginning with the collection of COVID-19-related Twitter and Instagram posts using a combination of web scraping on Instagram and filtering the public streaming Twitter application programming interface for keywords associated with suspect marketing and sale of COVID-19 products. The second phase involved data analysis using natural language processing (NLP) and deep learning to identify potential sellers that were then manually annotated for characteristics of interest. We also visualized illegal selling posts on a customized data dashboard to enable public health intelligence.

Results: We collected a total of 6,029,323 tweets and 204,597 Instagram posts filtered for terms associated with suspect marketing and sale of COVID-19 health products from March to April for Twitter and February to May for Instagram. After applying our NLP and deep learning approaches, we identified 1271 tweets and 596 Instagram posts associated with questionable sales of COVID-19-related products. Generally, product introduction came in two waves, with the first consisting of questionable immunity-boosting treatments and a second involving suspect testing kits. We also detected a low volume of pharmaceuticals that have not been approved for COVID-19 treatment. Other major themes detected included products offered in different languages, various claims of product credibility, completely unsubstantiated products, unapproved testing modalities, and different payment and seller contact methods.

Conclusions: Results from this study provide initial insight into one front of the "infodemic" fight against COVID-19 by characterizing what types of health products, selling claims, and types of sellers were active on two popular social media platforms at earlier stages of the pandemic. This cybercrime challenge is likely to continue as the pandemic progresses and more people seek access to COVID-19 testing and treatment. This data intelligence can help public health agencies, regulatory authorities, legitimate manufacturers, and technology platforms better remove and prevent this content from harming the public."

4 International organisations

Interpol. **COVID-19 Cybercrime Analysis Report.** *Report.* 2020 August, viewed 16 September 2020. Available from <u>https://www.interpol.int/en/News-and-Events/News/2020/INTERPOL-report-shows-alarming-rate-of-cyberattacks-during-COVID-19</u>

Conclusion. "Cybercriminals are developing and boosting their attacks at an alarming pace, exploiting the fear and uncertainty caused by the unstable social and economic situation around the world. At the same time, the higher dependency on connectivity and digital infrastructure due to the global lockdown increases the opportunities for cyber intrusion and attacks.

Despite this outlook, INTERPOL is taking proactive steps and all relevant measures to support member countries in an unprecedented crisis. It is also preparing for the post COVID-19 threat landscape. The pandemic has created pivotal opportunities to reflect on current capabilities and resources for improvement to achieve better preparedness and resilience for any future shocks.

Finally, the global pandemic has proved the importance of a global response in a collaborative and coordinated manner. The most urgent priority to address these growing cyberthreats is to further enhance international police cooperation for operational activities and to improve cybercrime information exchange with diverse partners within the global ecosystem of cybersecurity.

Focusing on the core pillars of the cybercrime threat response, cybercrime operations and cyber capabilities development, the INTERPOL Cybercrime Directorate will continue to strive to reduce the global impact of cybercrime and protect communities for a safer world."

5 Lay literature

5.1 **Disclaimer & Notes**

The information included below is based on the data used to create the Medicine Quality Monitoring Globe (MQM Globe). It contains publicly available information on the quality of medical products from non-peer-reviewed lay literature. We report the information as it is stated in the articles and can thus be biased towards the authors perspective. It does not necessarily reflect our vision or judgment on the issue. Also, this information usually will not have scientific confirmation. Therefore, the information needs to be interpreted with the greatest caution. We regard the reports as early warnings of potential problems. No or few articles from a region does not imply that the medical product quality there is good, but probably reflects a lack of accessible information. Full disclaimer and caveats can be found at MQM Globe disclaimer and caveats¹⁴.

The Google News search tool is used to capture data from online news sources. Articles matching the search terms are loaded into a database and curated by trained analysts. Because the Globe system extracts newspaper articles from journals referenced in Google News only, reports not referenced in Google News would not be captured. Please consult the website for full <u>methodology</u>¹⁵. On the 20th of March, the search terms were adapted to capture more papers on substandard and falsified (SF) medical supplies for COVID-19.

