Medical Quality Product Report - COVID-19 issues

Issue 15. Data from January, February & March 2022

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

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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Any remarks or additions to content are greatly appreciated (please write to medicinequality@iddo.org).

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Summary of findings

Since the beginning of the pandemic we have identified 1028 relevant articles on quality problems with COVID-19 medical products in the English language lay press. In this issue we report on 77 further incidents reported during the months of January, February and March 2022. All concern incidents with products that were reported as substandard, falsified, diverted, unregistered or of unclear quality that were included in the Medicine Quality Monitoring (MQM) Globe.

Part A of the report covers incidents with COVID-19 vaccines. Between 12th March 2020 and 31st March 2022, we found, excluding duplicates, 184 reports of incidents on quality issues with COVID-19 vaccines linked to 48 different countries and/or online. Six new incidents were reported. For the first time incidents in Ireland, Rwanda, and Singapore are reported. Five incidents involved falsified COVID-19 vaccines including those labelled as manufactured by Covishield, Zydus Cadila, and Pfizer/BioNTech. One incident was related to diversion of COVID-19 vaccines out of the regular supply chain.

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'. In March, WHO issued an alert for falsified remdesivir in Guatemala and India containing no active ingredient. The Pan African enforcement operation codenamed Flash-IPPA, on Illicit Pharmaceutical Products in Africa, jointly coordinated by Interpol and Afripol, has led to the arrest of hundreds of suspects and the seizure of over 12 million illicit health products, including hundreds of COVID-19 test kits and several thousand masks. Several articles reported on issues with falsified products in the Philippines from falsified COVID-19 antigen test kits, and face masks, to many different medicines such as molnupiravir, herbal medicines and paracetamol.

This issue of the report contains summary data of 2 years on diverted, substandard and falsified COVID-19 medical products. During the pandemic existing vulnerabilities such as impaired access, poor governance, weak technical capacity combined with high demand and shortages of genuine products contributed to an increased global risk of substandard and falsified medical products. We will further analyse the data that were gathered in the last 2 years to inform strategies for better preparedness in preventing, detecting and responding to substandard and medical products for the next pandemic.

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 of products for COVID-19 if they mention concerns about 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 medicines 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 products 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 fifteenth issue of the 'Medical Product Quality Report – COVID-19 Issues' covers information published during the months of January, February and March 2022. Previous issues covered publications from January 1st 2020 onwards and are available on the IDDO[2] and MORU[3] websites.

Any remarks or additions to content are greatly appreciated (please write to medicinequality@iddo.org).

[1]Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe. Web Page. Published 2020. Accessed Apr 08, 2022. https://www.iddo.org/medicine-quality-monitoring-globe
[2]Infectious Diseases Data Observatory. Medical Product Quality Reports. Medical Product Quality Reports. Published 2020. Accessed Apr 08, 2022. https://www.iddo.org/mq/research/medical-product-quality-reports
[3] MORU Tropical Health Network. Medical Product Quality Report - Covid-19 issues. Medicine Quality. Published 2020. Accessed Apr 08, 2022. https://www.tropmedres.ac/research-areas/medicine-quality/covid-19-pandemic

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, Seventieth World Health Assembly, Appendix)[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 product.

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[4]Source: World Health Organisation. Appendix 3 WHO MEMBER STATE MECHANISM ON SUBSTANDARD/SPURIOUS/FALSELY-LABELLED/FALSIFIED/COUNTERFEIT (SSFFC) MEDICAL PRODUCTS WORKING DEFINITIONS. In: Seventieth World Health Assembly; 2017. Document no longer available online. Definitions available on the WHO website: World Health Organisation. Substandard and falsified medical products. Published January 31, 2018. Accessed April 19, 2022. https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products

[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 April 08, 2022. 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 April 08, 2022. 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	**'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.
Substandard	**'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.
Unregistered or Unlicensed	**'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).
When the above concepts are not applicable	
Substandard or Falsified	**'Substandard or Falsified'** (SorF) was suggested by Saraswati et al. 2019[7] 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.
Diverted	**'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.
Unclear	**'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.

[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 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

[8]Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe. Web Page. Published 2020. Accessed April 08, 2022. https://www.iddo.org/medicine-quality-monitoring-globe
[9]Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe methodology. Web Page. Published 2020. Accessed April 08, 2022. 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 treatment[10], 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 website[11] or COVID-19 vaccines sold over the phone[12] 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 <u>not</u>

[10] Hashemian SRM. Evaluation the effects of Oxycodone administration on pain control in patients with COVID-19. Iranian Registry of Clinical Trials. Published June 8, 2020. Accessed April 08, 2022. 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 April 08, 2022.

[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 April 08, 2022.

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

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

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[13].

[13] Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe disclaimer and caveats. Web Page. Published 2020. Accessed April 08, 2022. 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. 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 WHO[14]) 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 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.

A.2.1. Incidents since the beginning of the pandemic

Between 12th March 2020 and 31st March 2022, we found, excluding duplicates, 184 reports of incidents on quality issues with COVID-19 vaccines linked to 48 different

[14] 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

countries and/or online (see Figure 2). Out of these reports, 22 were published in 2020; 156 reports were published in 2021; 6 reports were published in 2022 (see Figure 1).

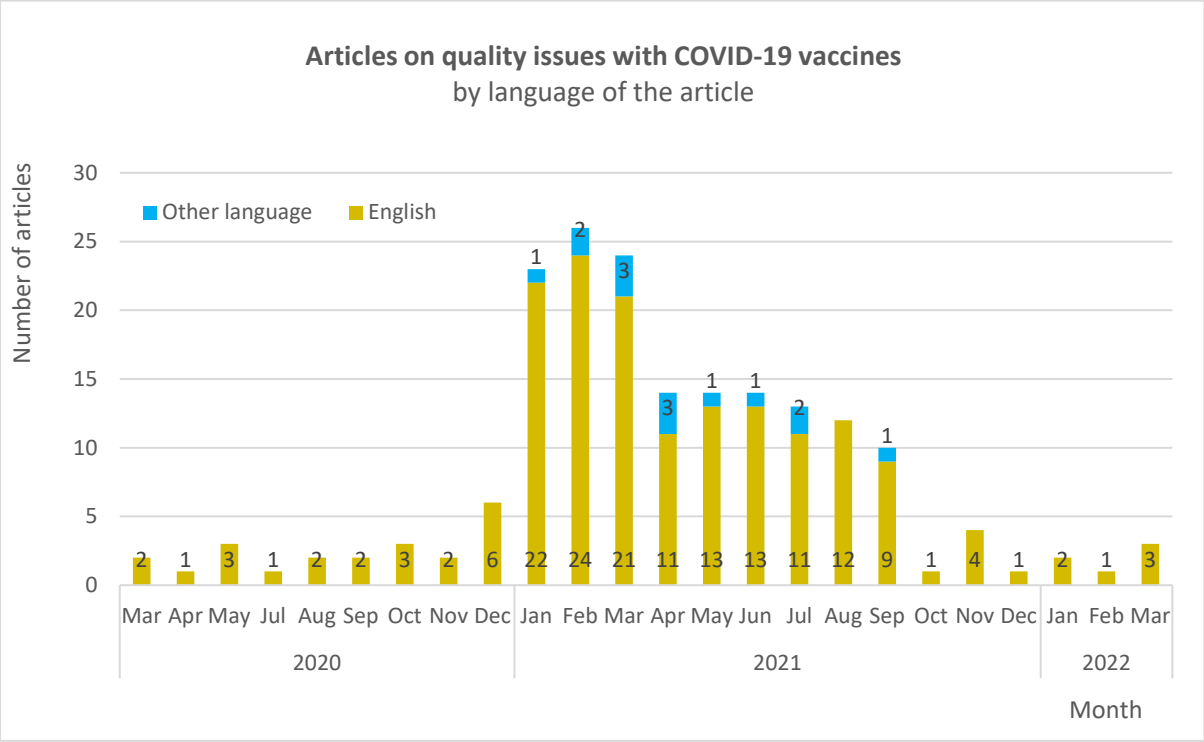

Figure 1. Number of articles on the Medicine Quality Monitoring Globe reporting quality issues with COVID-19 vaccines.
Reports date from 12 March 2020 until 31 March 2022. We count here only one article per incident– there are many other articles describing the same incidents. From January 2021 onwards, we report not only on incidents covered in the English lay press but also in Chinese, French, Spanish and Vietnamese languages.

Table 2 gives more details 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. Table 3 gives more details on the reports that were published from June 2021 to March 2022. For further details on the incidents reported during 2020 please consult Annex B.

In this issue we discuss in more detail the 6 incidents that were reported during the months of January (2), February (1) and March (3) 2022 (see Table 3). We report for the first time on incidents in Ireland, Rwanda, and Singapore. Five incidents involved falsified COVID-19 vaccines including those labelled as manufactured by Covishield, Zydus Cadila, and Pfizer/BioNTech. One incident was related to diversion of COVID-19 vaccines out of the regular supply chain.

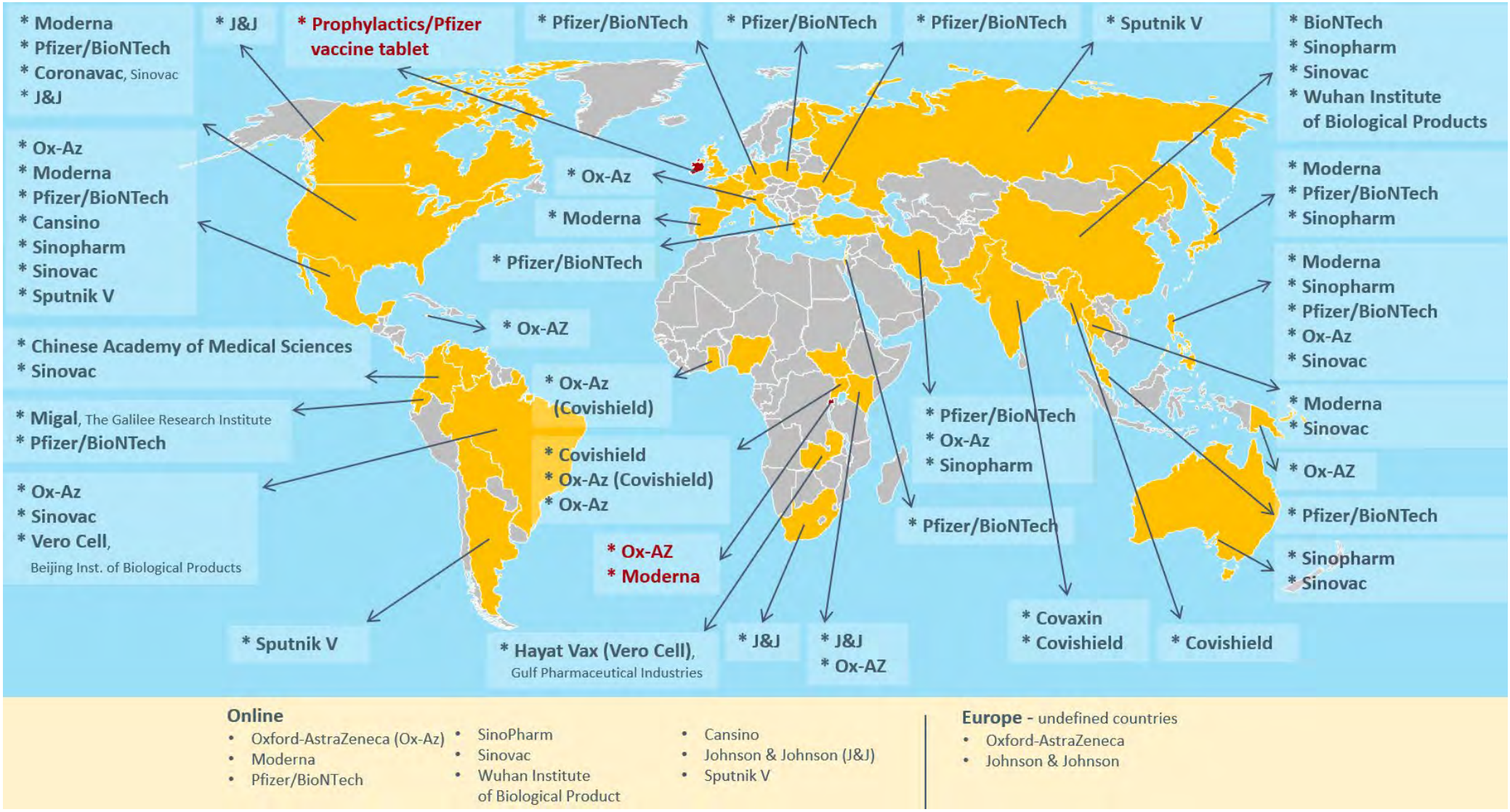

Figure 2 Countries with public reports on COVID-19 vaccine quality issues on the Medicine Quality Monitoring Globe.
Countries linked to incidents are indicated in orange. If a public report mentions a product name or a company, these details are indicated on the map, with in red the information that 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 reports we plan to retrospectively categorise prior reports in the same way as in Table 3 with reports from June up to September 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.

January – May 2021

Publication date	Location	Product/ Organization	Additional information	Title	MQM Globe report ID	URL[15]
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/ Original message: 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/

[15] Over time some URLs might not work anymore, and in that case one can find a summary/extract of the article on the 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/ Original message: 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-t6nnwtc2vvad5jr4dmtlxyf7mq-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.itnewsafrica.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 Original message: 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 Original message: 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 Additional information: '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 Additional information: 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 between June 2021 and March 2022.

Each article is available in the Medicine Quality Monitoring (MQM) Globe linked to a report ID. Reports date from 1 June 2021 until 31 March 2022. Each type of quality issue has an attributed colour in this table (falsified: red, substandard: grey, diverted: blue, unregistered: white, unclear: turquoise). For the definition of the different terms of quality issues, please consult Table 1. In the next reports we plan to retrospectively categorise prior reports according to these definitions. 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 may be 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.

June - December 2021

Publication date	Probable quality issue	Location	Product/Organisation	Title	MQM Globe report ID	Quantities involved	Constituent
JUNE 2021							
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	-

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 ▷ Kenya News	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)
JULY 2021							
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	**Unclear**	Philippines	**Oxford-AstraZeneca, Pfizer/BioNTech, Sinovac**	Pasay City police arrest fake nurse, cohort for illegal sale of COVID vaccines	1129126	unknown	-
07 July 2021	**Falsified, Unclear**	Iran	**Sinopharm, Oxford-AstraZeneca, Pfizer/BioNTech**	Iran Cracks Fake COVID Vaccine Ring, Seizing Large Shipment	1216975	unknown	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	1157058	unknown	Unknown

				(Alert for the discovery of false vaccines against Covid-19 in Ciudad Juárez)			
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?
AUGUST 2021							
04 August 2021	**Falsified**	Zambia	-	2 in court for administering fake Covid vaccine – Zambia	1170735	one person vaccinated	-
10 August 2021	**Falsified**	India	-	Health supervisor held for giving 'fake' Covid jabs	1171346	-	dexamethasone, ranitidine
10 August 2021	**Falsified**	Germany	**Pfizer/BioNTech**	8,900 May Have Received Fake COVID-19 Vaccines, Injected With Saline Instead	1172699	up to 8,557 people vaccinated	saline solution
16 August 2021	**Falsified**	Uganda, India	**Covishield**	Coronavirus - Africa: Medical Product Alert N°5/2021: Falsified COVISHIELD vaccine	1179721	-	-
19 August 2021	**Diverted**	India	**Covishield**	Navi Mumbai: 20-year-old held for black marketing of Covishield vaccine in Nerul	1183740	-	-
21 August 2021	**Diverted**	Myanma, India	**Covishield**	Brokers sell Covishield vaccine on Myanmar's black market for millions of kyat	1211006	-	-

25 August 2021	**Substandard**	Japan, Spain	**Moderna**	Moderna probes reports of COVID-19 vaccine contamination in Japan Additional information: report ID 1195784	1191874	1.63 million doses	'metallic particle'
28 August 2021	**Substandard**	Japan (Okinawa)	**Moderna**	Contaminants found in Moderna vaccine not belonging to suspended lots Additional information: report ID 1196215	1195426	4 vials	'rubber pieces'
29 August 2021	**Substandard**	Japan (Gunma)	**Moderna**	Contaminants found in more Moderna COVID vaccine in Japan	1196215	4,500 people received shots	'blackish foreign matter'
30 August 2021	**Substandard**	Japan	**Moderna**	Japan's Moderna vaccine woes widen	1197034	1 million	'foreign substances'
31 August 2021	**Falsified**	Myanmar	**Covishield**	Medical Product Alert N°5/2021: Falsified COVISHIELD vaccine (Update)	1198523	-	-
31 August 2021	**Substandard**	Japan (Kanagawa)	**Moderna**	Japan finds black particles in Moderna vaccine	1199556	3,790 people received shots	'black particles'
SEPTEMBER 2021							
01 September 2021	**Unregistered**	Zambia	**Hayat Vax (Vero Cell, Gulf Pharmaceutical Industries)**	10,000 doses of fake COVID-19 vaccines destroyed by ZAMRA	1199738	-	-
06 September 2021	**Unclear**	Brazil	**Sinovac**	Brazil Bans China's Sinovac Covid Vaccine Over Fears Of Contamination	1206268	12.1 million doses + 9 million doses	-
08 September 2021	**Falsified**	Kenya	**Johnson & Johnson**	Two suspected of administering fake Covid-19 vaccine	1208719	-	-
09 September 2021	**Falsified**	China	-	福州这2人制造假新冠疫苗共牟利54万余元,目前已有200人接种! - 2021-09-09 (Two people in Fuzhou made a total of more than 540,000 yuan in the production of fake new COVID-19 vaccines, and currently 200 people have been vaccinated!)	1209582	454 falsified vaccines sold (allegedly administrated to 200 people)	'saline'
13 September 2021	**Diverted**	Turkey	**Unknown**	Nurses accused of selling siphoned COVID-19 vaccines in Turkey | Daily Sabah	1215059	-	-
13 September 2021	**Falsified**	India	-	Three Moga women held for holding fake Covid vaccination camp	1215054	-	multi-vitamins

14 September 2021	**Substandard**	Japan	**Pfizer/BioNTech**	Contaminated Pfizer Covid-19 vaccines found in Japan	1216365	5 vials	floating white substance
15 September 2021	**Substandard**	Japan	**Pfizer/BioNTech**	Pfizer says substances found in COVID-19 vaccine vials in Japan harmless - Reports	1217459	95 vials	floating substances
15 September 2021	**Diverted**	Canada	**Unknown**	Winnipeg police investigating possible theft of COVID-19 vaccine from convention centre supersite	1217927	-	-
23 September 2021	**Substandard**	South Africa	**Johnson & Johnson (Aspen's Gqeberha facility)**	30 million 'contaminated' J&J vaccines destroyed in South Africa	1227495	30 million	-
OCTOBER 2021							
19 October 2021	**Substandard**	Papua New Guinea	**Oxford-AstraZeneca**	AstraZeneca vaccines exposed, contaminated	1259608	First order: 200 vials Second order: 150 vials	-
NOVEMBER 2021							
04 November 2021	**Falsified**	Iran	**Pfizer/BioNTech**	Medical Product Alert N°6/2021: Falsified Pfizer-BioNTech COVID-19 Vaccine	1277375	-	-
04 November 2021	**Falsified**	Iran	**Oxford-AstraZeneca**	Medical Product Alert N°7/2021: Falsified COVID-19 Vaccine AstraZeneca	1276986	-	-
11 November 2021	**Diverted**	India	-	Fake vaccination racket unearthed in Uttar Pradesh's Unnao district	1284769	more than 3,000 vaccine doses	-
28 November 2021	**Unregistered**	Germany	-	Germany: Dozens take illegal mystery COVID vaccine before police shut it down. Additional information report ID 1337288	1321353	50 + 20,000 individuals received a homemade dose	-
DECEMBER 2021							
06 December 2021	**Diverted**	Kenya	**Oxford-AstraZeneca, Johnson & Johnson**	Kenya: Inside Top Secret Covid-19 Vaccine Smuggling Racket - AllAfrica	1310033	10 vials of Johnson & Johnson COVID-19 vaccine (5 doses/vial)	-