The news articles discussed in the sections below are available in the Globe-reports, in this report's annexes, or on the online <u>MQM Globe</u>, using the report ID (six digits code). The MQM Globe-reports are generated with pre-defined search terms, which enable quick access to reports of (a) COVID diagnostics, (b) Personal protective equipment, (c) COVID medicines, and (d) Ventilators and Positive end-expiratory pressure (PEEP).

In this report we share articles captured by the MQM Globe that are linked to medical products potentially used in the context of Covid-19 or to active pharmaceutical ingredients (APIs) that are being trialed for Covid-19 treatment and/or prevention. In theory there is a distinction between (a) SF incidents that are due to or increased by the COVID-19 epidemic; and (b) incidents that would have happened in any case. It can be difficult to make the distinction between the two types of incidents and some reports cited below are not directly linked to the treatment of COVID-19. Nevertheless we have included them as crossover risks and to assess the evolution of the alerts on these medical products over time.

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

¹⁴ Infectious Diseases Data Observatory. **Medicine Quality Monitoring Globe disclaimer and caveats**, viewed 14 August 2020. Available from <u>https://www.iddo.org/medicine-quality-monitoring-globe-disclaimer-and-caveats</u>

¹⁵ Infectious Diseases Data Observatory. **Medicine Quality Monitoring Globe methodology**, viewed 14 August 2020. Available from <u>https://www.iddo.org/medicine-quality-monitoring-globe-methodology</u>

5.2 Articles on SF medical products for COVID-19 – main characteristics

Since the beginning of the pandemic we identified 326 different articles on problems in the supply and quality of COVID-19 medical products. For August alone we report on 62 relevant articles linked to SF COVID-19 supplies alerted through the MQM Globe database (see table 1). It is comparable to the number of articles in June, after a decline in July. Within those articles, 2 alerted on vaccines, 8 on diagnostics, 20 on COVID-19 related treatments and 42 are linked to personal protective equipment (PPE) (see figure 2). As for July, in August the MQM Globe did not identify any report linked to ventilation equipment.



Figure 1. Number of alerts on the Medicines Quality Monitoring Globe by category and by week. Alerts are for substandard or falsified products linked to COVID-19. Week 4 starts on Monday 20th of January 2020 and week 36 ends on Monday 31th of August 2020. Weeks with an asterisk are overlapping 2 months, each time the week is attributed to the earliest month.

Table 1. Number of articles on the MedicinesQuality Monitoring Globe linked to substandardor falsified COVID-19 supplies by month.As some articles describe more than one category ofproducts, the sum of alerts per month as shown infigures 1 and 2 may exceed the sum of articles permonth.

Month	Number of articles
January	2
February	10
March	49
April	50
May	47
June	64
July	42
August	62



Figure 2. Number of alerts on the Medicines Quality Monitoring Globe by category of products and by month. Alerts are for substandard or falsified products linked to COVID-19. As some articles describe more than one category of products, the sum of alerts per month may exceed the sum of articles per month as shown in table 1.

Online substandard and falsified products

Interpol's report 'Covid-19 Cybercrime Analysis Report-August 2020' highlights some issues linked to medical supply¹⁶. In the top themes of COVID-19 phishing there is the offer of vaccines and medical supplies. Some findings by region : in Asia Interpol perceives a trend of illicit online sale of falsified PPE, medical supplies and medicines (report ID: 676025); in the Middle East and North African region social media platforms are used for illegal sale of medicines for COVID-19 treatment. An article reported on the Darknet Analysis project led by the Evidence-Based Cybersecurity Research Group of the Georgia State University¹⁷. The researchers warn of low quality or falsified products when buying on darknet markets. Their research shows the emergence of COVID-19 offerings since February: COVID-19 diagnostics, masks, gowns, thermometers, hand sanitizers, oxygen ventilators and medicines, including remdesivir and hydroxychloroquine.

¹⁶ Interpol. **COVID-19 Cybercrime Analysis Report. Report.** 2020 August, viewed 16 September 2020. Available from https://www.interpol.int/en/News-and-Events/News/2020/INTERPOL-report-shows-alarming-rate-of-cyberattacks-during-COVID-19

¹⁷ Maimon David. From selling ineffective medicines and used masks to stealing data, darknet sites are conning buyers, 2020 August 23, viewed 18 August 2002. Available from https://scroll.in/article/970939/from-selling-ineffective-medicines-and-used-masks-to-stealing-data-darknet-sites-are-conning-buyers

United States officials continues to seize items linked to COVID-19

In the first report, covering alerts from January to June 2020, multiple alerts reported on seizures by customs or federal agents in the United States of America (USA). The seizures continued in August. Articles reported on cases in Baltimore, Harrisburg, Philadelphia, Pittsburgh, Washington DC and Wilmington of falsified or unauthorized testing kits (report ID: 679747, 679801, 679888, 686396, 687559), respirators and/or other masks (report ID: 679801, 679888, 686396, 687559), and COVID-19 treatments (report ID: 679747, 679801, 679888, 686396, 687559, 699470), including dipyridmole, doxycycline, hydroxychloroquine sulphate, Lianhua Qingwen Jianonangcee and Pian capsules. The products came from a wide range of senders including some from Ghana, Hong Kong, Kenya, Mexico, to Poland, Spain, Switzerland and the United Kingdom (report ID: 686396, 687559).

5.3 Vaccines

Most countries in the world are hoping for the availability of a vaccine against SARS-CoV-2 for the coming year 2021. In August, Russia was the first country to approve a new vaccine, Sputnik V. To date we have not identified any SF alerts for this vaccine. According to the WHO, another 26 vaccine candidates are in the human clinical trial phase¹⁸. In the spring Interpol¹⁹ and Europol²⁰ had warned of a wave of offers for falsified vaccines once a genuine approved vaccine for COVID-19 would be announced. Again we came across some examples that a vaccine does not even need to be approved for criminals to make profit. Some of the Chinese COVID-19 vaccines that are entering in phase three clinical trials are subject to illicit online sale already. In China, WeChat and individual messing apps are used to sell trial vaccines of SVA-Sinovac Biotech (named Coronavac) and Sinopharm, Wuhan Institute of Biological Products (report ID: 688388; 723320). Chinese authorities and both of the companies warned against the illegal sale of the vaccines.

5.4 COVID-19 diagnostics

In Sweden, the PCR kits of the Chinese company BGI Genomics were found to be of substandard quality leading to false positive results for people with mild or no symptoms of COVID-19 (Report ID: 705332). An article reports that although the quality of the Covid-19 tests of two Korean companies (SD Biosensor and RapiGen Inc) was questioned (report ID: 700713) by foreign agencies in the previous months, these tests were still being purchased by some hospitals and clinics in the Philippines. In Russia, 3 people were found guilty of selling falsified COVID-19 tests in spring 2020 (report IDA: 693557). As reported in the general section on articles on SF medical products for COVID-19 of the current report, many SF test kits were seized in the USA (report ID: 679747; 679801; 679888; 686396; 687559).

¹⁸ World Health Organisation. **The push for a COVID-19 vaccine**, viewed 14 September 2020. Available from <u>https://www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-vaccines</u>

¹⁹ Interpol. **COVID-19: the global threat of fake medicines.** News release. 2020 Mai , viewed 14 September 2020. Available from <u>https://www.interpol.int/en/content/download/15305/file/20COM0356%20-</u> %20IGGH COVID-19%20threats%20to%20medicines 2020-05 EN.pdf

²⁰ Europol. **Viral marketing - counterfeits, substandard goods and intellectual property crime in the COVID-19 pandemic.** Report. 2020 April 17, viewed 14 September 2020. Available from <u>https://www.europol.europa.eu/newsroom/news/viral-marketing-counterfeits-in-time-of-pandemic</u>

5.5 Personal protective equipment including sanitizers

5.5.1 Personal Protective Equipment

The Malaysian Pharmaceutical Society warned about falsified masks circulating in Malaysia (report ID: 695097). In Finland officials warned about SF masks in the market (report ID: 699234). Some masks do not have a product testing report and for other masks labels do not hold the right information concerning their usage and protection level.

In India, the police arrested four people who were alleged to have been selling falsified masks for two months (report ID: 682741) and a man was arrested for allegedly distributing and selling falsified "Venus" N95 masks (report ID: 698070). In Maharashtra state the FDA charged 5 manufacturers for producing poor quality PPE kits and/or charging high prices (report ID: 723565). In the USA an Islamic State hacker was accused for online selling of falsified N95 masks which were allegedly manufactured in Turkey (report ID: 687581). One article reported on a variety of cases (report ID: 695097): in Indonesia in February, local police arrested 10 people for allegedly producing falsified medical masks; in the Philippines in July, there was a seizure of falsified personal protective equipment; and in Thailand a seizure of 3,300 unregistered thermometers was reported.