January – March 2022

JANUARY 2022							
04 January 2022	**Falsified**	USA	-	Teacher arrested for giving COVID-19 vaccine to teen	1349246	1 vial	-
20 January 2022	**Diverted**	Rwanda	***Oxford-AstraZeneca** ***Moderna**	Rwanda: 8 health workers arrested for stealing COVID-19 vaccines, test kits	1370792	* 30 vials Oxford-AstraZeneca (300 doses) * 45 vials Moderna (675 doses)	-
FEBRUARY 2022							
03 February 2022	**Falsified**	India	***Covishield** ***ZyCoV-D (Zydus Cadila)**	Officials Seize Large Cache of Fake COVID Vaccines, Drugs, Test Kits in Varanasi – The Wire Science	1390161	*6,000 vials of Covishield * 880 vials (2 ml each) of ZyCoV-D	* Covishield: "transparent fluid" * ZyCoV-D: distilled water
MARCH 2022							
18 March 2022	**Falsified**	Italy	-	Health worker arrested in fake COVID jabs for cash case - English	1432612	-	-
24 March 2022	**Falsified**	Ireland	**'COVID-19 Prophylactics/ Pfizer Vaccine tablets'**	T&T on alert as fake COVID-19 vaccine pills seized abroad | Loop Trinidad & Tobago	1438727	-	tablets containing sugar
28 March 2022	**Falsified**	Singapore	-	Doctor linked to Healing the Divide group suspended, accused of giving patients saline solution instead of COVID-19 vaccine	1441852	-	saline solution

A.2.2. Incidents published in January, February and March 2022

A.2.2.1. Falsified COVID-19 vaccines

Covishield and ZyCoV-D

A large quantity of illegal and falsified COVID-19-related medical products, including falsified COVID-19 vaccines, have been seized in Uttar Pradesh, India (report ID 1390161). According to the state FDA, the total seizure was worth Rs 4 crore (Indian Rupee, approximately 515,600 USD). Officials found 880 vials (2 ml each) of Zydus Cadila's COVID-19 vaccine, ZyCoV-D, filled with distilled water. The forgery cost around Rs 25 per vial (approximately 0.32 USD), while the selling price was Rs 300 (approximately 4 USD). The drug administration team also recovered 6,000 vials of Covishield with green caps filled with *"transparent fluid".* The majority of the falsified vaccines were sold to private hospitals in the city. Officials also seized four sealing machines, two cartons of empty vials, blue and green sealing caps (for ZyCoV-D and Covishield, respectively), and numerous falsified labels.

Pfizer/BioNTech

In Ireland, there has been a seizure of falsified COVID-19 'Prophylactics/Pfizer Vaccine tablets' (report ID 1438727). Following the incident, the Ministry of Health of Trinidad and Tobago issued an alert to the public about the falsified pills. The Ministry noted that these pills are being sold online. However, Pfizer does not make such tablets. The Ministry also stated that the tablets contain sugar and no active ingredient.

Unknown 'COVID-19 vaccines'

In USA, a New York biology teacher, with no medical qualifications, was arrested for allegedly administering a falsified COVID-19 vaccine (report ID 1349246). A 17-year-old boy was given the dose at the teacher's home without permission from the boy's parents. According to the police, the vial could be falsified as it is unclear how she obtained the vaccine and which brand it was.
In Italy, a health worker was arrested allegedly giving falsified COVID-19 vaccines for 150 euros (approximately 157 USD) per shot at the Capodimonte COVID hub (report ID 1432612).
In Singapore, a medical doctor has been suspended for allegedly injecting patients with saline solution instead of the COVID-19 vaccine (report ID 1441852). Around 15 patients were administered with the falsified vaccines and at least three people were charged between 1,000 and 1,500 USD per dose[16].

A.2.2.2. Diverted COVID-19 vaccines

Oxford-AstraZeneca and Moderna

In Rwanda, eight health workers were arrested for allegedly stealing COVID-19 vaccines (report ID 1370792). Four of the suspects were unable to explain the

[16] Additional information in report ID 1455510: Linette Lai. GP suspended for administering fake Covid-19 jabs allegedly charged between $1,000 and $1,500 a dose | The Straits Times. THE STRAITS TIMES. Published April 11, 2022. Accessed June 13, 2022. https://www.straitstimes.com/singapore/health/doctor-suspended-for-administering-fake-covid-19-jabs-allegedly-charged-between-1000-and-1500-a-dose

whereabouts of 30 vials of AstraZeneca vaccines and 45 vials of Moderna vaccines, which contained 300 and 675 doses, respectively. They have been charged with *"misuse of property of public interest"*.

A.3. Reports from scientific literature

Maloney KR. **Patient Harm Associated with Illegal Online Sellers of COVID-19 Patient Harm Associated with Illegal Online Sellers of COVID-19 Drug Products: A Year in Review.** Published online September 2021. Accessed June 13, 2022. https://digitalcommons.butler.edu/cgi/viewcontent.cgi?article=1606&context=ugtheses

> Abstract. *"As the online marketplace continues to expand, more patients are turning to the internet for their needs, including COVID-19 pharmaceuticals. However, the current online marketplace is saturated with illegal sellers offering substandard and falsified (SF) products with the potential of causing harm to patients. The primary objective of this thesis is to identify documented cases of harm resulting from illegal online sale of SF COVID-19 related drug or vaccine products. This review utilizes reports by the Medicines Quality Monitoring Globe (MQM Globe) to assess patient harm associated with illegal online sales of COVID-19 marketed pharmaceuticals. This review found 28 references to drug products or vaccines sold illegally online; however, none of these reported specific cases of harm resulting from this activity. This report represents a year in review from January 2020 until December 2020. Currently, COVID-19 vaccine products have been granted emergency use authorizations by the US FDA. As the hopeful end to this pandemic draws near, it is vital to retrospectively evaluate healthcare supply chain vulnerabilities, particularly the complexities added by expanding use of the internet worldwide."*

Saliou P, Duteil Q, Plotkin SA, Gentilini M. **The scourge of vaccine falsification.** *Vaccine*. 2022;40(14):2126-2128. doi:10.1016/J.VACCINE.2022.01.063

> Abstract. *"Fake vaccines trafficking is a recent but growing phenomenon, which represents a severe threat to public health. During the Covid-19 pandemic, anti-Covid vaccines have been a prime target for traffickers, but all types of vaccines are falsified by profit-hungry criminals. The consequences of falsification on global health are serious: decline in vaccination coverage, loss of control of epidemics which will claim yet more victims, and resurgence of diseases that were under control. Fake vaccines also fuel the mistrust of populations towards science and authorities. In order to tackle this scourge, a general and coordinated mobilization of all actors concerned is urgently needed: health professionals, political decision-makers, police and customs forces, judges and prosecutors, without forgetting the crucial awareness-raising of public opinion."*

Usman M, Husnain M, Akhtar MW, Ali Y, Riaz A, Riaz A. **From the COVID-19 pandemic to corrupt practices: a tale of two evils.** Environ Sci Pollut Res Int. 2022;29(20):30310. doi:10.1007/S11356-022-18536-0

> Abstract. *"Emergencies and corruption go hand in hand in times of crisis. We are currently living in a pandemic phase, and corruption is even more damaging during these times of crisis that the world is experiencing with COVID-19. Vaccination is the only survival option that we have. The development of a nation will soon be measured by the criteria of who owns more vaccines. This study has four objectives. The first is to explore the most recent relevant literature. Moreover, we also investigate the unique trilogy of corruption, the environment, and the COVID-19 pandemic. The second is to identify adequate channels for distributing the COVID-19 vaccines. The vaccines should be dispersed based on the categories of age, gender, ethnicity, profession, and health conditions. Third, we explored the factors that are causing corruption in the distribution of the COVID-19 vaccines. Our findings show that unequal distribution, theft and black markets, weaponization of vaccines, logistical challenges,*

and substandard and falsified vaccines are the factors that potentially lead to corruption. The fourth objective is to investigate solutions for mitigating corruption. We revealed that blockchain, awareness, well-planned distribution channels, and prioritization of vulnerable groups are the steps that could effectively reduce corruption."

Coalition C-19 CR, Oxford U of. COVID-19 Vaccine Access. **Achieving Equitable Access to Quality COVID-19 Vaccines, Using Digital, AI, and GIS Tools**.; 2022. https://www.kff.org/coronavirus-COVID-19/issue-brief/tracking-global-COVID-19-vaccine-equity-an-update/

Extract: *"Vaccine nationalism has led to significant immunisation disparities between high-income countries and low- and middle-income countries. By early September 2021, for example, only 2% of the population of people in low-income countries had received one vaccine dose compared with 65% of people in high-income countries. Countries like the US, UK, and Canada have secured enough vaccines to cover multiples of their populations and have moved on to giving boosters while billions of other people barely have access to these life-saving vaccines. Such disparities have accelerated the emergence and proliferation of both substandard and falsified (SF) and diverted COVID-19 vaccines. Constrained supply of vaccines, poor traceability of medical products, weak infrastructure, and inadequate tracking across borders have all worsened the situation. As of July 2021, for example, approximately 150 unique reports of SF vaccines had been published in the lay literature, highlighting the breath and complexity of the challenge."*

Additional publications from December 2021

Shiferie F, Sada O, Fenta T, Kaba M, Fentie AM. Article **Exploring reasons for COVID-19 vaccine hesitancy among healthcare providers in Ethiopia.** Pan Afr Med J. 2021;40(213):1-11. doi:10.11604/pamj.2021.40.213.30699

Extract. *"lack of trust on the quality of donated and imported medicines and vaccines to LMICs like Ethiopia were frequently mentioned as reasons for vaccine hesitancy. Participants were very skeptical about the quality of COVID-19 vaccine and this hindered them from being vaccinated. One participant said (VH001): "Most donated medical products for developing countries have low quality and short shelf life. The products are imported with push system without checking their quality and safety. If a certain product is donated, the regulatory authority will simply make a skimmed inspection. They don´t strictly check their qualities as they do for other imported medical products".*

Additional publications from April 2022

Amankwah-Amoah J. **COVID-19 and counterfeit vaccines: Global implications, new challenges and opportunities.** Health Policy Technol. 2022 Jun;11(2):100630. doi: 10.1016/j.hlpt.2022.100630.

Abstract. *"This research note (RN) examines the drivers and consequences of proliferation of counterfeit (substandard and falsified) COVID-19 vaccines. An integrated framework was advanced which sheds light on the domestic contributory factors such a desperation by citizens to "return to normalcy", institutional impediments, minimum standards of enforcement of laws related to intellectual property rights and lack of access to vaccines in tandem with international environmental drivers such as the growth of online pharmacies, international market intermediaries and vaccine nationalism. Consequently, counterfeit COVID-19 vaccines appear to serve as a disincentive to innovation and investment in research and development activities. The analysis highlights health-related consequences including providing a false sense of security against a dangerous virus and potentially loss of confidence in reliable medicines. This analysis led to the generation of some vital socio-economic implications for public policy and enterprises, which are discussed."*

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 1,028 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 69 new relevant articles in the English language: 26 articles for January, 25 for February and 18 articles for March 2022 (see Figure 3).

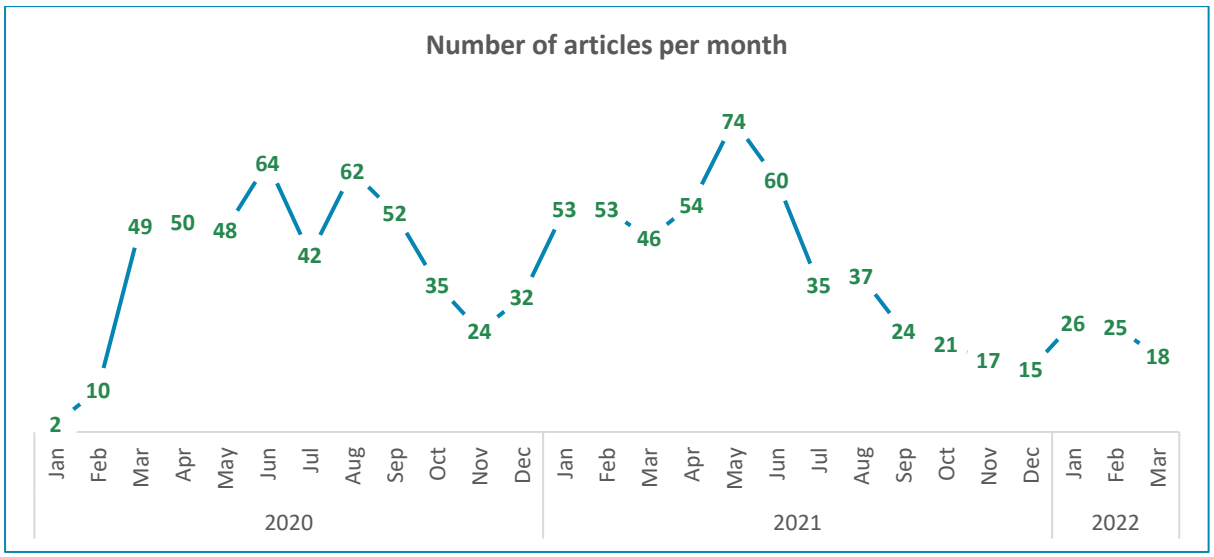

Figure 3. Number of articles on the Medicines Quality Monitoring Globe on quality issues of COVID-19 supplies by month.

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 2020, non-COVID-19 medicines containing hidden (i.e. unstated) 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 in November 2020 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 in English language that we discuss for January, February and March 2022 include 77 incidents: 6 on vaccines (see part A of this report), 38 on COVID-19 related medicines, 9 on PPE, 8 on sanitisers & disinfectants, 13 on diagnostics and 3 on ventilation & oxygenation equipment and consumables. Figure 4 shows the number of alerts for each category by month since the beginning of the pandemic.

Some articles summarize or describe multiple product categories used during the COVID-19 pandemic. When an article discusses 2 or more 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.

Falsified COVID-19 antigen test kits, face masks, and medicines were seized during a raid in a warehouse in Manila, Philippines (report ID 1377074). Thousands of Clungene COVID-19 antigen test kits, falsified Chinese herbal medicine LianHua, and falsified 3M N95 face masks were discovered during the inspection.

Falsified hand sanitizers and COVID-19 test kits worth Rs 37 lakh (approximately 47,878 USD) were seized in Andhra Pradesh, India (report ID 1388981). The products were discovered in companies without medicine-licenses.
Furthermore, in Uttar Pradesh, India, falsified COVID-19 rapid antigen test kits were seized along with falsified (injectable) remdesivir (report ID 1390161). Officials discovered 10,800 kits of 'Standard Q Covid-19 Ag SD BIOSENSOR Rapid Test Kits' with falsified batch numbers and expiration dates. According to FDA officials, the COVID-19 rapid antigen test kits were made from pregnancy kits that were simply wrapped in the antigen kit wrapper. The production cost was Rs 50 per kit, but it was sold for Rs 500. They also recovered 1,550 vials of falsified remdesivir. According to the raiding team, the accused filled empty vials with water mixed with Glucon-D (a glucose containing energy drink https://www.zyduswellness.com/glucon-d.php) and wrapped it with a falsified label. The manufacturing cost of one such vial was Rs 100 (approximately 1.29 USD), while the selling price was Rs 3,000 (approximately 38.64 USD).

The Pan African enforcement operation Flash IPPA[17] (Illicit Pharmaceutical Products in Africa) jointly coordinated by Interpol and Afripol, led to the arrest of hundreds of suspects and the seizure of over 12 million illicit health products, including 1,600 COVID-19 test kits and 208,000 COVID-19 masks (report ID 1420044).

[17] INTERPOL. Pharmaceutical crime: first INTERPOL-AFRIPOL front-line operation sees arrests and seizures across Africa. Published March 2, 2022. Accessed June 14, 2022. https://www.interpol.int/en/News-and-Events/News/2022/Pharmaceutical-crime-first-INTERPOL-AFRIPOL-front-line-operation-sees-arrests-and-seizures-across-Africa

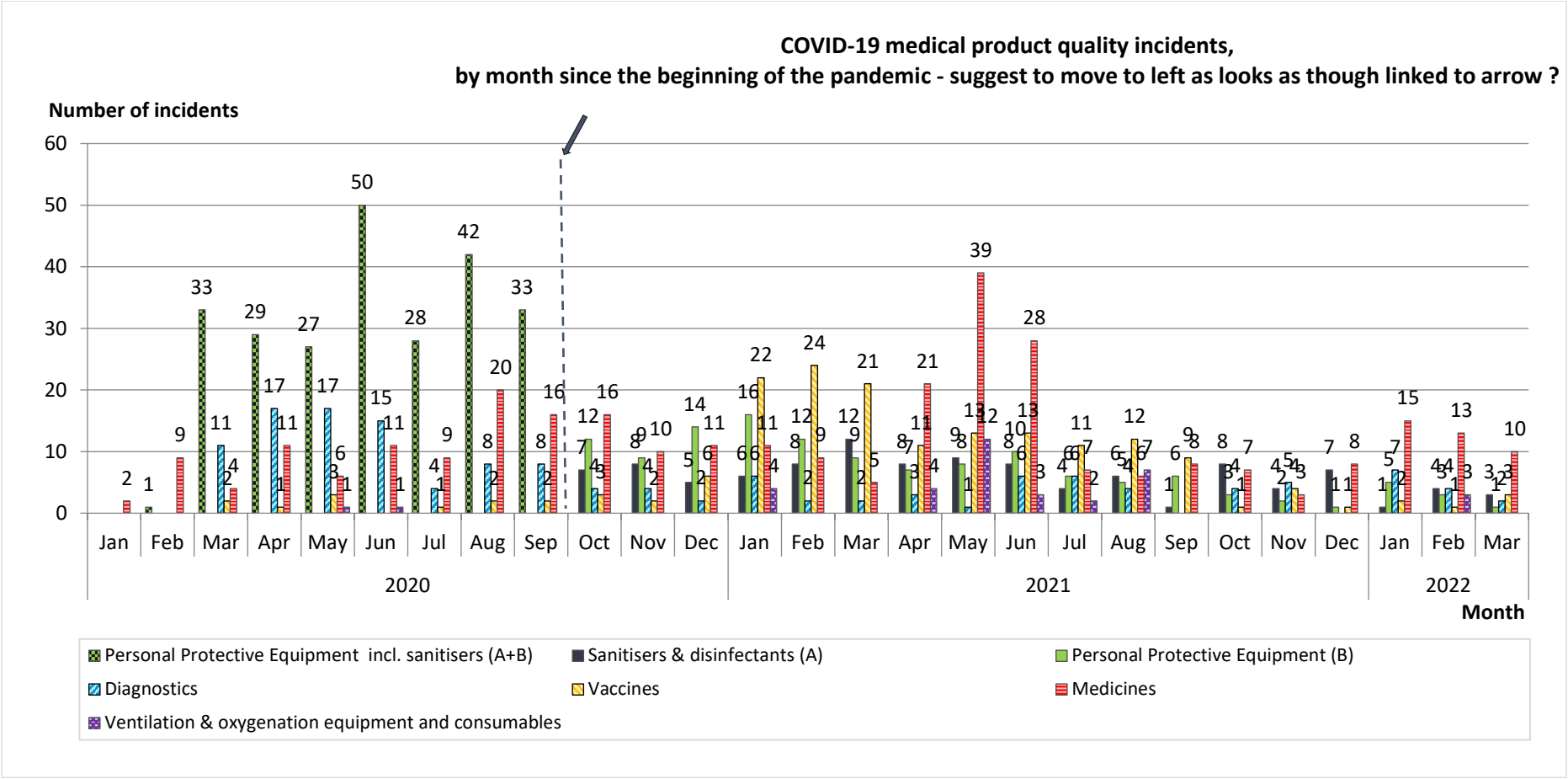

Figure 4. Incidents on the Medicines Quality Monitoring Globe on quality issues with COVID-19 medical products by month.