In previous months we did not identify many alerts on SF products in Taiwan but in the month of August several issues with falsified masks were reported. At the beginning of August an alert reported the sale of Chinese masks falsely labelled as produced by the Taiwanese company Universal Incorporation, on the online platform Shopee (report ID: 681333). There have been reports in the Philippines and in Japan of Chinese falsified masks labelled as made in Taiwan (report ID: 681333, 686826). The Taiwanese authorities tightened inspections on import and sales to track falsified masks, originating from dubious sources or falsely claiming to be "Made in Taiwan". Between August 10 and August 16, over 480,200 falsified masks were seized (report ID: 693049). By mid-August at least five cases were reported of SF medical masks on the online platform Shopee (report ID: 686826). A supplier was arrested for allegedly selling falsified surgical masks (report ID: 690721). More than 16,900 masks were seized with misleading label, not stating the country of origin and putting a false license number.

In previous issues of the Medical Product Quality Report on Covid-19 issues, Vietnam was mentioned because seized shipments were allegedly coming from the country but we found no alerts originated from Vietnam. In August the MQM Globe holds a report on a raid in Vietnam at a factory belonging to Nam Anh Equipment Trading Production Company Limited (report ID: 682872). More than 151,000 falsified 3M masks were seized. The article claims that since the start of the pandemic it is the largest case of mask intellectual property infringement in Vietnam.

Governments facing problems with substandard PPE.

The Ugandan government has set up a system of distributing free masks to all Ugandans above the age of 6 in the battle against the spread of COVID-19. An article (report ID: 700354) reports that the "government is getting information that some of the masks being produced by some of the companies contracted are of poor quality and do not meet the standards issued by the Ministry of Health" without details on the quality issue. Previously in Zimbabwe, each government department

was purchasing its own COVID-19 supplies (report ID: 703345). Now the government has set up a centralised procurement system to prevent purchases of substandard products.

An alert reported on the low quality of PPE provided to front-line workers by the Kenya Medical Supplies Authority (report ID: 693558). In South Africa, many PPE not reaching the standards set by the South African Bureau of Standards were intercepted, but some allegedly substandard PPE nevertheless reached frontline healthcare workers (report ID: 680431).

5.5.2 Sanitizers and disinfectant

In Bangladesh 10 people were found guilty for manufacturing falsified "Savlon antiseptic liquid" (report ID: 701583). In the USA a man was charged for putting SF disinfectant on the market. He repackaged pesticides and advertised it online as "Kills 99.9% Bacterias & Viruses" and "Kills Covid 19 & Seasonal Flu" using a false US Environmental Protection Agency registration number (report ID: 705838).

Out of the 22 reports on issues with hand sanitizers, 13 were in the USA. Although, the United States Food and Drugs Administration (US FDA) does not 'approve' hand sanitizers for use, they do regulate the market and perform regular checks of the products available on the market. During the month of August the US FDA continued to recall hand sanitizers and steadily expanded its Do-Not-Use-List of hand sanitizers²¹, adding 72 more lines to count up to 171 lines, each line potentially including several products (report IDs: 675623, 677798, 679232, 680774, 682959, 684482, 686003, 689343, 694090, 704243). Problems encountered are reduced amount of active ingredient compared to what is stated, labels with false claims or contamination with potentially toxic types of alcohol (report ID: 704243). Only ethyl alcohol (ethanol) and isopropyl alcohol (2-propanol) are acceptable in hand sanitizers. In the Middle of June the US FDA warned about sanitizers containing methanol. Mid-August the US FDA warned consumers about hand sanitizers packaged in containers that may appear as food and drinks (report ID: 707279). Ingestion of hand sanitizers can be potentially toxic, especially for young infants. The US FDA informed consumers they can use the FDA's Hand Sanitizer Do-Not-Use List for checking each hand sanitizer before using it (report ID: 701735, 704243).