The arrow indicates the end of September 2020 when the category of 'Personal Protective Equipment Incl. sanitisers' was split in two distinct categories: (A) Sanitisers & 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 2020, non-COVID-19 medicines containing hidden (i.e. unstated) 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 in November 2020 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 2021 can be at least partially due to this change.

B.1.2. COVID-19 diagnostics

In January 2022, seven articles reported on incidents with COVID-19 diagnostics, in February four articles, and in March two articles.

B.1.2.1. Falsified COVID-19 test kits

In Sri Lanka, a suspect was arrested for allegedly importing a stock of falsified COVID-19 test kits worth over Rs 2 million (approximately 25,799 USD) and distributing them to hospitals and laboratories (report ID 1409609).

B.1.2.2. Substandard COVID-19 test kits

In Ireland, the Health Products Regulatory Authority (HPRA) was investigating the 'Genrui SARS-CoV-2 Rapid Antigen Test' (report ID 1364915). Numerous people claimed to have a positive result from a Genrui antigen test but later received a negative PCR test result. The antigen tests were sold in several Irish shops and pharmacies. According to an additional source[18], the regulator received over 550 consumer complaints about false-positive Genrui antigen test results. The HPRA advised retailers to voluntarily remove the tests from the market pending further investigation. Similar issues have been reported in Germany. In December, authorities issued a warning about the Genrui tests, stating that if a faint line appears to detect the presence of COVID-19, the person should do a second antigen test from a different brand.

B.1.2.3. Unregistered COVID-19 test kits

The US FDA issued a warning to stop using the LuSys Laboratories Antigen Test (Nasal/Saliva) and COVID-19 IgG/IGM Antibody Test (report ID 1358463). According to the FDA, the tests could be sold under a variety of brand names, including 'Luscient Diagnostics', 'Vivera Pharmaceuticals', and 'EagleDX'. Those tests were thought to be distributed for use in laboratories or for at home testing. The tests were later recalled by LuSys Laboratories because they were not authorized, cleared, or approved by the FDA[19]. According to the FDA, the company failed to provide adequate validation data to demonstrate that the tests were accurate.

The US FDA issued multiple safety warnings against using certain brands of *at home COVID-19 tests*. These tests have not been authorized, cleared, or approved for distribution or use in the USA. The FDA is concerned about the possibility of false results when using these tests. The following tests were mentioned in articles on the MQM Globe:

- The Flowflex 'SARS-CoV-2 Antigen Rapid Test (Self-Testing)' (report ID 1362816; 1424695): The test comes in a blue box and has been approved in

[18] Additional information in report ID 1365949: MICHELLE MCGLYNN & REBECCA LAFFAN. Genrui antigen tests pulled from sale amid reports of false positives. Irish Examiner. Published January 5, 2022. Accessed June 13, 2022. https://www.irishexaminer.com/news/arid-40779093.html

[19] Additional information in report ID 1429452: Megan Ziegler. 3 COVID-19 tests recalled after FDA warns about 'high risk' of false results. FOX10. Published March 15, 2022. Accessed June 13, 2022. https://www.fox10phoenix.com/news/3-covid-19-tests-recalled-after-fda-warns-about-high-risk-of-false-results

European and other markets, but did not receive the required emergency use authorization by the FDA. The US FDA issued a recall of 200,000 tests.

- The E25Bio 'COVID-19 Direct Antigen Rapid Test' also marketed as E25Bio 'SARS-CoV-2 Antigen Test Kit' (report ID 1412835): The test may present with a false label claiming that it is authorized by the US FDA. E25Bio has not provided adequate data demonstrating the test's accuracy.
- The SD Biosensor 'STANDARD Q COVID-19 Ag Home Test' (report ID 1424695): The test comes in a white and magenta box and. "*There is not sufficient data demonstrating that the test's performance is accurate*." An FDA recall has been initiated. Up to 397,700 of the tests were distributed between 26 August 2021 and 30 January 2022[20].
- The Celltrion 'DiaTrust COVID-19 Ag Rapid Test' (report ID 1424695): The test comes in a green and white box. They show a high number of false-positive results and indicate a wrong shelf life. A recall has been issued by the FDA, and involved a specific lot that was used by healthcare providers (lot number: COVGCCM0008)[20]. About 45,500 of those tests were distributed between 2 June 2021 and 21 December 2021.

Furthermore, in the USA, Empowered Diagnostics LLC recalled nearly 300,000 rapid COVID-19 tests (report ID 1385066). The recall affected at least 284,575 'CovClear' COVID-19 rapid antigen tests and at least 2,100 'ImmunoPass' COVID-19 neutralizing antibody rapid tests. There were concerns about the test potentially providing false results and their label incorrectly indicated that the tests are authorized by the US FDA. There had been no reports of adverse health consequences or deaths linked to use of the affected tests.

In the Philippines, four online sellers were arrested in Cebu and Mandaue, for allegedly selling unregistered and adulterated COVID-19 Rapid Antigen test kits (report ID 1383728). Around 200 boxes of test kits worth P1 million (Philippine pesos, approximately 19,126 USD) were confiscated. The initial investigation by the National Bureau of Investigation (NBI) revealed that the items originated in Manila. Some of the test kits were also sent to the FDA for inspection to check their safety and content. According to NBI, the test kits they openly sold online were not FDA registered and authorized to be sold, traded, and distributed for public use, administration, or consumption. However, these products were widely available for purchase on the internet. Depending on the quantity, sellers usually charge between P3,500 and P7,000 per box (approximately 67 - 134 USD). Each box contains 25 test kits.

B.1.2.4. Diverted COVID-19 test kits

In Rwanda, eight health workers were arrested for allegedly stealing COVID-19 test kits and vaccines (report ID 1370792). Over 1,250 COVID-19 testing kits worth Rwf 6.125 million (Rwandan francs, approximately 6,000 USD) were stolen.

[20] Additional Information in report ID 1460001: Deb Kiner. Two more COVID-19 test kits recalled, one for 'high number of false positives' - pennlive.com. Pennlive. Published March 18, 2022. Accessed June 13, 2022. https://www.pennlive.com/coronavirus/2022/03/two-more-covid-19-test-kits-recalled-one-for-high-number-of-false-positives.html

B.1.3. Personal Protective Equipment

Nine articles discussed quality issues with PPE: five in January, three in February and one in March 2022.

B.1.3.1. Falsified

Masks

Some N95 and KN95 masks that could be falsified were distributed in several states across the USA.

The city of New Orleans (Louisiana) unwittingly distributed falsified N95 masks as part of a giveaway program (report ID 1363062). At least some of the masks have not been approved by the National Institute for Occupational Safety and Health (NIOSH). It is unclear whether all of the masks distributed throughout the program were falsified.

Emerson College (Boston, Massachusetts) possibly distributed falsified masks to professors, students, and other staff members (report ID 1382293). The masks were supposed to be Greencare branded KN95 respirators. However, the masks obtained were visibly distinct from Greencare masks. According to those who received the masks, they were plain white in the typical KN95 shape, but without the KN95 mark or any approval number.

American University (Washington DC) unknowingly distributed falsified KN95 masks to the students (report ID 1391384). Those being distributed on campus did not contain the Chinese standard code, which should have been printed on the mask by the manufacturer. Furthermore, the KN95 mask packaging included a "certificate of conformity" that identified a Chinese manufacturer and China's standard code, but the certificate contained several spelling errors.

CJFS Corp., a Texas company, was sued for allegedly selling 4 million USD worth of falsified N95 masks to a university and hospital in Washington state (report ID 1398672). According to the complaint, the company allegedly sold the hospital association 600 cases of 3M 1860-model N95 masks for 1.4 million USD and the University of Washington Medicine 4,700 cases of 1860-model and 1860S-model N95 masks for 2.6 million USD. In December 2020 employees of the University of Washington Medicine noticed incorrect expiration dates on some boxes upon arrival. The masks had lot codes that corresponded to specific falsified mask models that were not manufactured by 3M. The 3M company confirmed that the supplies were falsified.

Gloves

In Thailand, two women were arrested for allegedly selling used medical gloves (report ID 1381147). The case dates back to July 2020 when a Taiwanese firm paid 2.78 million USD for one million boxes of gloves but received used gloves and boxes of bricks instead.

B.1.3.2. Substandard

Masks

The Swiss army pharmacy circulated large quantities of substandard masks to cantons, municipalities, homes, and schools (report ID 1378901). Around 3.3 million masks were sold for the symbolic price of CHF 0.01 (Swiss franc, approximately 0.01

USD) per mask since February 2021. According to Tamedia newspaper research, the masks came from a Chinese company called Sichuan Zhengning Medical Instrument Co., with the label *"WS Protection, Love is Power"* written on the packaging. The Spiez Laboratory tested the mask and revealed that particles penetrated the fabric two to four times more than the reference mask and the other tested masks.
The US FDA issued a public warning that several categories of FDA-regulated products from Family Dollar stores in six states of America were discovered in insanitary conditions, including a rodent infestation (report ID 1404932). Some examples of these products include surgical masks.

B.1.4. Sanitisers & disinfectants

Eight articles discussed quality issues with sanitisers and disinfectants: one in January, four in February and three in March 2022.

B.1.4.1. Falsified hand sanitisers

A Triple Five company was accused of selling falsified hand sanitiser at the beginning of the COVID-19 pandemic (report ID 1398834). According to documents filed, Triple Five Worldwide LLC allegedly participated in a scheme to manufacture, import, and market falsified hand sanitiser produced in Mexico that was put on the FDA's *"do not use"* list due to potential methanol contamination. The falsified hand sanitiser was marketed under the name, logo, and design of a U.S. company, the 'URBĀNE' brand.

B.1.4.2. Substandard hand sanitisers and antiseptics

Health Canada recalled hand sanitizers for a variety of reasons. Nineteen different hand sanitizers from four different companies were recalled: Canadian National Pharma Group Inc, Dollarama L.P., Luxe Decor Sales Ltd., and Haywick Industries (report ID 1365051). Some of the causes include undeclared impurities or incorrect labelling.
Furthermore, another article reports on three more hand sanitizers that were recalled due to potential health risks (report ID 1408093). Alcohol Antiseptic 80 % (v/v) Topical Solution Hand Sanitizer and Fighting Spirit sanitizer due to possible health risks resulting from "undeclared" elevated levels of acetaldehyde. Both were allegedly sold by The Newfoundland Distillery Company. A third item, Rapid Protectant Hand Sanitizer Gel, is also being recalled due to improper labelling, including "missing risk statements and missing information for vulnerable populations." The product was allegedly sold by D&L Distribution and Logistic Services Inc.

According to a new study[21], many hand sanitizer brands sold in Johannesburg, South Africa, during the early stages of the COVID-19 pandemic contained traces of toxic ingredients and less alcohol than required (report ID 1440571). The study was

[21] Matatiele P, Southon B, Dabula B, Marageni T, Poongavanum P, Kgarebe B. Assessment of quality of alcohol-based hand sanitizers used in Johannesburg area during the CoViD-19 pandemic. Sci Reports 2022 121. 2022;12(1):1-7. doi:10.1038/s41598-022-08117-z

conducted by researchers from the National Health Laboratory Service (NHLS). Between March and June 2020, ninety-four samples of hand sanitiser were collected from shops and street vendors. According to the study, 44% of the samples were substandard and possibly subpotent preparations. Some hand sanitizers contained toxic ingredients. Only 30% of the hand sanitisers tested (ten gels and nine liquids) contained 80% alcohol. The researchers reported that unscrupulous South African manufacturers deceived the public by labelling their products as *"SABS* [South African Bureau of Standards] *approved."*

The US FDA published warning letters sent to Frozen Wheels, LLC concerning the quality of their antiseptic products (report ID 1387296). Their products were labelled to contain 70% volume/volume (v/v) of ethyl alcohol. However, the concentration of ethanol stated on the label was wrong, and for some products, the active ingredient was wholly or in part substituted with methanol.

- Greenfrog HAND SANITIZER was found to contain an average of 0% ethyl alcohol and 54% of methanol v/v.
- Cleansepure was found to contain an average of 9.6% ethyl alcohol and an average of 58% of methanol v/v.
- Antibacterial Gel, 70% Ethanol Concentration was found to contain < 0.25% of ethyl alcohol and instead was comprised of 63% isopropanol.

B.1.4.3. Unregistered hand sanitisers and antiseptics

The US FDA sent a warning letter to various companies regarding their websites due to the sale of their products that were claimed to mitigate, prevent, treat, diagnose, or cure COVID-19 and marketed without FDA approval.

- Iotech International, LLC, www.iotechinternational.com (report ID 1431684): oral antiseptic ioRinse and topical antiseptic ioCleanse Molecular iodine Hand Cleanser.
- Viraldine, LLC, www.viraldine.com (report ID 1422031): topical antiseptics such as 1.5%, 1% and 0.5% povidone iodine USP antiseptic nasal spray; and oral antiseptic 1.5% povidone iodine USP antiseptic throat spray.

B.1.5. COVID-19 medicines

Thirty-eight articles discussed quality issues with COVID-19 medicines: fifteen in January, thirteen in February and ten in March 2022.

B.1.5.1. Falsified COVID-19 medicines

Eculizumab

According to WHO[22], four different falsified batches of Soliris medicine (eculizumab) were discovered in South America, Europe, and India (report ID 1361171). The WHO alert was published in December 2021 but the first article in the MQM Globe database was only report in the beginning of January. Falsified copies of Soliris with the lot number 1012401, an expiry date of September 2022, and Spanish packaging have been discovered in Argentina and Uruguay. Another Spanish version was discovered in Uruguay (lot 1013715, expiry date February 2022). An English version was intercepted in Estonia (lot 1001600, expiry date 03/2023). In India, a Turkish language packaging was found (lot 1001701, expiry date 03/2023). According to the WHO alert, the suspect batches are all confirmed as falsified.

Montelukast

Two people were arrested for allegedly manufacturing and distributing falsified medicines across Bangladesh by imitating the logos of various well-known brands (report ID 1445496). One of the accused was arrested with large quantities of falsified Monas-10 and Pantonix-20 medicines. Later, another suspect was arrested, along with the equipment used to manufacture Monas-10 and Pantonix-20 medicines. The group was manufacturing falsified medicines under the guise of an Ayurvedic (herbal medicine) business, using the brand logos of Square Pharmaceuticals, Incepta Pharmaceuticals, Zenith Pharmaceuticals, and The Acme Laboratories. A large volume of falsified medicines was also seized from the factory.

Molnupiravir

In the Philippines, health authorities warned the public about the spread of falsified COVID-19 medicine molnupiravir after receiving reports of possible falsified versions of this antiviral medicine (report ID 1369174). Authorities also advised patients not to buy medicines from unauthorized sources.

Many witnesses in Cambodia claimed having taken falsified COVID-19 medicine because it was not in the same box or container as the government-recommended medicine (report ID 1408533). Molnatris (molnupiravir 200 mg) capsules were recommended by the Health Ministry for at-home treatment. One of the witnesses paid 75 USD for two boxes from a community pharmacy, but the medicine box was orange instead of blue (which is recommended by the ministry). Another witness paid 78 USD for a green box that was claimed to be from the USA. The ministry state that they will crack down on all pharmacies that sell falsified medicines or try to persuade customers to buy medicines that are not recommended by the government.

[22] WHO. Medical Product Alert N°9/2021: Falsified Soliris. Medical product alert. Published December 22, 2021. Accessed May 31, 2022. https://www.who.int/news/item/22-12-2021-medical-product-alert-n-9-2021-falsified-soliris

Paracetamol

Four articles reported on the sale of falsified paracetamol in multiple cities in the Philippines.

Firstly, the Valenzuela City government closed a sari-sari store (neighbourhood convenience store) after it was discovered to be selling falsified Biogesic tablets (report ID 1353688). The crackdown was prompted by reports of people having difficulty purchasing cough and cold medicines. Personnel from the city's business inspection and audit team delivered an order to close the store immediately.

Secondly, in Quezon City, a delivery rider was arrested with falsified paracetamol tablets worth more than P100,000 (approximately 1,908 USD) (report ID 1367574). The police received a complaint from a victim who developed rashes after purchasing medicine from a motorcycle rider. According to the police, the seized medications had a falsified lot number and falsified security marks. The suspect explained that he only delivered the (falsified) medicine from a supplier.

Thirdly, a business establishment in Bacolod City was arrested for allegedly selling suspected falsified paracetamol (report ID 1378479).

The fourth article reports on authorities in Laguna seizing several boxes suspected of containing falsified paracetamol (report ID 1389812). The couple selling the medicines were unable to produce documents proving their status as authorized sellers. The samples were delivered to the FDA office for analysis.

Pembrolizumab

In Mexico, the Federal Commission for the Protection against Sanitary Risks (Cofepris) issued a warning following the discovery of nine falsified batches of Keytrude (pembrolizumab) (report ID 1399152). The pharmaceutical company, Merck Sharp and Dohme Comercializadora S. de RL de CV, filed a complaint after discovering irregularities in nine batches of the Keytruda product in a 100 mg/4 mL solution presentation. Lots T009249, S035357, S012080, T021792, LT87333, LT78236, DC68976, DE68005, and VZ01380 were found to be falsified. In some cases, secondary packaging with English text was also found, which is another inconsistency that users and distributors can identify.

Remdesivir

In March, WHO issued an alert[23] for two falsified batches of DESREM Remdesivir (Injection 100mg/vial) discovered in Guatemala and India (report ID 1423472). Mylan Laboratories Ltd, the genuine manufacturer of DESREM, confirmed that the products identified in this alert are falsified. The genuine manufacturer's laboratory analysis of these falsified products revealed that they do not contain any of the stated active pharmaceutical ingredient (remdesivir). The vials may be smaller than the genuine ones, and the labels may contain multiple spelling errors as well as incorrect font styles and colours. The batch 7605854B with an expiry date of 09/2022 was found in Guatemala, while the batch CRM21001MA with an expiry date of 07/10/2022 was found in India.

[23] WHO. Medical Product Alert N°2/2022: Falsified DESREM (Remdesivir). Medical Product Alert. Published March 9, 2022. Accessed March 11, 2022. https://www.who.int/news/item/09-03-2022-medical-product-alert-n-2-2022-falsified-desrem-(remdesivir)

Rivaroxaban

In Mexico, Cofepris issued a warning after discovering three falsified batches of Xarelto (rivaroxaban), an anticoagulant (report ID 1404858). The batches BXJG6V2 and BXJG6V3 are considered falsified and adulterated if they contain 14 tablets, which is half of the number of tablets in the original medicine. The packages also present anomalies in colours and fonts. The packaging for lot 765289 contains 100 capsules; however, this presentation is not available for the original medicine.