The Indian Central Drugs Standard Control Organization (CDSCO) released the results of their monthly routine quality tests on a range of pharmaceutical products. Twelve hand sanitizers were declared as "Not of Standard Quality", after failing the tests for the identification of isopropyl alcohol and/or assay of ethyl/isopropyl alcohol and/or the limit of non-volatile residue (report ID: 708562). An article reports that the Maharashtra FDA acted against over 80 companies for producing or selling poor quality hand sanitizers (report ID: 723565). The quality of hand sanitizers in India was studied by the Consumer Guidance Society of India (report ID: 710496). The results reveal that nearly 50% of the 122 tested samples were substandard or falsified. For 45 products, the content of the product and the information on the label did not match. Five samples contained methanol and were allegedly produced by Krivi Herbals Pvt. Ltd, Avon Laboratories, Misty Gold Equinox Industries, Aan Pharma Pvt. Ltd, and Avadh Engineering Pvt Ld. Several alerts on the MQM Globe report on investigations by

²¹ United States Food and Drug Administration. **FDA updates on hand sanitizers consumers should not use.** Viewed 16 September 2020, Available from <u>https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-consumers-should-not-use</u>

the Indian authorities of hand sanitizers contaminated with methanol (report ID: 672035, 676714; 685390). Two men were arrested for selling falsified hand sanitizers, baring no label or manufacturing certificate. Laboratory tests showed that the products contained methanol instead of ethanol (report ID: 672035). In the state of Andhra Pradesh, a special investigation team found that the hand sanitizer "Perfect Gold" was made of methanol instead of ethanol, it caused the death of at least 16 people. Due to the COVID-19 lockdown, regular liquor shops were closed so the victims allegedly turned to drinking hand sanitizers instead (report ID: 685390).

An article reported on the removal of substandard hand sanitizers form the market in Guyana (report ID: 703769). In Bangladesh a pharmacy chain, Al Shefa Pharmacy and Health and Housing Distribution, was found guilty of manufacturing and selling falsified hand sanitizers (report ID: 701583). In Mexico federal agents warned the public not to buy hand sanitizers from street vendors after they seized SF sanitizers contaminated with methanol (report ID: 690047).

5.6 **COVID-19 medicines**

Remdesivir and corticosteroids have shown to be beneficial in the treatment of some well defined subgroups of COVID-19 patients. In parallel the number of clinical trials of repurposed and investigational antiviral and immune-based COVID-19 therapies continues to grow. In addition patients turn to some medicines that are generally used for a cold, pain, fever or to boost the immunity. For all these medicines vigilance is needed considering the risk of substandard or falsified versions.

Corticosteroids

Apart from dexamethasone, methylprednisolone and hydrocortisone are now part of the WHO guidance for COVID-19 treatments²². In August no alerts on dexamethasone were identified by the MQM Globe. One alert reported on problems with methylprednisolone in the USA from before the pandemic. Two pharmacists were sent to trial for the death of 11 people in 2012 (report ID: 698052). The New England Compound Center did not follow the required sterility procedures and allegedly created fraudulent cleaning records and falsified testing results. They misrepresented the safety of the products produced in rooms with mold and bacteria, which led to patients receiving epidural injections of contaminated methylprednisolone triggering a deadly fungal meningitis. This illustrates the risk, even in wealthy countries, of SF steroids that we need to be aware of for the pandemic. With increased demand, the cost is likely to rise and the availability to fall of these steroids, risking SF products that will be deleterious for both COVID-19 patients and those with the multiple other conditions requiring these medicines.

Remdesivir and others

The MQM Globe has not yet identified reports of falsified remdesivir but does show reports of illicit sale in India. In Maharashtra state the FDA started acting against people selling the product at high prices (report ID: 723565). Eleven people linked to at least 5 different shops in different Indian states were arrested for black marketing of Remdesivir (Report ID: 678201).

²²World Health Organisation. **Corticosteroids for COVID-19**, viewed 16 September 2020. Available from <u>https://www.who.int/publications/i/item/WHO-2019-nCoV-Corticosteroids-2020.1</u>

Two molecules named in the context of COVID-19 were already available on the black market prior to the COVID-19 outbreak to treat cats with feline infectious peritonitis: GS-441524, the parent nucleoside of remdesivir, and GC376²³. In August the Australian Therapeutic Goods Administration issued a warning that these unapproved medicines available online might be of poor quality or falsified and thus could harm people (or their pets) (report ID: 709496).