Vitamin D

In India, the pharmaceutical company 'Madhav Pharma' was shut down after it was discovered to be selling falsified and substandard vitamin D tablets (report ID 1389697). According to an official, Macleods Pharmaceuticals filed a complaint alleging that falsified tablets bearing their company name were being sold in Delhi. Following that, officials raided the location and seized some samples. Some of them were found to be falsified and others substandard. The tablets were discovered to have originated in Agra. The investigation into the manufacturing site was still ongoing.

Tocilizumab

In India, Roche Products Pvt Ltd filed a complaint with Drugs Controller General of India (DCGI) about the distribution and sale of suspected falsified tocilizumab injections (report ID 1357205). According to Roche, their partner reported images of suspected falsified packs. Following an investigation, it was discovered that the batch details did not correspond to any genuine batch in Roche records.

Various active ingredients

Several articles reported on seizures in the Philippines of various medicines that are potentially used in the treatment of COVID-19. The first article describes how the Bureau of Customs (BOC) seized P30 million (approximately 569,400 USD) worth of falsified popular medicine brands (report ID 1357602). The falsified medicines bore the names of brands such as Biogesic (paracetamol), Neozep (phenylephrine HCl, chlorphenamine maleate, and paracetamol), Bioflu (phenylephrine HCl, chlorphenamine maleate, and paracetamol), Immunpro (vitamin C and zinc), Ivermectin, Medicol (ibuprofen), Planax (naproxen), Alaxan FR (paracetamol and ibuprofen), and others. The medicines were confirmed to be falsified by the FDA and Unilab, the manufacturer of Biogesic. They were packed in cartons with tags of Chinese characters.

A second article, reports that the Special Mayor's Reaction Team (SMaRT) in the Philippines arrested an online seller of falsified medicines (report ID 1375739). According to SMaRT, 18,000 Bioflu (phenylephrine HCl, chlorphenamine maleate, and paracetamol) tablets and a box of Neozep (phenylephrine HCl, chlorphenamine maleate, and paracetamol) tablets worth P1.1 million (approximately 18,972 USD) were recovered.

A third article reports that Philippine authorities seized falsified medicines worth PHP3.5 million (approximately 66,401 USD) during a raid (report ID 1422610). Among the confiscated items were 27,000 losartan potassium tablets, 31,500 amoxicillin trihydrate capsules, and other medications. According to the police, the suspect ran a mini drugstore in his home and also set up a distribution network

outside the region. The FDA has certified that all of the seized medicines were falsified.
The fourth article describes that during a store raid in the Philippines, two Chinese nationals were arrested for allegedly selling falsified medicines (report ID 1435936). Amoxicillin capsules and Lianhua Qingwen Jian, herbal medicine that supposedly treats COVID-19, were among the falsified medicines. The confiscated items were estimated to be worth at least P500,000 (approximately 9,464 USD).

Pakistan local officials seized suspected falsified and unregistered medicines, including falsified Tanzo 4.5gm injection (piperacillin and tazobactam) (report ID 1363284). According to an official, samples of suspected medicines were sent to the Drug Testing Laboratory for analysis.
Furthermore in Pakistan, five men were arrested for allegedly selling falsified medicines (report ID 1391738). During the raid, a huge quantity of falsified and substandard medicines was found including Aldactone tablets (spironolactone) and Inocef Injection (ceftriaxone). The Central Drug Laboratory confirmed that the seized medicines were falsified and substandard.

Unknown COVID-19 medicines

Around 14,000 fraudulent e-commerce listings and 4,000 social media posts suspected of peddling falsified medicines, including COVID-19 medicines, were removed from several websites (report ID 1430757).

B.1.5.2. Substandard COVID-19 medicines

Ivermectin

Customs seized Ivermectin medications at the New Zealand border (report ID 1443486). A suspended doctor imported ivermectin from India in order to treat COVID-19 patients. According to the Crown Research Institute ESR test, some were found to be contaminated with bacteria.

Metformin

In the USA, Nostrum Laboratories, Inc. voluntarily recalled one lot of its Metformin HCl Extended-Release tablets, USP 750 mg (report ID 1352529). The affected product is packaged in 100-tablet bottles with the NDC 29033-056-01, lot number MET200501, and expiration date July 2022.

Paracetamol

During an inspection of some medical stores in Pakistan in February 2021, drug inspectors discovered that the suspension Campol, manufactured by Syntex Phamaceuticals Attock, did not meet the prescribed standard (report ID 1352117).
The accused involved in the manufacturing and sale of the substandard medicine were arrested by the drug court in Rawalpindi.
In Nigeria, the National Agency for Food and Drug Administration and Control (NAFDAC) issued a recall and warned pharmaceuticals importers and distributors to stop selling and using Lefin Pediatric Suspension (report ID 1378693). The recall of the substandard product was initiated by M/S. Leama Chemi Pharma (PVT) Ltd., the manufacturer in Pakistan.

Plastikon Healthcare, LLC voluntarily recalled one lot of Acetaminophen 650mg/ 20.3mL and other medicines across the USA due to microbial contamination (report ID 1438852). The affected lot was 20040A with expiry of May 2022.

Various active ingredients

Three 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 trialled in the treatment for COVID-19. The reasons why the samples were defined as "Not of Standard Quality" included the failure of the assay, the failure of the dissolution test, the failure of disintegration, the failure of the identification test, failure of the sterility test, failure of the assay of methylcobalamin & vitamin D3 assay, etc.

For December 2021 (report ID 1377176), the list contained 33 medicines that were not of standard quality, including remdesivir, ivermectin, montelukast, bromelain, telmisartan, dexamethasone injection, and omeprazole.

For January 2022 (report ID 1397229), the list contained 27 medicines that were not of standard quality, including clopidogrel, enalapril, doxycycline, favipiravir, bromelain, paracetamol, vitamins, itraconazole, and hand sanitiser.

For February 2022 (report ID 1431500), the list contained 39 medicines that were not of standard quality, including enalapril, bromelain, metformin, omeprazole, paracetamol, telmisartan, atorvastatin, doxycycline, vitamins, and hand sanitiser.

B.1.5.3. Unregistered COVID-19 medicines

The US FDA sent a warning letter to various websites and companies regarding the sale of products that were claimed to mitigate, prevent, treat, diagnose, or cure COVID-19 and marketed without FDA approval.

- To the website www.ivermectin24h.com regarding ivermectin (report ID 1429442).
- To Pharmacy2Home/LandiCom Holding LTD, www.pharmacy2home.com regarding chloroquine 500 Mg (Aralen), Antiflu 75 mg (oseltamivir), CoronaVirus pack (ritonavir 50mg + lopinavir 200mg, ribavirin 200mg, oseltamivir 75mg, Ribasure (ribavirin) 200 mg, Hivus-LR (lopinavir + ritonavir 200/50 mg), and ivermectin 12mg (Covid/Corona) (report ID 1401107).
- To the website www.extrapharmacy.ru in relation to Plaquenil (hydroxychloroquine) and Areplivir (favipiravir) (report ID 1407898).
- To the website www.rxshopmd.com for Hivus-LR (lopinavir + ritonavir 200/50 mg) (report ID 1407899).

B.1.5.4. Diverted COVID-19 medicines

Ketamine

U.S. Customs and Border Protection (US CBP) in Louisville seized several illicit medicines, including 75 pounds of ketamine (report ID 1394224), while US CBP in Indianapolis 12-and-a-half pounds of ketamine (report ID 1396572).

Molnupiravir

In Mexico, Cofepris warned against the illegal marketing of molnupiravir manufactured by Merck & Co (report ID 1363858). The following presentations are being sold fraudulently:

- Merit laboratory's Mpiravir (200 mg) comes in a white box presentation with green and yellow lines. It has an expiration date of October 2023 and contains 40 capsules.
- Azista's Molaz (200 mg) comes in a white box with orange and purple lines. It contains 200 mg capsules.

Molnupiravir was discovered on the black market in Vietnam (report ID 1421477). Because molnupiravir requires a doctor's prescription, patients are turning to online sellers to obtain it illegally, with product prices ranging from VND 250,000 to VND1.2 million (Vietnamese dong, approximately 11 to 518 USD) per box.

B.1.6. Ventilation & oxygenation equipment and consumables

In February 2022, three articles discussed quality issues with ventilation & oxygenation equipment and consumables.

B.1.6.1 Substandard ventilator

In USA, Philips Respironics recalled 215 of its Trilogy Evo ventilators and 51 repair kits due to the risk of death or serious injury posed by potentially carcinogenic polyester-based polyurethane (PE-PUR) sound abatement foam included in the products (report ID 1398682). The company recalled the Trilogy Evo ventilators with model numbers DS2110X11B and KR2110X15B (not distributed in the U.S.) and repair kits for Trilogy Evo muffler assembly with part number 1135257 and lot numbers between 210414 and 210524. The devices were made and distributed in the U.S. and South Korea between April and May 2021.

Vyaire issued a notice that its Bellavista ventilators were at risk of malfunctioning due to a software update (report ID 1418955). The flaw might occur in Bellavista 1000 and 1000e series ventilators that are running at least the software version 6.0.1600.0 and have their data communication ports set to "HL7." Vyaire's corrective action calls for all healthcare facilities using the ventilators to immediately disable the HL7 port until another software update addressing the issue has been released. The company initiated a voluntary correction for the affected machines at the end of December. The correction spans nearly 4,200 ventilators that were distributed across the globe.

B.1.6.2 Diverted Ventilation & oxygenation equipment

A large number of falsified and substandard products were seized in Thailand, including medical equipment such as fingertip oximeters, temperature scanners, and oxygen generators (report ID 1400860). An investigation revealed that these products were illegally imported from China.

B.2. Reports from scientific literature

B.2.1. General

Burnett K, Martin S, Goudy C, et al. **Ensuring the quality and quantity of personal protective equipment (PPE) by enhancing the procurement process in Northern Ireland during the coronavirus disease 2019 pandemic: Challenges in the procurement process for PPE in NI.** J Patient Saf Risk Manag. 2022;27(1):49. doi:10.1177/25160435211057385

Extract: *"A process was implemented whereby the Medicines Optimisation Innovation Centre validated all pertinent essential documentation relating to products to ensure that all applicable standards were met, with the Business Services Organisation Procurement and Logistics Service completing all procurement due diligence tasks in line with both normal and coronavirus disease 2019 emergency derogations. It is evident from the data presented that whilst there were a significant number of potential options for supply, a large proportion of these were rejected due to failure to meet the quality assurance criteria. Thus, by the process that was put in place, a large number of unsuitable products were not purchased and only those that met extant standards were approved."*

Dagrou A, Chimhutu V. **I Buy Medicines From the Streets Because I Am Poor: A Qualitative Account on why the Informal Market for Medicines Thrive in Ivory Coast.** Inq A J Med Care Organ Provis Financ. 2022;59:1-10. doi:10.1177/00469580221086585

Extract: *"The informal market for medicines has been growing. In Ivory Coast, this informal market is an unofficial core part of the health system. Given the risks associated with the informal market for medicines, it is important to understand why this market continues to grow. It becomes even more important in the context of COVID-19, as a huge chunk of falsified medical products end up at the informal market. A qualitative case study design was chosen for this study, with in-depth interviews (IDIs) and focus group discussions (FGDs) being the methods for data collection. 20 IDIs and 3 FGDs were conducted. Participants in this study are sellers, buyers, and pharmaceutical experts. We found out that the informal market for medicines thrives because it is highly accessible, convenient, affordable, and that it is used for various social, cultural, and religious reasons. The study concludes that although this informal market presents a clear danger to public health, it is thriving. For authorities to address this public health challenge, there is need for a holistic and multi-pronged approach, which includes addressing health systems factors and strengthening regulatory framework."*

Masini T, Macé C, Heide L, et al. **Out of the boxes, out of the silos: The need of interdisciplinary collaboration to reduce poor-quality medical products in the supply chain.** Res. Social Adm. Pharm. 2022;18:1–5. doi.org/10.1016/J.SAPHARM.2022.03.006

Extract: *"Conclusion. The COVID-19 pandemic has increased the vulnerability of global supply chains to poor-quality medical products, but it also brought the issue under the spotlight. This may provide a favorable environment to promote interdisciplinary research collaborations for a comprehensive investigation of the roots, prevalence and features of SF medical products, aimed at suggesting general and contextualized corrective actions at regulatory, policy and societal level."*

Peepliwal AK, Narula S, Sharma R, Bonde C, Jain K. **Theoretical Blockchain Architecture Model (t-BAM) to Control Covid-19 Related Counterfeit Medical Products Across Supply Chain.** Int J Supply Oper Manag. 2021;0:xx-xx. doi:10.22034/IJSOM.2021.108656.1848

Abstract. *"Covid-19 pandemic affected millions of people across the globe. Healthcare professionals need various kind of medical product like drugs, vaccines, other biologicals, and*

diagnostic equipment to combat pandemics. Fake vendors introduced falsified medical products in national and international markets during pandemic. These counterfeit products are life threatening due to inferiority in quality and available in noncompliance of label claim. Europol confiscated 34,000 counterfeit surgical masks in just one coordinated assignment of fake goods. The data for the unauthorized medical product sell is higher than expectation during this Covid-19 pandemic. World Health Organization reported that up to $200 billion worth of counterfeit pharmaceutical products are sold globally every year. It is a challenge to track and trace counterfeit medical products because these products must pass through many complicated distribution channels which allows opportunity for counterfeit drugs to enter in supply chain. In current supply chain methods, central authorities control transacted data among parties. Multiple intermediates needed to enable activities and creating trust. In this scenario, there is chance of manipulation in data fabrication. Blockchain protects supply chain and maintain a shared source of data information. Trust enabled by cryptographic algorithms and immutability of data preserved in Blockchain. In this paper, a Theoretical Blockchain Architecture Model (t-BAM) proposed using Hyperledger Fabric as a Blockchain platform and Byzantine Fault Tolerance (BFT) Algorithm for mutual consensus in supply chain of medical products during COVID-19 pandemic. This model validated for immutability, Mutual consensus, Transparency and Accountability, Privacy and Security, Temperature and Humidity control parameters."

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

Manuel CS, Yeomans DJ, Williams JA, et al. **Presence of unsafe chemical impurities, accelerated evaporation of alcohol, and lack of key labeling requirements are risks and concerns for some alcohol-based hand sanitizers and dispenser practices during the COVID-19 pandemic.** PLoS One. 2022;17(3):e0265519. doi:10.1371/JOURNAL.PONE.0265519

Extract: *"To understand the risks associated with low quality ABHS and bulk refilling practices, we collected 77 ABHS samples sourced from community settings (restaurants, grocery stores, etc.) and 40 samples from a single school district. All samples were obtained from bulk refillable dispensers that were in use. Samples were analyzed for alcohol content, chemical impurities, aesthetic qualities, and presence of drug labeling information. Additionally, we performed laboratory-based experiments to determine the impact of dispenser design on alcohol evaporation rates. Over 70% of samples for which photos were available showed lack of essential labeling information, including missing "Drug Facts Labels". For ABHS samples acquired from community settings, nearly 14% of samples had visible impurities, and over 30% of samples had concentrations of acetal and acetaldehyde in excess of FDA interim limits. Subpotent ethanol concentrations were observed in 9.09% and 82.05% of samples from community settings and the school district, respectively, with the school district sample results being associated with dispenser misuse."*

Matatiele P, Southon B, Dabula B, Marageni T, Poongavanum P, Kgarebe B. **Assessment of quality of alcohol-based hand sanitizers used in Johannesburg area during the CoViD-19 pandemic.** Sci Reports 2022 121. 2022;12(1):1-7. doi:10.1038/s41598-022-08117-z

Abstract. *"Since the outbreak of the Coronavirus Disease 2019 (CoViD-19), the World Health Organization has recommended that, in absence of soap and water, alcohol-based hand sanitizer can be used to prevent the transmission of coronaviruses. Unfortunately, many media and anecdotal reports indicate that many alcohol-based hand sanitizers sold in South Africa are substandard and some contain potentially toxic ingredients. The study aimed to identify hand sanitizers used in the Johannesburg area during the CoViD-19 pandemic that do not contain the recommended alcohol concentration of at least 70% propanol or 60% ethanol, and contain traces of toxic ingredients. Hand sanitizers randomly collected from various traders around Johannesburg were analyzed using Agilent auto sampler coupled to a gas chromatograph utilizing flame ionisation detection. Of the 94 hand sanitizer samples*

collected, three preparations contained no alcohol, whereas the rest contained either ethanol, 2-propanol or 1-propanol or a combination of two alcohols. Of the alcohol-containing hand sanitizers, 37 (41%) contained less than 60% alcohol. Ethyl acetate, isobutanol and other non-recommended alcohols (methanol and 3-methyl-butanol) were also identified. Consumers are therefore warned that among the many brands of hand sanitizers found around Johannesburg, there are some substandard preparations and some that contain traces of toxic ingredients."

B.2.3. Additional publications from April 2022

The below articles were published after March 2022, but we include them in this report as we believe they are of interest to people reading this.

Ahmed J, Modica de Mohac L, Mackey TK, Tolulope Raimi-Abraham B. **A critical review on the availability of substandard and falsified medicines online: Incidence, challenges and perspectives The illicit trade of medicines online and falsified medicines-Review.** J Med Access. 2022;6:1-18. doi:10.1177/23992026221074548

Extract: *"the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) identified more than 34,000 falsified COVID-19 products seized worldwide in 2020.[...] With the recent COVID-19 pandemic, the pharmaceutical industry has begun investigating treatment with new and existing medications for its potential in fighting the SARS-CoV-2 virus. Criminals have also profited from this by selling SFMs through online platforms. Given the dangers this poses, not only for the treatment of COVID-19 but for other ailments too, SFMs online are a significant threat to health and well-being. As highlighted in this literature review, there are significant challenges in combating this concern. Overcoming these challenges will have positive real-world outcomes which will help safeguard patients from fake medicines, as well as prevent criminal enterprises from expanding and profiting. Changes in consumer practices, education and online safety may result from this research, which provides greater insight into the latest trends and activities in this ever-evolving area. With advances in technology, greater use of online platforms and the demand from patients to obtain medication online, this area must be addressed, and action is needed to be taken sooner than later."*

Sharma SK. **A Study on Drug Counterfeiting in the Light of COVID-19 Pandemic: Indian Scenario.** Supremo Amic. 2021;25:456-469. https://heinonline.org/HOL/Page?handle=hein.journals/supami25&id=456&div=48&collection=journals

Abstract. *"The world has been facing one of the most challenging times due to the COVID-19 pandemic. [...] the pandemic has exploded the drug market and as a result, it has attracted many globally to take it as an emerging lucrative business opportunity. The arrival of new medicines and vaccines has increased their demands many folds, and so the temptations of the looters and fraudsters, who want fast cash. The consequence of the ongoing menace is the sharp hike in counter pharmaceutical products globally. However, in the present alarming state, where the racketeers are devising innovative techniques and methods to engulf the pharma market with counterfeit products, it is imperative to realize that drug counterfeit is a serious crime and not limited to IPR Crime. It is an economic or a white-collar crime which affects the social order. Furthermore, using online portals as an interface for advertising and selling fake pharma products has brought the crime of drug counterfeiting into the ambit of cybercrime. Therefore, in this milieu, a robust mechanism is required to control and prevent the menacing pose by drug counterfeiting. This paper has attempted to study and explore the linkage or intersectional area between the economic or white-collar crime, corporate crime, IPR crime and cybercrime from the viewpoint of the multidimensional effect and consequences caused by the commission of counterfeit drugs or medicines. An attempt has*

been made to explore that up to what extent the law provided in the criminal statute book of India is effective in preventing and controlling the crime efficiently."

Ozawa S, Billings J, Sun Y, Yu S, Penley B. **COVID-19 Treatments Sold Online Without Prescription Requirements in the United States: Cross-sectional Study Evaluating Availability, Safety and Marketing of Medications.** J Med Internet Res. 2022;24(2). doi:10.2196/27704

Abstract. *"Background: The COVID-19 pandemic has increased online purchases and heightened interest in existing treatments. Dexamethasone, hydroxychloroquine, and lopinavir-ritonavir have been touted as potential COVID-19 treatments.*
Objective: This study assessed the availability of 3 potential COVID-19 treatments online and evaluated the safety and marketing characteristics of websites selling these products during the pandemic. […] Results: We found 117 websites: 30 selling dexamethasone (19/30, 63% rogue), 39 selling hydroxychloroquine (22/39, 56% rogue), and 48 selling lopinavir-ritonavir (33/48, 69% rogue). This included 89 unique online pharmacies: 70% were rogue (n=62), 22% were unapproved (n=20), and 8% were considered legitimate (n=7). Prescriptions were not required among 100% (19/19), 61% (20/33), and 50% (11/22) of rogue websites selling dexamethasone, lopinavir-ritonavir, and hydroxychloroquine, respectively. Overall, only 32% (24/74) of rogue websites required prescriptions to buy these medications compared with 94% (31/33) of unapproved and 100% (10/10) of legitimate websites (P<.001). Rogue sites rarely offered pharmacist counseling (1/33, 3% for lopinavir-ritonavir to 2/22, 9% for hydroxychloroquine). Drug warnings were unavailable in 86% (6/7) of unapproved dexamethasone sites. It was difficult to distinguish between rogue, unapproved, and legitimate online pharmacies solely based on website marketing characteristics. Illegitimate pharmacies were more likely to offer bulk discounts and claim price discounts, yet dexamethasone and hydroxychloroquine were more expensive online. An inexpensive generic version of lopinavir-ritonavir that is not authorized for use in the United States was available online offering US shipping. Some websites claimed hydroxychloroquine and lopinavir-ritonavir were effective COVID-19 treatments despite lack of scientific evidence. In comparing IP addresses to locations claimed on the websites, only 8.5% (7/82) matched their claimed locations."

B.3. Reports from international organisations

EUROPOL. **Counterfeit and pirated goods get boost from pandemic, new report confirms | Europol.** Published March 7, 2022. Accessed June 14, 2022. https://www.europol.europa.eu/media-press/newsroom/news/counterfeit-and-pirated-goods-get-boost-pandemic-new-report-confirms

Extract. *"The latest Intellectual Property Crime Threat Assessment, produced jointly between Europol and the European Union Intellectual Property Office (EUIPO), reveals that the distribution of counterfeit goods has been thriving during the COVID-19 pandemic. The health crisis has presented new opportunities for trade in counterfeit and pirated products, and criminals have adjusted their business models to the meet the new global demand. […] Counterfeit pharmaceutical products, ranging from a variety of medicines to personal protective equipment or face masks, have been increasingly identified in recent years. Distribution has shifted almost entirely from physical to online markets, raising public health concerns. These illicit products largely continue to originate from outside the EU, but they may also be produced in illegal laboratories within the EU, which are difficult to detect and can be set up with relatively few resources."*

INTERPOL. **Pharmaceutical crime: first INTERPOL-AFRIPOL front-line operation sees arrests and seizures across Africa.** Published March 2, 2022. Accessed June 14, 2022. https://www.interpol.int/en/News-and-

Events/News/2022/Pharmaceutical-crime-first-INTERPOL-AFRIPOL-front-line-operation-sees-arrests-and-seizures-across-Africa

Extract. *"A pan-African police operation jointly coordinated by INTERPOL and AFRIPOL has identified hundreds of suspects and resulted in seizures of more than 12 million illicit health products. Codenamed "Flash-IPPA" (Illicit Pharmaceutical Products in Africa), the two-month operation, which ended in December, brought together law enforcement and drug regulatory agencies from 20 African countries to dismantle the organized crime networks behind regional pharmaceutical crime. […] Frontline officers conducted inspections at roadblocks, open markets, pharmacies, warehouses and other locations suspected of producing, smuggling, storing or distributing fake pharmaceuticals. Flash-IPPA seizures at a glance: 2 million illicit anti convulsing tablets, 300 000 other epilepsy treatment tablets, 1,600 rapid COVID tests, more than 208,000 COVID-19 protection masks."*

WHO. **Medical Product Alert N°2/2022: Falsified DESREM (Remdesivir).** Medical Product Alert. Published March 9, 2022. Accessed June 14, 2022. https://www.who.int/news/item/09-03-2022-medical-product-alert-n-2-2022-falsified-desrem-(remdesivir)

Extract. *"This WHO Medical Product Alert refers to two falsified batches of DESREM Remdesivir for Injection 100mg/vial. The falsified batches have been identified in Guatemala and India and were reported to WHO in February 2022. The genuine manufacturer of DESREM, Mylan Laboratories Ltd, has confirmed that the products identified in this Alert are falsified. Laboratory analysis of these falsified products, conducted by the genuine manufacturer, established that they do not contain any of the stated active pharmaceutical ingredient (remdesivir). The vials of these falsified products may be smaller than genuine DESREM and the labels have multiple spelling errors and use the wrong font styles and colours. Although the identified batch numbers are genuine, the expiry dates listed below are falsified."*

OECD/EUIPO. **Dangerous Fakes: Trade in Counterfeit Goods That Pose Health, Safety and Environmental Risks.** OECD; 2022. doi:10.1787/117e352b-en

Extract. *[…] "The challenges related to illicit trade in pharmaceuticals became more significant with the COVID-19 pandemic, which provided criminals that run illicit trade networks with new opportunities for profits. Broken supply chains, strong demand for medicines, personal protective equipment and tests, combined with limited capacities of law enforcement officials to intercept the counterfeit products, contributed to a reshaping of the market for illicit products. Criminals clearly took advantage of the global pandemic, with enforcement authorities reporting a sharp increase in seizures of fake and substandard medicines, test kits and personal protective equipment (PPEs) as well as other medical products. In addition, recently, instances of counterfeit COVID-19 vaccines have been reported, posing a serious threat to the vaccination programmes."*

Additional publications from December 2021

WHO. **Medical Product Alert N°9/2021: Falsified Soliris.** Medical product alert. Published December 22, 2021. Accessed May 31, 2022. https://www.who.int/news/item/22-12-2021-medical-product-alert-n-9-2021-falsified-soliris

Extract: *"This WHO Medical Product Alert refers to several batches of falsified Soliris (eculizumab) identified in Argentina, Estonia, India and Uruguay and reported to WHO between November and December 2021. The genuine manufacturer of Soliris, has confirmed that the products listed in this alert are falsified. The falsified products were reported at patient level and regulated supply chains in the above-mentioned countries."*

B.4. Reports – Miscellaneous

Authority HPR. **Over 1.6 million units of illegal medicines detained by HPRA.** Med - News Events. Published online 2022:1. https://www.hpra.ie/homepage/medicines/news-events/item?t=/over-1.6-million-units-of-illegal-medicines-detained-by-hpra&id=612b1126-9782-6eee-9b55-ff00008c97d0

> Extract: *"The Health Products Regulatory Authority (HPRA) today stated that the volume of detained illegal medicines in 2021 remained at a near record high, with its enforcement section detaining 1,604,589 million dosage units of falsified and other illegal products in 2021. Announcing its annual detention figures, the HPRA once again stressed the health dangers associated with sourcing prescription medicines online and advised the general public to only seek medicines from authorised sources. The HPRA states that the online supply of prescription products into and within Ireland is illegal and stresses that consumers can have no guarantee of the safety or quality of medicines they are seeking to buy outside of the regulated pharmacy supply chain. In the 12 months of 2021, the most significant categories of illegal products detained included sedatives (46%), anabolic steroids (13%), analgesics (10%) and erectile dysfunction medicines (6%)."*

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.[24]

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.

[24]Infectious Diseases Data Observatory. Medical Product Quality Reports. Medical Product Quality Reports. Published 2020. Accessed January 24, 2022. 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 1ste 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[25]**
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

[25] 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=rn&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. 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 Annexs C.1 to C.6 or they are available on the online MQM Globe[26], when introducing "reportID:XXXXXXX" in the search box.

Annex C.1. Vaccines

Annex C.2. COVID-19 diagnostics

Annex C.3. Personal Protective Equipment

Annex C.4. Sanitisers & disinfectants

Annex C.5. COVID-19 medicines

Annex C.6. Ventilation & oxygenation equipment and consumables

[26]Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe. Web Page. Published 2020. Accessed January 24, 2022. https://www.iddo.org/medicine-quality-monitoring-globe

Annex C

C.1. Vaccines

Medicine Quality Monitoring Globe

September 7, 2022

This is a summary of the information available in the Medicine Quality Monitoring Globe for the search terms selected between the dates selected. For more information on the terminology used, caveats and the work of the medicine quality group please see the information at: https://www.iddo.org/medicine-quality

Non-Curated reports are those that have been automatically flagged as relevant by the system but have not been manually curated by the curators.

We would be grateful for any feedback on this summary and for the details of any reports that we may have missed.

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Filters applied for this report

Search ((”AZD1222” OR ”Tế bào Vero” OR ”BNT162b2” OR ”BBIBP-CorV” OR ”Sputnik V” OR ”Ad26.COV2.S” OR ”mRNA-1273” OR ”CoronaVac” OR ”EpiVacCorona” OR ”Covishield” OR ”Ad5-nCoV” OR ”Covaxin”) OR ((”vắc-xin” OR ”vaccine”) AND (”BioNTech” OR ”Johnson & Johnson” OR ”Pfizer” OR ”Oxford/AstraZeneca” OR ”Sinopharm” OR ”Sinovac” OR ”Gamaleya” OR ”Moderna” OR ”Pfizer/BioNTech” OR ”CanSino” OR ”AstraZeneca” OR ”Viện huyết thanh Ấn Độ” OR ”Oxford”)) OR ((”vắc-xin” OR ”vaccine”) AND (”COVID-19” OR ”SARS-CoV-2” OR ”Coronavirus” OR ”SARS” OR ”CoV-2” OR ”vi rút corona”))) OR ((”BNT162b2” OR ”BBIBP-CorV” OR ”Ad26.COV2.S” OR ”CoronaVac” OR ”Covishield” OR ”Ad5-nCoV” OR ”AZD1222” OR ”FBRI” OR ”Sputnik V” OR ”mRNA-1273” OR ”EpiVacCorona” OR ”Vero Cells” OR ”Covaxin”) OR ((”vaccine”) AND (”Barat Biotech” OR ”BioNTech” OR ”Johnson & Johnson” OR ”Pfizer” OR ”Oxford/AstraZeneca” OR ”Serum Institute of India” OR ”Sinopharm” OR ”Sinovac” OR ”Gamaleya” OR ”Moderna” OR ”Pfizer/BioNTech” OR ”CanSino” OR ”AstraZeneca” OR ”Oxford”)) OR ((”vaccine”) AND (”COVID-19” OR ”COVID” OR ”SARS-CoV-2” OR ”Coronavirus” OR ”CV19” OR ”CV-19” OR ”SARS” OR ”CoV-2”))) OR ((”AZD1222” OR ”BNT162b2” OR ”BBIBP-CorV” OR ”Ad26.COV2.S” OR ”mRNA-1273” OR ”Spoutnik V” OR ”CoronaVac” OR ”EpiVacCorona” OR ”Covishield” OR ”Ad5-nCoV” OR ”Covaxin” OR ”Cellules Vero”) OR ((”Vaccin”) AND (”Gamaleïa” OR ”BioNTech” OR ”Johnson & Johnson” OR ”Pfizer” OR ”Oxford/AstraZeneca” OR ”Bharat Biotech” OR ”Sinopharm” OR ”Sinovac” OR ”Gamaleya” OR ”Moderna” OR ”Pfizer/BioNTech” OR ”CanSino” OR ”AstraZeneca” OR ”Oxford”)) OR ((”Vaccin”) AND (”COVID-19” OR ”COVID” OR ”SARS-CoV-2” OR ”Coronavirus” OR ”SRAS” OR ”CoV-2”))) OR ((”AZD1222” OR ”BNT162b2” OR ”FBRI” OR ”BBIBP-CorV” OR ”sputnik v” OR ”Células Vero” OR ”Ad26.COV2.S” OR ”mRNA-1273” OR ”CoronaVac” OR ”EpiVacCorona” OR ”Covishield” OR ”Covaxin”) OR ((”vacuna”) AND (”Barat Biotech” OR ”BioNTech” OR ”Johnson & Johnson” OR ”Pfizer” OR ”Oxford/AstraZeneca” OR ”Sinopharm” OR ”Sinovac” OR ”Gamaleya” OR ”Moderna” OR ”Pfizer/BioNTech” OR ”CanSino” OR ”AstraZeneca” OR ”Oxford” OR ”Instituto Suero de India”)) OR ((”vacuna”) AND (”COVID-19” OR ”COVID” OR ”SARS-CoV-2” OR ”Coronavirus” OR ”CV19” OR ”CV-19” OR ”SRAS” OR ”CoV-2”))) OR ({(”BNT162b2” OR ”BBIBP-CorV” OR ”Ad26.COV2.S” OR ”克尔来福” OR ”重组新型冠状病毒疫苗” OR ”Covishield” OR ”vero 细胞” OR ”AZD1222” OR ”FBRI” OR ”卫星-V” OR ”mRNA-1273” OR ”非洲绿猴肾细胞” OR ”Covaxin”) OR ((”疫苗”) AND (”牛津/阿斯利康” OR ”Barat Biotech” OR ”辉瑞” OR ”牛津” OR ”拜恩泰科” OR ”阿斯利康” OR ”北京科兴生物制品有限公司” OR ”科兴生物” OR ”强生” OR ”中国医药集团” OR ”辉瑞/拜恩泰科” OR ”印度血清研究所” OR ”Gamaleya” OR ”Moderna” OR ”国药” OR ”康希诺生物”)) OR ((”疫苗”) AND (”新冠病毒” OR ”武汉新型冠状病毒” OR ”非典” OR ”SARS” OR ”CoV-2” OR ”武汉肺炎” OR ”新冠疫情” OR ”COVID” OR ”COVID-19” OR ”新型冠状病毒肺炎” OR ”SARS-CoV-2” OR ”新型冠状病毒” OR ”新冠”))})

Start date 2022-01-01

End date 2022-03-31

Language

Report type incident

Curation status validated

Number of Reports 7

1 Rwanda: 8 health workers arrested for stealing COVID-19 vaccines, test kits

Publication date	2022-01-20
Create date	2022-01-24
Score	151.99
Report id	1370792
Category	Vaccine, Medical device for screening/diagnosis/monitoring
Quality	Diverted/Unregistered
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Rwanda: 8 health workers arrested for stealing COVID-19 vaccines, test kits Down To Earth Magazine

Click here to see the Original Article

Table 1: Places for report 1370792

Region Name	Country	Location	Latitude	Longitude
Eastern Africa	Rwanda	Republic of Rwanda	-2	30

Table 2: Drugs for report 1370792

Medicine Name	Medicine Class	Action	ATC Code
			J07

Notes: Five men and three women health workers were arrested in Rwanda from January 4-8, 2022, the Rwanda Investigation Bureau (RIB) announced. The accused allegedly misused COVID-19 vaccines and stole testing kits. [...] Four of the suspects failed to justify the whereabouts of 30 vials of vaccines by AstraZeneca plc and 45 vials of vaccines by Moderna Inc, containing 300 and 675 doses of the respective candidates. [...] The others stole over 1,250 COVID-19 testing kits worth Rwf 6.125 million ($6,000). [...]

2 Officials Seize Large Cache of Fake COVID Vaccines, Drugs, Test Kits in Varanasi – The Wire Science

Publication date 2022-02-03

Create date 2022-05-11

Score 93.56

Report id 1390161

Category Vaccine, Antiviral others, Medical device for screening/diagnosis/monitoring

Quality Falsified

Source Clandestine laboratory

Curation Manually curated

Incident or General Incident

Snippet: Officials Seize Large Cache of Fake COVID Vaccines, Drugs, Test Kits in Varanasi – The Wire Science The Wire Science

Click here to see the Original Article

Table 3: Places for report 1390161

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Varanasi	25.31668	83.01041
Southern Asia	India	Uttar Pradesh	27.25	80.75
Southern Asia	India	Delhi	28.65195	77.23149

Table 4: Drugs for report 1390161

Medicine Name	Medicine Class	Action	ATC Code
			J07
remdesivir	Nucleosides and nucleotides excl. reverse transcriptase inhibitors	direct acting antivirals	J05AB16

Table 5: Other Stories

ID	Title	Link
1388119	Manufacture of fake corona vaccine stirred up the country, STF confiscated fake goods worth crores	Link

Table 5: Other Stories(continued)

ID	Title	Link
1388191	Uttar Pradesh: Fake Covid vaccine manufacturing unit busted in Varanasi	Link
1388268	5 Arrested By UP STF For Supplying Fake Vaccines, Testing Kits	Link
1388316	Gang making fake Covid vaccines, testing kits busted in Varanasi, 5 held	Link
1388953	Varanasi: Fake vaccine racket busted, 5 arrested	Link
1389061	Fake vaccine unit unearthed in Uttar Pradesh, 5 held	Link
1389177	Be careful! Millions of people have got fake corona vaccine	Link
1389213	Uttar Pradesh: Fake Covid-19 vaccines and testing kits worth Rs 4 crore. seized , 5 arrested	Link
1389245	Uttar Pradesh: Fake Covid-19 vaccines, testing kits worth Rs 4 crore seized, 5 arrested - 2022-02-03	Link
1390198	Fake vaccine racket busted in Varanasi; UP Police arrests five	Link
1391998	Varanasi: Fake COVID-19 vaccines, testing kits confiscated - Goa Chronicle	Link

Notes: In a raid conducted on February 2, the Uttar Pradesh Food and Drug Administration (FDA) has secured a large tranche of spurious COVID-19 vaccines, drugs and rapid antigen test kits from Varanasi. [...] Officials also seized as many as 10,800 kits of 'Standard Q Covid-19 Ag SD BIOSENSOR Rapid Test Kits'. In normal course, the kits are manufactured by SD Biosensor Healthcare Pvt. Ltd., a Gurugram-based company. The seized materials had fake batch numbers and fake expiry dates.

To make these kits, the accused used pregnancy strips. The COVID-19 rapid antigen test kits look similar to pregnancy kits; both are strip-based tests. According to FDA officials, the accused would procure pregnancy kits from the market and simply paste a wrapper of the antigen kit on it. The production cost was Rs 50 per kit but the accused sold it at Rs 500. Officials also recovered 880 vials (2 ml each) of Zydus Cadila's COVID-19 vaccine, ZyCoV-D. Note that Zydus Cadila had initiated its supply of this vaccine to the Centre only on February 2, and that the Centre had planned to begin administering it in Bihar. Yet the spurious doses had already been available in Varanasi. To make the spurious COVID-19 vaccine vials, the accused would fill empty vials with distilled water and slap the company's (Cadila's) wrapper on it. Doing this cost Rs 25 but the selling price was Rs 300.