Chloroquine & Hydroxychloroquine

Caution is needed against the use of chloroquine or hydroxychlorquine for COVID-19 patients outside clinical trials. The WHO stopped the hydroxychloroquine treatment arms for COVID-19 in the beginning of July²⁴. Nevertheless the product still has been subject to multiple seizures in Australia (report ID: 723320) and the USA (report ID: 679888; 686396; 687559). In the end of August a man was sentenced in the USA for smuggling chloroquine from China earlier this year (report ID: 707393). He tried to conceal the shipment from customs authorities as ammonium polyphosphate describing it as a sample with "no commercial value" although evidence shows he was planning to sell it online as a COVID-19 treatment.

Other medicines

During August the MQM Globe did not alert on falsified tocilizumab in India, which was reported in July. But the Mumbai police arrested a men for selling tocilizumab injections on the black market at nearly three times the original price (report ID: 676168).

Sildenafil is a well known medicine for erectile dysfunction. Studies for its use in the treatment of COVID-19 are continuing. In China (report ID: 705308), Kenya (report ID: 680191), and the USA (report ID: 683102), people were accused for selling and/or manufacturing falsified sildenafil. In the USA, Master Pharm LCC recalled a whole range of products, including sildenafil, "due to a lack of assurance of conformity to specifications" (report ID: 705051).

The Indian CDSCO released the results of their monthly routine quality tests. Some of the medicines that failed testing contained the same active pharmaceutical ingredients as used or are being trialed for COVID-19 treatment. In July samples of ramipril, paracetamol, vitamin complexes containing Vitamin D3 and vitamin complexes containing alpha lipoic acid were reported as "Not Of Standard Quality" (report ID: 708562). In India, the Maharashtra FDA found Vitamin C tablets "with duplicate labels of date and content" and tablets at unapproved high doses (report ID: 723565). In the Philippines there are recent reports of falsified paracetamol (report ID: 678507). In the USA aspirinlooking medicines have been found to contain fentanyl (report ID: 694649).

False claims

Although we do not aim to include alerts on the multiple false claims on COVID-19 treatment we do want to highlight the dangers by sharing the example of "Miracle Mineral Solution". It has been

²³ Vin News Services. **Hope, despair fuel black market for drugs in fatal cat disease.** Wogan L, viewed 15 September 2020. Available from https://news.vin.com/default.aspx?pid=210&ld=9235321

²⁴World Health Organisation. **WHO discontinues hydroxychloroquine and lopinavir/ritonavir treatment arms for COVID-19.** News release, viewed 15 September 2020. Available from <u>https://www.who.int/news-room/detail/04-07-2020-who-discontinues-hydroxychloroquine-and-lopinavir-ritonavir-treatment-arms-for-covid-19</u>

persistently sold (online) for a variety of illnesses and has now been claimed as effective for the treatment of COVID-19. The US FDA has repeatedly cautioned against its use²⁵. In Columbia, two American men were arrested for shipping the solution to the USA, Colombia and Africa (report ID: 693396). Although in April they were ordered to stop selling the product, they continued their activities. Seven Americans have allegedly died after using the substance. In the past months the Federal Trade Commission has send nearly 300 warning letters to companies and individuals to stop selling products falsely claiming to treat COVID-19 (report ID: 692693).

6 Annexes

The annexes contain the reports generated by the MQM-Globe using pre-defined search terms. The report IDs (six digits code) discussed in section 5 'Lay literature' are detailed in the annexes. To consult the annexes, please see the extended version of the report and/or consult the online \underline{MQM} <u>Globe</u>²⁶, using the report ID in the search box.

²⁵ United States Food and Drug Administration. Danger: Don't Drink Miracle Mineral Solution or Similar Products. Viewed 15 September 2020. Available from <u>https://www.fda.gov/consumers/consumer-updates/danger-dont-drink-miracle-mineral-solution-or-similar-products</u>

²⁶Infectious Disease Data Observatory. **Medicine Quality Monitoring Globe**. Viewed 22 September 2020. Available from <u>https://www.iddo.org/medicine-quality-monitoring-globe</u>