The drug administration team also recovered 6,000 vials "filled with transparent fluid meant for packing as Covishield with green cap". The accused were allegedly selling the spurious vaccines mostly to private hospitals in the city. They also recovered 1,550 vials of spurious (injectable) remdesivir vials. According to information shared by the raiding team, the accused would fill water mixed with Glucon-D in an empty vial and paste a fake wrapper around it. The manufacturing cost of one such vial would be Rs 100 – and the selling price, Rs 3,000. [...] In all, according to the STF's statement, the police and the FDA officials had together seized four sealing machines, two cartons of empty vials, blue and green sealing caps (for ZyCoV-D and Covishield, respectively), and many fake wrappers. [...]

3 Health worker arrested in fake COVID jabs for cash case - English

Publication date	2022-03-18
Create date	2022-03-22
Score	78.66
Report id	1432612
Category	Vaccine
Quality	Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Health worker arrested in fake COVID jabs for cash case - English Agenzia ANSA

Click here to see the Original Article

Table 6: Places for report 1432612

Region Name	Country	Location	Latitude	Longitude
Europe	Italy	Naples	40.85216	14.26811

Table 7: Drugs for report 1432612

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 8: Other Stories

ID	Title	Link
1474421	Singapore Doctor Caught Injecting Saline Solution Instead Of Covid Vaccine	Link

Notes: A health worker was arrested Friday on suspicion of giving fake COVID-19 jabs for cash in Naples. The woman was arrested by NAS health police. She is accused of charging 150 euros a shot for bogus coronavirus vaccine doses in the Capodimonte COVID hub in the southern port city. (ANSA).

4 T&T on alert as fake COVID-19 vaccine pills seized abroad | Loop Trinidad & Tobago

Publication date	2022-03-24
Create date	2022-03-29
Score	68.98
Report id	1438727
Category	Other
Quality	Falsified
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: T&T on alert as fake COVID-19 vaccine pills seized abroad | Loop Trinidad & Tobago Loop News Trinidad & Tobago

Click here to see the Original Article

Table 9: Places for report 1438727

Region Name	Country	Location	Latitude	Longitude
Europe	Ireland	Ireland	53	-8
Americas	Trinidad and Tobago	Republic of Trinidad and Tobago	11	-61
Online	Online	Online	0	0

Table 10: Other Stories

ID	Title	Link
1439932	Ministry warns public against bogus Pfizer vaccine tablets	Link
1439989	MOH warns public about fake COVID-19 vaccine tablets	Link

Notes: The Ministry of Health has alerted the public to counterfeit COVID-19 Prophylactics/ Pfizer Vaccine tablets following a seizure in Ireland. In an advisory today, the Ministry said it was advised of the threat to public health by the Trinidad and Tobago Police Service. It noted that these pills are being touted on several websites and online spaces as a cure/prevention to the COVID-19 virus, but Pfizer does not produce any such tablets. Further, the Ministry said

the tablets have been found to contain sugar and no active ingredient. The Ministry warned that people who take this medication may falsely believe they are protected from COVID-19. In this respect, it said any tablets labelled "Pfizer Vaccine" should be considered as counterfeit. [...]

5 Teacher arrested for giving COVID-19 vaccine to teen

Publication date	2022-01-04
Create date	2022-01-06
Score	62.08
Report id	1349246
Category	Vaccine
Quality	Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Teacher arrested for giving COVID-19 vaccine to teen WKMG News 6 & ClickOrlando

Click here to see the Original Article

Table 11: Places for report 1349246

Region Name	Country	Location	Latitude	Longitude
Americas	United States	New York City	40.71427	-74.00597

Table 12: Other Stories

ID	Title	Link
1352228	US Teacher Accused of Administering Adult Covid Vaccine to 17-year-old	Link
1352415	School science teacher arrested for giving boy, 17, a Covid vaccine	Link

Notes: A New York biology teacher, with no medical qualifications, is coming under fire for allegedly administering a COVID-19 vaccine to a teenage boy, at her home, without permission from the teen's parents. [...] Dr. Audie Liametz of NYU Langone explains a vial could be COVID counterfeit. [...]

6 Doctor linked to Healing the Divide group suspended, accused of giving patients saline solution instead of COVID-19 vaccine

Publication date	2022-03-28
Create date	2022-05-10
Score	61.05
Report id	1441852
Category	Vaccine
Quality	Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Doctor linked to Healing the Divide group suspended, accused of giving patients saline solution instead of COVID-19 vaccine CNA

Click here to see the Original Article

Table 13: Places for report 1441852

Region Name	Country	Location	Latitude	Longitude
Southern Asia	Singapore	Singapore	1.36667	103.8

Table 14: Other Stories

ID	Title	Link
1442468	Singapore suspends doctor for injecting patients with saline solutions in place of Covid vaccine	Link
1442477	Singapore Doctor Caught Injecting Saline Solution Instead Of Covid Vaccine	Link
1443663	Saline Solution instead of COVID-19 Vaccine Singapore doctor booked for fraud	Link
1450512	Singapore Suspends Doctor for Injecting Patients with Saline Solutions in Place of Covid Vaccine	Link
1450648	Doctor Caught Injecting Saline Solution Instead Of Covid Vaccine in Singapore, Suspended	Link
1455510	GP suspended for administering fake Covid-19 jabs allegedly charged between $1000 and $1500 a dose	Link

Table 14: Other Stories(continued)

ID	Title	Link
1455724	Suspended doctor linked to Healing the Divide group allegedly charged up to S$1500 for fake COVID-19 jabs	Link
1456229	Jipson Quah suspended 18 months for allegedly charging up to $1,500 for fake COVID jabs	Link
1456538	Jipson Quah suspended 18 months for allegedly charging up to $1500 for fake COVID jabs	Link
1456595	Dr Jipson Quah Gets 18-Month Suspension For Giving Fake Covid-19 Jabs & Allowing Remote Tests	Link

Notes: A doctor linked to the Healing the Divide group has been suspended after being accused of injecting patients with saline solution instead of a COVID-19 vaccine and uploading false vaccination statuses to the Ministry of Health's (MOH) National Immunisation Registry. [...] Among other things, it was alleged that Quah had administered saline solution instead of a COVID-19 vaccine to patients and that he uploaded false vaccination statuses to the MOH's National Immunisation Registry to record that these patients have been vaccinated against the disease. [...] Additional information: ID 1455510 (https://www.straitstimes.com/singapore/health/doctor-suspended-for-administering-fake-covid-19-jabs-allegedly-charged-between-1000-and-1500-a-dose): General practitioner Jipson Quah, who has been suspended for administering fake Covid-19 jabs to some 15 patients, allegedly charged at least three people between $1,000 and $1,500 per dose. [...]

7 Crackdown on falsified meds in Africa nets 12m illegal products - 2022-03-06

Publication date 2022-03-06

Create date 2022-03-09

Score 55.65

Report id 1420044

Category Other, Erectile dysfunction medicine, Antiepileptic, Medical devices for disease prevention, Anti-inflammatory medicine, Vaccine, Medical device for screening/diagnosis/monitoring, Antibiotic, Analgesic

Quality Diverted/Unregistered

Source Private pharmacy

Curation Manually curated

Incident or General Incident

Snippet: Seizures included 2m anticonvulsant medicines, 300,000 other epilepsy drugs, 208,000 masks and 1,600 rapid COVID tests.

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Table 15: Places for report 1420044

Region Name	Country	Location	Latitude	Longitude
		Africa	7.1881	21.09375

Table 16: Drugs for report 1420044

Medicine Name	Medicine Class	Action	ATC Code
	Antibiotics	intestinal antiinfectives	A07AA
	Antibiotics	agents for treatment of hemorrhoids and anal fissures for topical use	C05AB
	Antibiotics	antifungals for topical use	D01AA
	Antibiotics	antiinfectives and antiseptics, excl. combinations with corticosteroids	G01AA
	Antibiotics	antimycotics for systemic use	J02AA

Table 16: Drugs for report 1420044(continued)

Medicine Name	Medicine Class	Action	ATC Code
	Antibiotics	drugs for treatment of tuberculosis	J04AB
	Antibiotics	throat preparations	R02AB
	Antibiotics	antiinfectives	S01AA
			J07
			N02

Table 17: Other Stories

ID	Title	Link
1420050	Crackdown on falsified meds in Africa nets 12m illegal products	Link
1426178	Zimbabwe: ZRP, Interpol Operation Nets 2 000 - AllAfrica	Link
1438597	ZRP, Interpol operation nets 2 000	Link

Notes: A pan-African enforcement operation has identified hundreds of suspects and resulted in seizures of more than 12 million illicit health products, including epilepsy medicines. [...] Inspections were carried out at roadblocks, open markets, pharmacies, warehouses and other locations suspected of producing, smuggling, storing or distributing fake pharmaceuticals, with notables seizures including 2 million anticonvulsant medicines, 300,000 other epilepsy drugs, more than 208,000 COVID-19 protection masks and 1,600 rapid COVID tests. Other commonly seized illicit medicines included antibiotics, anti-inflammatories, analgesics and medication used to correct erectile dysfunction, rheumatism and epilepsy, said Interpol. [...] West African operations revealed the use of counterfeit COVID-19 vaccination certificates in several countries, whilst East African operations saw the use of unregulated and unlawful distribution and sale of genuine COVID-19 vaccines. [...]

Annex C

C.2. COVID-19 diagnostics

Medicine Quality Monitoring Globe

September 7, 2022

This is a summary of the information available in the Medicine Quality Monitoring Globe for the search terms selected between the dates selected. For more information on the terminology used, caveats and the work of the medicine quality group please see the information at: https://www.iddo.org/medicine-quality

Non-Curated reports are those that have been automatically flagged as relevant by the system but have not been manually curated by the curators.

We would be grateful for any feedback on this summary and for the details of any reports that we may have missed.

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Filters applied for this report

Search	(”Thermometer” OR ((”coronavirus kit” OR ”RDT” OR ”covid test” OR ”lateral flow assay” OR ”test kit” OR ”LFA” OR ”COVID kit” OR ”Medical device for screening/diagnosis/monitoring” OR ”rapid diagnostic test” OR ”coronavirus test” OR ”antigen test” OR ”COVID-19 test” OR ”test cassette” OR ”In-vitro-diagnostic” OR ”cassette test” OR ”RT-PCR” OR ”IVD” OR ”testing kit” OR ”qPCR” OR ”antibody test” OR ”COVID-19 kit” OR ”PCR” OR ”polymerase chain reaction” OR ”ELISA”) AND (”COVID-19” OR ”COVID” OR ”SARS-CoV-2” OR ”Coronavirus” OR ”CV19” OR ”CV-19” OR ”SARS” OR ”CoV-2”)))
Start date	2022-01-01
End date	2022-03-31
Language	en
Report type	incident
Curation status	validated
Number of Reports	13

1 Do Not Use E25Bio COVID-19 Tests: FDA Safety Communication | FDA

Publication date	2022-02-04
Create date	2022-03-01
Score	84.31
Report id	1412835
Category	Medical device for screening/diagnosis/monitoring
Quality	Diverted/Unregistered
Source	Not applicable
Curation	Manually curated
Incident or General	Incident

Snippet: Do Not Use E25Bio COVID-19 Tests: FDA Safety Communication | FDA FDA.gov COVID Test Recall 2022: Which At-Home Tests Does FDA Recommend Using? Newsweek At-Home COVID-19 Test Recall List | Health.com Health.com FDA warns against E25Bio COVID-19 tests Boston 25 News View Full Coverage on Google News

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Table 1: Places for report 1412835

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5

Table 2: Other Stories

ID	Title	Link
1432341	E25Bio Recalls COVID-19 Tests Not Authorized by the FDA	Link

Notes: The U.S. Food and Drug Administration (FDA) is warning people not to use the E25Bio COVID-19 Direct Antigen Rapid Test. This test has not been authorized, cleared, or approved by the FDA for distribution or use in the United States, and it may include false labeling representing that the test is authorized by the FDA. The E25Bio COVID-19 Direct Antigen Rapid Test may also be sold under the trade name E25Bio SARS-CoV-2 Antigen Test Kit.

The FDA is concerned about the risk of false results when using this test because E25Bio has not provided the FDA with adequate data demonstrating that the test's performance is accurate. In addition, the FDA is aware that the E25Bio COVID-19 Direct Antigen Rapid Test

was sold directly to consumers and may have been accompanied by labeling with instructions for collecting a sample from deep inside the nose, reaching the back of the throat (nasopharyngeal) or from the middle part of the throat (pharynx) just beyond the mouth (oropharyngeal). Self-collecting nasopharyngeal or oropharyngeal samples for SARS-CoV-2 testing could result in serious injury when this is not done by trained professionals. [...]

2 Genrui antigen tests: HPRA and company to investigate after multiple reports of false positives

Publication date	2022-01-04
Create date	2022-05-18
Score	61.74
Report id	1364915
Category	Medical device for screening/diagnosis/monitoring
Quality	Substandard
Source	Private pharmacy
Curation	Manually curated
Incident or General	Incident

Snippet: Genrui antigen tests: HPRA and company to investigate after multiple reports of false positives TheJournal.ie

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Table 3: Places for report 1364915

Region Name	Country	Location	Latitude	Longitude
Europe	Ireland	Ireland	53	-8
Europe	Germany	Federal Republic of Germany	51.5	10.5

Table 4: Other Stories

ID	Title	Link
1365949	Genrui antigen tests pulled from sale amid reports of false positives	Link
1366997	HPRA calls for removal of popular antigen tests from shelves as investigation launched into false positives	Link
1367942	Some Genrui antigent tests recalled from shelves over false positives	Link
1374234	Regulator advises removal of Genrui antigen tests from shelves	Link
1395630	Some Genrui antigen tests recalled from shelves over false positives	Link

Notes: THE HEALTH PRODUCTS Regulatory Authority (HPRA) and a pharmaceutical company which makes antigen tests are to investigate after a number of complaints were made about apparent false positives. The HPRA has received a number of complaints about the Genrui SARS-CoV-2 Rapid Antigen Test, which is sold in a number of Irish shops and pharmacies, returning false positives. [...] Similar issues have been reported in other countries. Authorities in Hamburg in Germany issued a warning about the Genrui tests in December – saying that if a faint line appears to detect the presence of Covid-19, the person should do a second antigen test from a different brand.

Genrui's tests have a CE marking, meaning they have been approved for use in the EU. The company is based in China but sells products in over 120 countries worldwide. [...] Additional Information: ID 1365949 (https://www.irishexaminer.com/news/arid-40779093.html): The Health Products Regulatory Authority (HPRA) has advised the removal of the Genrui brand of antigen tests from shelves following widespread reports of false-positive results. The regulator received over 550 complaints from consumers in recent days that they had received false-positive results from the Genrui SARS-CoV-2 Rapid Antigen Test. The HPRA said retailers should remove the tests from sale on a voluntary basis pending further investigation. [...]

3 NBI nabs 4 covid test kit sellers| SUNSTAR

Publication date	2022-01-28
Create date	2022-02-02
Score	58.29
Report id	1383728
Category	Medical device for screening/diagnosis/monitoring
Quality	Diverted/Unregistered
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: NBI nabs 4 covid test kit sellers| SUNSTAR Sun.Star

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Table 5: Places for report 1383728

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Philippines	Cebu City	10.31672	123.89071
South-Eastern Asia	Philippines	Mandaue City	10.32361	123.92222

Notes: FOUR online sellers in the cities of Cebu and Mandaue have been arrested for allegedly selling unregistered and adulterated Covid-19 Rapid Antigen test kits. [...] According to NBI 7 Director Rennan Augustus Oliva, the sellers had no authority and license to sell, distribute, or trade any Covid-19 Rapid Antigen test kits.

Apart from that, the test kits which they openly sold online were neither FDA registered and authorized to be sold, traded and distributed for public use, administration, or consumption. [...] Confiscated from the subjects were around 200 boxes of test kits with an estimated value of P1 million, which will serve as evidence in the prosecution of the sellers. [...]

4 FDA Recalls 200,000 Unauthorized Flowflex COVID Rapid Tests

Publication date	2022-01-14
Create date	2022-01-17
Score	57.51
Report id	1362816
Category	Medical device for screening/diagnosis/monitoring
Quality	Diverted/Unregistered
Source	Distributor/Wholesaler
Curation	Manually curated
Incident or General	Incident

Snippet: FDA Recalls 200,000 Unauthorized Flowflex COVID Rapid Tests NBC New York

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Table 6: Places for report 1362816

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5

Table 7: Other Stories

ID	Title	Link
1360490	US shopping channel slammed by news anchor for selling Covid test	Link
1368100	No, Nevada didn't order recalled COVID-19 tests - KLAS	Link
1425659	ACON Laboratories Issues a Recall of Non-EUA Authorized "Flowflex™ SARS-CoV-2 Antigen Rapid Test (Self-Testing)" Tests From the U.S. Market - 2022-03-11	Link
1425705	ACON Laboratories Issues a Recall of Non-EUA Authorized "Flowflex™ SARS-CoV-2 Antigen Rapid Test (Self-Testing)" Tests From the U.S. Market	Link
1426949	A company says a counterfeit version of its COVID home test kit is on the U.S. market	Link
1427596	Company recalls unauthorized COVID-19 tests	Link
1428063	COVID-19 antigen test recalled after officials say it was counterfeit, not FDA approved	Link

Table 7: Other Stories(continued)

ID	Title	Link
1428329	ACON Laboratories recalls non-authorized COVID-19 tests	Link
1429609	A company says its COVID home test kit has been counterfeited	Link
1433370	Do Not Use Certain ACON Flowflex COVID-19 Tests	Link
1457606	FDA Warns Against Some COVID Tests From Popular Brand Flowflex	Link
1459090	Nevada COVID-19 Antigen home tests not part of FDA recall	Link

Notes: A common rapid at-home COVID test has become the subject of a recent product recall over concerns the antigen test hasn't received proper U.S. authorization.

The Food and Drug Administration issued a recall late last month for "Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)," a product sold at an unknown number of pharmacies and distributed by local health officials. The easy-to-use at-home test has been approved in European and other markets, but did not receive the required emergency use authorization by the FDA.

The recall of the test, which the government estimates has 200,000 in U.S. circulation, may confuse consumers between two Flowflex branded antigen tests. [...]

5 NDRA hunt of fake COVID test kit importer

Publication date	2022-02-23
Create date	2022-02-28
Score	55.66
Report id	1409609
Category	Medical device for screening/diagnosis/monitoring
Quality	Falsified
Source	Unspecified outlet
Curation	Manually curated
Incident or General	Incident

Snippet: NDRA hunt of fake COVID test kit importer Newsfirst.lk

Click here to see the Original Article

Table 8: Places for report 1409609

Region Name	Country	Location	Latitude	Longitude
Southern Asia	Sri Lanka	Democratic Socialist Republic of Sri Lanka	7.75	80.75

Notes: The National Drug Regulatory Authority (NDRA) has launched a special investigation to located a perspn who imported a stock of fake COVID-19 test kits and distributed them to Hospitals and Laboratories.
The Chief Food and Drug Inspector of NDRA, Amit Perera said the separate suspect was recently arrested for distributing a stock of counterfeit COVID-19 test kits worth over Rs. 2 million brought into the Country.

6 BOC seizes P150M worth of fake COVID test kits, goods

Publication date 2022-01-23

Create date 2022-01-24

Score 55.52

Report id 1377074

Category Medical devices for disease prevention, Herbal medicine, Medical device for screening/diagnosis/monitoring

Quality Falsified

Source Unlicensed outlets

Curation Manually curated

Incident or General Incident

Snippet: BOC seizes P150M worth of fake COVID test kits, goods Manila Bulletin

Click here to see the Original Article

Table 9: Places for report 1377074

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Philippines	Manila	14.6042	120.9822

Table 10: Other Stories

ID	Title	Link
1377884	P150 million fake COVID-19 test kits, drugs seized	Link
1378348	P150-M fake antigen test kits, medicines seized from Chinese national	Link
1378696	P150M worth of fake Covid test kits, medicines seized| SUNSTAR	Link
1378946	P150 million worth of fake COVID-19 test kits, meds seized; warehouse owner arrested	Link
1379359	Bureau of Customs seizes fake Covid test kits, medicines worth P150M| SUNSTAR	Link
1380996	PNP intensifies crackdown vs fake COVID-19 test kits, other medical supplies - UNTV News	Link
1383666	Bureau of Customs seizes fake Covid test kits, medicines worth P150M	Link
1385925	P150M worth of fake COVID test kits, other medical products seized	Link

Notes: Operatives of the Bureau of Customs (BOC) confiscated some P150-million worth of fake COVID-19 antigen test kits, face masks, medicines as well as counterfeit products during a raid in a warehouse on Friday, Jan. 21 in a warehouse in Manila. [...] During the inspection, authorities found thousands of Clungene COVID-19 antigen test kits, counterfeit Chinese herbal medicines LianHua and fake 3M N95 face masks. They also found counterfeit Nike, Fila, Converse, Adidas, Louis Vuitton and Gucci bags, wallets, phone accessories, and others. [...]

7 FDA Issues Warning for LuSys Labs COVID Tests, Citing 'High Risk of False Results'

Publication date	2022-01-11
Create date	2022-01-17
Score	52.61
Report id	1358463
Category	Medical device for screening/diagnosis/monitoring
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: FDA Issues Warning for LuSys Labs COVID Tests, Citing 'High Risk of False Results' Newsweek

Click here to see the Original Article

Table 11: Places for report 1358463

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5

Table 12: Other Stories

ID	Title	Link
1359852	FDA: Stop using LuSys Laboratories COVID-19 tests due to potential false results	Link
1381179	Stop Using LuSys Laboratories COVID-19 Tests: FDA Safety Communication | FDA	Link
1387373	FDA warns this brand of at-home Covid test may give false results	Link
1396733	Stop Using These At-Home COVID-19 Antigen Tests, FDA Warns	Link
1398331	Don't use this at-home COVID test, FDA warns. It could give you a false positive	Link
1421939	Lusys Laboratories, Inc. - Center for Devices and Radiological Health - Adulterated and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19) - 2022-03-08	Link

Table 12: Other Stories(continued)

ID	Title	Link
1429386	Recall alert: FDA announces recall of 3 COVID-19 tests	Link
1429452	3 COVID-19 tests recalled after FDA warns about 'high risk' of false results	Link
1429467	Don't use these 3 unauthorized COVID tests, FDA warns. You might get a false result	Link
1429501	FDA slaps LuSys Labs with Class I label for recall of antibody, antigen COVID tests	Link
1440850	Stop Using LuSys Laboratories COVID-19 Tests: FDA Safety Communication | FDA	Link
1579875	FDA slaps LuSys Labs with Class I label for recall of antibody, antigen COVID tests	Link

Notes: The U.S. Food and Drug Administration (FDA) issued a warning Tuesday, urging consumers and health care providers to stop using the LuSys Laboratories Antigen Test (Nasal/ Saliva) and COVID-19 IgG/IGM Antibody Test. The agency "believes there is a high risk of false results when using these tests." [...] Additionally, the FDA says the tests may be sold under a variety of names such as Luscient Diagnostics, Vivera Pharmaceuticals or EagleDX. The FDA said it "believes that those tests were distributed for use in laboratories or for at-home testing." [...]

8 Spurious sanitizers, COVID -19 test kits worth Rs 37L seized in Krishna

Publication date	2022-02-02
Create date	2022-02-10
Score	51.69
Report id	1388981
Category	Antiseptic, Medical device for screening/diagnosis/monitoring
Quality	Falsified
Source	Clandestine laboratory
Curation	Manually curated
Incident or General	Incident

Snippet: Spurious sanitizers, COVID -19 test kits worth Rs 37L seized in Krishna NewsMeter

Click here to see the Original Article

Table 13: Places for report 1388981

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Krishna	16.66667	81

Table 14: Drugs for report 1388981

Medicine Name	Medicine Class	Action	ATC Code
	Antiseptics	throat preparations	R02AA

Notes: Drugs Control Administration (DCA) has seized spurious hand sanitizers and COVID -19 test kits worth Rs 37 lakh in the Krishna district. On credible information, DCA officials raided Vaishnavi Garments aka Vaishnavi Enterprises at Subbaramaiah Street and found spurious hand sanitizers and COVID-19 test kits worth Rs 37 lakh. During the investigation, they found that Vaishnavi Enterprises did not possess any drug licence. [...]

9 Rwanda: 8 health workers arrested for stealing COVID-19 vaccines, test kits

Publication date	2022-01-20
Create date	2022-01-24
Score	48.95
Report id	1370792
Category	Vaccine, Medical device for screening/diagnosis/monitoring
Quality	Diverted/Unregistered
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Rwanda: 8 health workers arrested for stealing COVID-19 vaccines, test kits Down To Earth Magazine

Click here to see the Original Article

Table 15: Places for report 1370792

Region Name	Country	Location	Latitude	Longitude
Eastern Africa	Rwanda	Republic of Rwanda	-2	30

Table 16: Drugs for report 1370792

Medicine Name	Medicine Class	Action	ATC Code
			J07

Notes: Five men and three women health workers were arrested in Rwanda from January 4-8, 2022, the Rwanda Investigation Bureau (RIB) announced. The accused allegedly misused COVID-19 vaccines and stole testing kits. [...] Four of the suspects failed to justify the whereabouts of 30 vials of vaccines by AstraZeneca plc and 45 vials of vaccines by Moderna Inc, containing 300 and 675 doses of the respective candidates. [...] The others stole over 1,250 COVID-19 testing kits worth Rwf 6.125 million ($6,000). [...]

10 Coronavirus: False result fears prompt recall of nearly 300K at-home COVID-19 tests

Publication date	2022-01-29
Create date	2022-02-03
Score	48.34
Report id	1385066
Category	Medical device for screening/diagnosis/monitoring
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Coronavirus: False result fears prompt recall of nearly 300K at-home COVID-19 tests WFTV Orlando

Click here to see the Original Article

Table 17: Places for report 1385066

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5

Table 18: Other Stories

ID	Title	Link
1385540	Coronavirus: False result fears prompt recall of nearly 300K rapid COVID-19 tests	Link
1386398	FDA issues warning about 2 recalled COVID-19 tests	Link
1387415	COVID-19 Rapid Test Recall: These Brands Give False Positives	Link
1387623	Stop using these COVID tests, FDA warns. There's a 'higher risk' of false positives	Link
1388323	Michigan! FDA States Do Not Use These Covid Rapid At-Home Tests!	Link
1388460	Recall Alert: FDA says don't trust these rapid tests	Link
1409519	Empowered Diagnostics lands FDA Class I recall tag for 286K unauthorized COVID tests	Link
1434065	Two More At-Home COVID-19 Tests Have Been Recalled by FDA	Link

Notes: Empowered Diagnostics LLC is recalling nearly 300,000 rapid COVID-19 tests that have not been cleared for use in the United States amid concerns that they could potentially provide false results. [...] The recall affects at least 284,575 CovClear COVID-19 rapid antigen tests and at least 2,100 ImmunoPass COVID-19 neutralizing antibody rapid tests. [...]

11 FDA issues ‘do not use’ warning for some at-home COVID tests

Publication date	2022-03-02
Create date	2022-05-30
Score	42.22
Report id	1424695
Category	Medical device for screening/diagnosis/monitoring
Quality	Diverted/Unregistered
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: FDA issues ‘do not use’ warning for some at-home COVID tests WGHP FOX8 Greensboro

Click here to see the Original Article

Table 19: Places for report 1424695

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5

Table 20: Other Stories

ID	Title	Link
1432892	FDA grappling with influx of illegal COVID-19 tests entering US	Link
1433459	FDA warns against use of certain unauthorized COVID antigen tests	Link
1440025	Do Not Use SD Biosensor STANDARD Q COVID-19 Ag Home Tests	Link
1441089	FDA says ‘do not use’ three more at-home COVID-19 tests because of risk of ‘false results’	Link
1444170	FDA adds another COVID-19 test to ’do not use’ list	Link
1444410	SD Biosensor Recalls STANDARD Q COVID-19 Ag Home Tests That Are Not Authorized, Cleared, or Approved by the FDA and May Give False Results | FDA	Link
1460001	Two more COVID-19 test kits recalled, one for ‘high number of false positives’	Link
1461359	Some COVID-19 rapid tests recalled over false results	Link

Table 20: Other Stories(continued)

ID	Title	Link
1503959	Celltrion tacks on a 3rd Class I recall for unauthorized use of rapid COVID tests	Link

Notes: The U.S. Food and Drug Administration (FDA) issued a safety warning against using some brands of home COVID-19 tests. The FDA said there is a risk of false results — either positive or negative for COVID-19 — when using these tests, which have not been "authorized, cleared or approved by the FDA for distribution or use in the United States." One is the SD Biosensor STANDARD Q COVID-19 Ag Home Test, packaged in a white and magenta box. The test is administered using a nasal swab sample. [...] Another is the Celltrion DiaTrust COVID-19 Ag Rapid Test, packaged in green and white packaging. The test also uses a nasal swab sample. [...] Recalls have been initiated for the unauthorized SD Biosensor and Flowflex tests. A recall has been issued for the unauthorized DiaTrust test. [...] Additional Information: ID 1460001 (https://www.pennlive.com/coronavirus/2022/03/two-more-covid-19-test-kits-recalled-one-for-high-number-of-false-positives.html): [...] The Celltrion DiaTrust COVID-19 Ag Rapid Test recall involves a specific lot and is used by healthcare providers. The tests are being recalled "due to a high number of false-positive results." The FDA said the tests also indicate they have a shelf life of 18 months but the FDA's emergency use authorization "specifies these tests may only be used for 12 months." About 45,500 of those tests were distributed from June 2, 2021, to Dec. 21, 2021. The lot number is COVGCCM0008.

The SD Biosensor Standard Q COVID-19 Ag Home Test uses a nasal swab. The FDA said the test "is not authorized, cleared or approved by the FDA for marketing or distribution in the United States. ... There is not sufficient data demonstrating that the test's performance is accurate." There is a risk the test will give false results.

According to the FDA, up to 397,700 of the tests were distributed from Aug. 26, 2021, to Jan. 30, 2022.

The recall does NOT include the SD Biosensor COVID-19 At-Home Test that was authorized on Dec. 24, 2021, and distributed by Roche Diagnostics. [...]

12 Officials Seize Large Cache of Fake COVID Vaccines, Drugs, Test Kits in Varanasi – The Wire Science

Publication date 2022-02-03

Create date 2022-05-11

Score 41.68

Report id 1390161

Category Vaccine, Antiviral others, Medical device for screening/diagnosis/monitoring

Quality Falsified

Source Clandestine laboratory

Curation Manually curated

Incident or General Incident

Snippet: Officials Seize Large Cache of Fake COVID Vaccines, Drugs, Test Kits in Varanasi – The Wire Science The Wire Science

Click here to see the Original Article

Table 21: Places for report 1390161

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Varanasi	25.31668	83.01041
Southern Asia	India	Uttar Pradesh	27.25	80.75
Southern Asia	India	Delhi	28.65195	77.23149

Table 22: Drugs for report 1390161

Medicine Name	Medicine Class	Action	ATC Code
			J07
remdesivir	Nucleosides and nucleotides excl. reverse transcriptase inhibitors	direct acting antivirals	J05AB16

Table 23: Other Stories

ID	Title	Link
1388119	Manufacture of fake corona vaccine stirred up the country, STF confiscated fake goods worth crores	Link

Table 23: Other Stories(continued)

ID	Title	Link
1388191	Uttar Pradesh: Fake Covid vaccine manufacturing unit busted in Varanasi	Link
1388268	5 Arrested By UP STF For Supplying Fake Vaccines, Testing Kits	Link
1388316	Gang making fake Covid vaccines, testing kits busted in Varanasi, 5 held	Link
1388953	Varanasi: Fake vaccine racket busted, 5 arrested	Link
1389061	Fake vaccine unit unearthed in Uttar Pradesh, 5 held	Link
1389177	Be careful! Millions of people have got fake corona vaccine	Link
1389213	Uttar Pradesh: Fake Covid-19 vaccines and testing kits worth Rs 4 crore. seized , 5 arrested	Link
1389245	Uttar Pradesh: Fake Covid-19 vaccines, testing kits worth Rs 4 crore seized, 5 arrested - 2022-02-03	Link
1390198	Fake vaccine racket busted in Varanasi; UP Police arrests five	Link
1391998	Varanasi: Fake COVID-19 vaccines, testing kits confiscated - Goa Chronicle	Link

Notes: In a raid conducted on February 2, the Uttar Pradesh Food and Drug Administration (FDA) has secured a large tranche of spurious COVID-19 vaccines, drugs and rapid antigen test kits from Varanasi. [...] Officials also seized as many as 10,800 kits of 'Standard Q Covid-19 Ag SD BIOSENSOR Rapid Test Kits'. In normal course, the kits are manufactured by SD Biosensor Healthcare Pvt. Ltd., a Gurugram-based company. The seized materials had fake batch numbers and fake expiry dates.

To make these kits, the accused used pregnancy strips. The COVID-19 rapid antigen test kits look similar to pregnancy kits; both are strip-based tests. According to FDA officials, the accused would procure pregnancy kits from the market and simply paste a wrapper of the antigen kit on it. The production cost was Rs 50 per kit but the accused sold it at Rs 500. Officials also recovered 880 vials (2 ml each) of Zydus Cadila's COVID-19 vaccine, ZyCoV-D. Note that Zydus Cadila had initiated its supply of this vaccine to the Centre only on February 2, and that the Centre had planned to begin administering it in Bihar. Yet the spurious doses had already been available in Varanasi. To make the spurious COVID-19 vaccine vials, the accused would fill empty vials with distilled water and slap the company's (Cadila's) wrapper on it. Doing this cost Rs 25 but the selling price was Rs 300.

The drug administration team also recovered 6,000 vials "filled with transparent fluid meant for packing as Covishield with green cap". The accused were allegedly selling the spurious vaccines mostly to private hospitals in the city. They also recovered 1,550 vials of spurious (injectable) remdesivir vials. According to information shared by the raiding team, the accused would fill water mixed with Glucon-D in an empty vial and paste a fake wrapper around it. The manufacturing cost of one such vial would be Rs 100 – and the selling price, Rs 3,000. [...] In all, according to the STF's statement, the police and the FDA officials had together seized four sealing machines, two cartons of empty vials, blue and green sealing caps (for ZyCoV-D and Covishield, respectively), and many fake wrappers. [...]

13 Crackdown on falsified meds in Africa nets 12m illegal products - 2022-03-06

Publication date 2022-03-06

Create date 2022-03-09

Score 20.92

Report id 1420044

Category Other, Erectile dysfunction medicine, Antiepileptic, Medical devices for disease prevention, Anti-inflammatory medicine, Vaccine, Medical device for screening/diagnosis/monitoring, Antibiotic, Analgesic

Quality Diverted/Unregistered

Source Private pharmacy

Curation Manually curated

Incident or General Incident

Snippet: Seizures included 2m anticonvulsant medicines, 300,000 other epilepsy drugs, 208,000 masks and 1,600 rapid COVID tests.

Click here to see the Original Article

Table 24: Places for report 1420044

Region Name	Country	Location	Latitude	Longitude
		Africa	7.1881	21.09375

Table 25: Drugs for report 1420044

Medicine Name	Medicine Class	Action	ATC Code
	Antibiotics	intestinal antiinfectives	A07AA
	Antibiotics	agents for treatment of hemorrhoids and anal fissures for topical use	C05AB
	Antibiotics	antifungals for topical use	D01AA
	Antibiotics	antiinfectives and antiseptics, excl. combinations with corticosteroids	G01AA
	Antibiotics	antimycotics for systemic use	J02AA

Table 25: Drugs for report 1420044(continued)

Medicine Name	Medicine Class	Action	ATC Code
	Antibiotics	drugs for treatment of tuberculosis	J04AB
	Antibiotics	throat preparations	R02AB
	Antibiotics	antiinfectives	S01AA
			J07
			N02

Table 26: Other Stories

ID	Title	Link
1420050	Crackdown on falsified meds in Africa nets 12m illegal products	Link
1426178	Zimbabwe: ZRP, Interpol Operation Nets 2 000 - AllAfrica	Link
1438597	ZRP, Interpol operation nets 2 000	Link

Notes: A pan-African enforcement operation has identified hundreds of suspects and resulted in seizures of more than 12 million illicit health products, including epilepsy medicines. [...] Inspections were carried out at roadblocks, open markets, pharmacies, warehouses and other locations suspected of producing, smuggling, storing or distributing fake pharmaceuticals, with notables seizures including 2 million anticonvulsant medicines, 300,000 other epilepsy drugs, more than 208,000 COVID-19 protection masks and 1,600 rapid COVID tests. Other commonly seized illicit medicines included antibiotics, anti-inflammatories, analgesics and medication used to correct erectile dysfunction, rheumatism and epilepsy, said Interpol. [...] West African operations revealed the use of counterfeit COVID-19 vaccination certificates in several countries, whilst East African operations saw the use of unregulated and unlawful distribution and sale of genuine COVID-19 vaccines. [...]

Annex C

C.3. Personal protective equipment

Medicine Quality Monitoring Globe

September 7, 2022

This is a summary of the information available in the Medicine Quality Monitoring Globe for the search terms selected between the dates selected. For more information on the terminology used, caveats and the work of the medicine quality group please see the information at: https://www.iddo.org/medicine-quality

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Filters applied for this report

Search	(("Personal protective equipment" OR "PPE" OR "protective glasses" OR "apron" OR "n95" OR "gowns" OR "facemask" OR "visor" OR "gloves" OR "goggles" OR "respirator" OR "KN95" OR "face shield" OR "mask") OR (("Medical devices for disease prevention") AND ("COVID-19" OR "COVID" OR "SARS-CoV-2" OR "Coronavirus" OR "CV19" OR "CV-19" OR "SARS" OR "CoV-2")))
Start date	2022-01-01
End date	2022-03-31
Language	en
Report type	incident
Curation status	validated
Number of Reports	13

1 City of New Orleans distributing counterfeit N95 masks in giveaway program

Publication date	2022-01-14
Create date	2022-01-17
Score	39.00
Report id	1363062
Category	Medical devices for disease prevention
Quality	Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: City of New Orleans distributing counterfeit N95 masks in giveaway program The Lens

Click here to see the Original Article

Table 1: Places for report 1363062

Region Name	Country	Location	Latitude	Longitude
Americas	United States	New Orleans	29.95465	-90.07507

Notes: Late last month, the city of New Orleans began giving away what it said were N95 masks — considered the best commonly available face coverings to protect against COVID-19 — to the public at New Orleans Public Library branches. But The Lens has learned that at least some of the free N95 masks the city has been distributing are counterfeits. The masks are labeled as "N95s," and in public announcements, the city has said they are N95s. But the masks available at the giveaways have not gotten the requisite approval from the National Institute for Occupational Safety and Health, or NIOSH — a federal agency responsible for certifying personal protective equipment. [...]

2 BOC seizes P150M worth of fake COVID test kits, goods

Publication date 2022-01-23

Create date 2022-01-24

Score 24.90

Report id 1377074

Category Medical devices for disease prevention, Herbal medicine, Medical device for screening/diagnosis/monitoring

Quality Falsified

Source Unlicensed outlets

Curation Manually curated

Incident or General Incident

Snippet: BOC seizes P150M worth of fake COVID test kits, goods Manila Bulletin

Click here to see the Original Article

Table 2: Places for report 1377074

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Philippines	Manila	14.6042	120.9822

Table 3: Other Stories

ID	Title	Link
1377884	P150 million fake COVID-19 test kits, drugs seized	Link
1378348	P150-M fake antigen test kits, medicines seized from Chinese national	Link
1378696	P150M worth of fake Covid test kits, medicines seized| SUNSTAR	Link
1378946	P150 million worth of fake COVID-19 test kits, meds seized; warehouse owner arrested	Link
1379359	Bureau of Customs seizes fake Covid test kits, medicines worth P150M| SUNSTAR	Link
1380996	PNP intensifies crackdown vs fake COVID-19 test kits, other medical supplies - UNTV News	Link
1383666	Bureau of Customs seizes fake Covid test kits, medicines worth P150M	Link
1385925	P150M worth of fake COVID test kits, other medical products seized	Link

Notes: Operatives of the Bureau of Customs (BOC) confiscated some P150-million worth of fake COVID-19 antigen test kits, face masks, medicines as well as counterfeit products during a raid in a warehouse on Friday, Jan. 21 in a warehouse in Manila. [...] During the inspection, authorities found thousands of Clungene COVID-19 antigen test kits, counterfeit Chinese herbal medicines LianHua and fake 3M N95 face masks. They also found counterfeit Nike, Fila, Converse, Adidas, Louis Vuitton and Gucci bags, wallets, phone accessories, and others. [...]

3 College-supplied masks could possibly be 'counterfeit,' warns faculty union

Publication date	2022-01-27
Create date	2022-02-24
Score	23.71
Report id	1382293
Category	Medical devices for disease prevention
Quality	Falsified
Source	Distributor/Wholesaler
Curation	Manually curated
Incident or General	Incident

Snippet: College-supplied masks could possibly be 'counterfeit,' warns faculty union Berkeley Beacon

Click here to see the Original Article

Table 4: Places for report 1382293

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Boston	42.35843	-71.05977

Notes: [...] The college announced on Jan. 17 that faculty members would be provided with two KN95 masks each, in order to comply with recent guidance by the Centers for Disease Control and Prevention. Only three days later, though, the Emerson College Chapter of the American Association of University Professors warned faculty that the union was unable to certify the efficacy of the masks. [...] Yarbrough said that Newman's email prompted him to take a second look at the masks he received to see if they had any writing or approval stamps on them.

"In fact, the masks that we had been given were plain white masks that didn't say anything," Yarbrough said. "They didn't say N95 or KN95. They didn't have any approval number … It seems pretty clear that it's not an N95 mask. I don't know what it is." The same masks have been provided to students over the past week at the Campus Life Office and the information desk at 172 Tremont. Beacon staff obtained a pack of five from the information desk on the first floor of 172 Tremont on Jan. 25. None had any sort of certification—all were blank, white masks in the typical shape of KN95s. [...] According to Lichtenstein, Müürisepp claimed that the college was distributing Greencare branded KN95 respirators—tested and approved by the CDC. However, the masks obtained by The Beacon from faculty are visibly distinct from Greencare masks.

KN95 masks come from China, which has a standard but not a certification agency, Lichtenstein

said; as a result, many fake KN95 masks come out of the country. The ”95” indicates 95 percent filtration, but if the masks do not have any approval markings on them, they are most likely not filtering 95 percent.

”The lowest [level of filtration] I’ve seen from [false] KN95s is about 60 percent filtration, all the way up to 90 percent or 93 percent,” she said. ”So they’re not meeting that 95 percent standard, but they’re coming awfully close.” [...]

4 Hong Kong customs seizes 15,000 fake N95 masks, arrests woman after raid

Publication date	2022-02-22
Create date	2022-03-22
Score	17.02
Report id	1433726
Category	Medical device for screening/diagnosis/monitoring
Quality	Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Hong Kong customs seizes 15,000 fake N95 masks, arrests woman after raid South China Morning Post

Click here to see the Original Article

Table 5: Places for report 1433726

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	Hong Kong	Hong Kong	22.27832	114.17469

Notes: (Need to Subscribe) – Hong Kong customs officers have seized more than 15,000 suspected fake surgical masks and arrested a woman after raiding a stall in a shopping centre. The bogus 3M-brand N95 respirators, with an estimated value of about HK$30,000 (US$3,800), were confiscated from a temporary stall at a mall in Ho Man Tin, the Customs and Excise Department revealed on Tuesday. [...]

5 Crackdown on falsified meds in Africa nets 12m illegal products - 2022-03-06

Publication date 2022-03-06

Create date 2022-03-09

Score 16.79

Report id 1420044

Category Other, Erectile dysfunction medicine, Antiepileptic, Medical devices for disease prevention, Anti-inflammatory medicine, Vaccine, Medical device for screening/diagnosis/monitoring, Antibiotic, Analgesic

Quality Diverted/Unregistered

Source Private pharmacy

Curation Manually curated

Incident or General Incident

Snippet: Seizures included 2m anticonvulsant medicines, 300,000 other epilepsy drugs, 208,000 masks and 1,600 rapid COVID tests.

Click here to see the Original Article

Table 6: Places for report 1420044

Region Name	Country	Location	Latitude	Longitude
		Africa	7.1881	21.09375

Table 7: Drugs for report 1420044

Medicine Name	Medicine Class	Action	ATC Code
	Antibiotics	intestinal antiinfectives	A07AA
	Antibiotics	agents for treatment of hemorrhoids and anal fissures for topical use	C05AB
	Antibiotics	antifungals for topical use	D01AA
	Antibiotics	antiinfectives and antiseptics, excl. combinations with corticosteroids	G01AA
	Antibiotics	antimycotics for systemic use	J02AA

Table 7: Drugs for report 1420044(continued)

Medicine Name	Medicine Class	Action	ATC Code
	Antibiotics	drugs for treatment of tuberculosis	J04AB
	Antibiotics	throat preparations	R02AB
	Antibiotics	antiinfectives	S01AA
			J07
			N02

Table 8: Other Stories

ID	Title	Link
1420050	Crackdown on falsified meds in Africa nets 12m illegal products	Link
1426178	Zimbabwe: ZRP, Interpol Operation Nets 2 000 - AllAfrica	Link
1438597	ZRP, Interpol operation nets 2 000	Link

Notes: A pan-African enforcement operation has identified hundreds of suspects and resulted in seizures of more than 12 million illicit health products, including epilepsy medicines. [...] Inspections were carried out at roadblocks, open markets, pharmacies, warehouses and other locations suspected of producing, smuggling, storing or distributing fake pharmaceuticals, with notables seizures including 2 million anticonvulsant medicines, 300,000 other epilepsy drugs, more than 208,000 COVID-19 protection masks and 1,600 rapid COVID tests. Other commonly seized illicit medicines included antibiotics, anti-inflammatories, analgesics and medication used to correct erectile dysfunction, rheumatism and epilepsy, said Interpol. [...] West African operations revealed the use of counterfeit COVID-19 vaccination certificates in several countries, whilst East African operations saw the use of unregulated and unlawful distribution and sale of genuine COVID-19 vaccines. [...]

6 American University unknowingly distributed counterfeit KN95 masks during return to in-person class

Publication date	2022-02-04
Create date	2022-02-11
Score	15.47
Report id	1391384
Category	Medical devices for disease prevention
Quality	Falsified
Source	Distributor/Wholesaler
Curation	Manually curated
Incident or General	Incident

Snippet: American University unknowingly distributed counterfeit KN95 masks during return to in-person class The Eagle

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Table 9: Places for report 1391384

Region Name	Country	Location	Latitude	Longitude
Americas	United States	District of Columbia	38.91706	-77.00025

Table 10: Other Stories

ID	Title	Link
1391535	American University distributed counterfeit masks to students on return to in-person learning	Link
1392891	American University to give new KN95 masks after unknowingly distributing counterfeit ones	Link
1392956	American U Distributed Masks That Didn't Meet Standards	Link
1393458	American University unknowingly distributed counterfeit KN95 masks, officials confirm	Link
1395440	How Student Journalists Discovered American University Was Handing Out Counterfeit KN95 Masks	Link
1402659	Staff Editorial: Counterfeit KN95 masks shed light on University's lack of communication	Link
1409444	American University unknowingly distributed counterfeit KN95 masks: Campus newspaper	Link

Table 10: Other Stories(continued)

ID	Title	Link
1410118	American Univ. says school distributed KN95 masks that 'did not meet' standards	Link

Notes: American University unknowingly distributed counterfeit KN95 masks to the student body during the first week of in-person classes, an Eagle investigation found. The authenticity of the masks was thrown into question after The Eagle identified several inconsistencies between international standards for KN95 masks and those being distributed on campus. In a Friday interview, Matthew Bennett, the University's chief communications officer, confirmed that despite conducting a "thorough procurement process" to secure legitimate KN95 masks, the ones distributed by the University "did not meet the standards that we were promised." [...] Bennett said the University only became aware of the issue after receiving concerns from the community. The University has since ordered a new batch of KN95 masks from the same vendor, which will be checked before distribution and available to students starting Monday, Bennett said. [...]

7 Texas company sued, accused of selling fake N95 masks to Washington health system

Publication date	2022-02-04
Create date	2022-02-17
Score	13.53
Report id	1398672
Category	Medical devices for disease prevention
Quality	Falsified
Source	Distributor/Wholesaler
Curation	Manually curated
Incident or General	Incident

Snippet: Texas company sued, accused of selling fake N95 masks to Washington health system Becker's Hospital Review

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Table 11: Places for report 1398672

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Washington	47.50012	-120.50147

Table 12: Other Stories

ID	Title	Link
1398933	Hospitals Sue Texas Company, Alleging It Sold Them $4M in Fake Masks	Link
1403352	Washington Suing Texas: COVID Masks Are Fake	Link
1408044	UW Medicine, WSHA sue Texas company for counterfeit N95s	Link

Notes: The University of Washington Medicine and Washington State Hospital Association are suing a Texas company for allegedly selling $4 million in counterfeit N95 masks, The Seattle Times reported Feb. 4.

The complaint, filed Feb. 3, alleges Dallas-based CJFS Corp. sold the hospital association 600 cases of 1860-model N95 masks from 3M, one of the largest global producers of N95 masks, for $1.4 million and University of Washington Medicine about 4,700 cases of 1860-model and 1860S-model N95 masks for $2.6 million. [...] The systems reached out to 3M, which confirmed

the supplies were counterfeit. They later received a counterfeit product alert from CJFS, the lawsuit said. CJFS has not sent a refund or genuine masks to the system, according to the lawsuit.

8 Two women arrested in B80m medical gloves fraud

Publication date	2022-01-26
Create date	2022-01-28
Score	9.34
Report id	1381147
Category	Medical devices for disease prevention
Quality	Substandard
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Two women arrested in B80m medical gloves fraud Bangkok Post

Click here to see the Original Article

Table 13: Places for report 1381147

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Thailand	Bangkok	13.75398	100.50144
Eastern Asia	Taiwan	Taiwan	24	121

Table 14: Other Stories

ID	Title	Link
1381885	2 women nabbed for glove scam	Link

Notes: Two women have been arrested for an alleged 80-million-baht medical swindle, accused of sending used gloves and boxes of bricks to customers of a Taiwanese buyer. [...] The first order of medical gloves had been sent, but the Taiwanese firm said they were used gloves, not new ones. The second delivery was sent directly to a client in Switzerland, but the Taiwanese firm said bricks were found inside boxes supposedly containing medical gloves, Pol Lt Gen Jirabhop Bhuridej said. [...]

9 Swiss army circulated millions of substandard masks - SWI swissinfo.ch

Publication date	2022-01-24
Create date	2022-01-25
Score	6.26
Report id	1378901
Category	Medical devices for disease prevention
Quality	Substandard
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Swiss army circulated millions of substandard masks - SWI swissinfo.ch swissinfo.ch

Click here to see the Original Article

Table 15: Places for report 1378901

Region Name	Country	Location	Latitude	Longitude
Europe	Switzerland	Switzerland	47.00016	8.01427

Notes: [...] But now research by Tamedia newspapersExternal link published on Monday shows that the army pharmacy also circulated large quantities of hygiene masks of inferior quality. The masks come from a Chinese company called Sichuan Zhengning Medical Instrument Co. "WS Protection, Love is Power" is written on the packaging. The purchase price in April 2020 was CHF0.70 per mask. [...] The Tages-Anzeiger said the army pharmacy's stock showed that the army had circulated around 3.3 million of the "Love is Power" masks since February 2021. When asked by the newspaper, the army did not disclose who exactly had received the questionable hygiene masks. It is possible that some of the 3.3 million masks were also used by the army itself, the paper said. [...]

10 Police: Area Man Busted for Possession of Cocaine, Counterfeit Fentanyl

Publication date	2022-03-19
Create date	2022-03-22
Score	5.61
Report id	1433697
Category	Opioid
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Police: Area Man Busted for Possession of Cocaine, Counterfeit Fentanyl exploreClarion.com

Click here to see the Original Article

Table 16: Places for report 1433697

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Emlenton	41.17728	-79.70783

Table 17: Drugs for report 1433697

Medicine Name	Medicine Class	Action	ATC Code
		opioids	N02A

Table 18: Other Stories

ID	Title	Link
1437377	Emlenton Man Busted for Possession of Cocaine, Counterfeit Fentanyl Due in Court Today	Link
1439279	Emlenton Man Busted for Possession of Cocaine, Counterfeit Fentanyl Waives Hearing	Link

Notes: An area man is facing felony charges for reportedly possessing cocaine and counterfeit fentanyl at an Emlenton residence on March 15. [...] The agent reportedly relinquished the

following items to the PSP Franklin Trooper:

– A clear tied plastic bag containing a large quantity of suspected cocaine; – A blue cut latex glove finger slot that was tied containing a clear plastic tied baggie of multi-colored round pills which are suspected counterfeit fentanyl; and – A clear, cut plastic straw containing suspected drug residue. [...]

11 Lawrence Man Arrested for Fentanyl Distribution Involving Multiple Large Pill Press Machines

Publication date	2022-03-25
Create date	2022-03-30
Score	4.57
Report id	1439972
Category	Opioid
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Lawrence Man Arrested for Fentanyl Distribution Involving Multiple Large Pill Press Machines Department of Justice

Click here to see the Original Article

Table 19: Places for report 1439972

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Lawrence	42.70704	-71.16311

Table 20: Drugs for report 1439972

Medicine Name	Medicine Class	Action	ATC Code
oxycodone	Natural opium alkaloids	opioids	N02AA05

Table 21: Other Stories

ID	Title	Link
1441989	Massachusetts man arrested on fake med-related charges - 2022-03-28	Link
1442029	Massachusetts man arrested on fake med-related charges	Link
1442133	100,000 counterfeit fentanyl pills seized in Lawrence	Link
1442533	DEA arrests Massachusetts man after seizing 100000 fentanyl pills, 1.5 kilos of fentanyl powder, ammunition, presses	Link

Table 21: Other Stories(continued)

ID	Title	Link
1543591	Lawrence Man Previously Arrested with Multiple Pill Press Machines Charged with Fentanyl Distribution	Link
1547213	Lawrence Man Previously Arrested With Multiple Pill Press Machines Charged With Fentanyl Distribution	Link
1552460	Massachusetts man charged after nearly 48000 counterfeit pills, multiple pill presses seized	Link

Notes: A Lawrence man was arrested today on drug distribution charges involving counterfeit prescription pills containing fentanyl. [...] According to the complaint, during a search of Fajardo's apartment this morning law enforcement found approximately 100,000 suspected fentanyl pills weighing an estimated seven kilograms, along with an industrial pill press and "M" and "30" pill stamps consistent with markings on pharmaceutical-grade Oxycodone pills. Pill stamps are commonly used to make counterfeit pills appear to be legitimate pharmaceutical-grade pills. Approximately 1.5 kilograms of suspected fentanyl powder and 50 rounds of .40 caliber ammunition concealed in a microwave, two individual finger presses in the living room, four kilograms of cutting agent and two air purifying respirators, which are commonly used when working with fentanyl powder, were also found. It is further alleged that investigators located two one-kilogram pill presses and another large pill press in the landing outside the apartment. [...]

12 FDA Alerts the Public to Potentially Contaminated Products from Family Dollar Stores in Six States | FDA

Publication date 2022-02-18

Create date 2022-02-21

Score 2.39

Report id 1404932

Category Other, Medical device used for cure/mitigation/treatment, Herbal medicine, Medical devices for disease prevention, Vitamin, Ophthalmic medicines, Analgesic, Nutritional supplement

Quality Falsified

Source Unlicensed outlets

Curation Manually curated

Incident or General Incident

Snippet: FDA Alerts the Public to Potentially Contaminated Products from Family Dollar Stores in Six States | FDA FDA.gov

Click here to see the Original Article

Table 22: Places for report 1404932

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Arkansas	34.75037	-92.50044
Americas	United States	Mississippi	32.75041	-89.75036
Americas	United States	Louisiana	31.00047	-92.0004
Americas	United States	Alabama	32.75041	-86.75026
Americas	United States	Tennessee	35.75035	-86.25027
Americas	United States	Missouri	38.25031	-92.50046

Table 23: Drugs for report 1404932

Medicine Name	Medicine Class	Action	ATC Code
			A12
			A11
	Vitamins	i.v. solution additives	B05XC
		antacids	A02A
			N02

Table 24: Other Stories

ID	Title	Link
1404962	FDA Alerts the Public to Potentially Contaminated Products from Family Dollar Stores in Six States - 2022-02-18	Link
1405004	FDA warns of contaminated products from Family Dollar stores in six states including Arkansas	Link
1405009	FDA says Family Dollar stores could have potentially contaminated products	Link
1405048	PUBLIC WARNING: Multiple Family Dollar items contaminated after major rat infestation	Link
1405110	Family Dollar products in the Mid-South could be contaminated due to rodent infestation, FDA says	Link
1405141	FDA warns rodent infestation could affect some Family Dollar products in Missouri	Link
1405241	Hundreds of rodents found inside Family Dollar facility	Link
1405243	Family Dollar items possibly contaminated by live and dead rodents, FDA warns	Link
1405352	FDA warns rodent infestation could affect products in Alabama, Tennessee	Link
1405483	FDA warns rodent infestation could affect products in Arkansas, Louisiana	Link
1405535	FDA issues warning after Family Dollar distribution center found infested with rodents	Link
1405538	1,110 rodents found in Family Dollar Arkansas warehouse: FDA	Link
1405582	1,110 rodents found in Family Dollar Arkansas warehouse: FDA - New York Daily News	Link
1405645	Look for Potentially Contaminated Products from Family Dollar Stores in Six States	Link
1405723	Family Dollar issues voluntary recall for possible rodent contamination of items	Link
1405724	Over 1,000 dead rodents found at Family Dollar distribution center	Link
1406298	Family Dollar Shutters 400 Stores After Recall	Link
1406344	FDA issues Alert about Potentially Contaminated Products from Family Dollar Stores in Six States	Link
1406887	Family Dollar Closes 400 Stores, Recalls Products After FDA Finds Dead Rats in Warehouse	Link
1407495	US Food and Drug Administration (FDA) issues recall of Family Dollar products following rodent infestation	Link
1407788	FDA Warns of Rat Feces, Dead Birds in Family Dollar Products	Link
1408146	Dollar Store Recall Hits Six States	Link
1408841	FDA inspectors found rodents, 'putrid odor' at Arkansas Family Dollar distribution facility	Link

Table 24: Other Stories(continued)

ID	Title	Link
1409563	Arkansas Department of Health releases Family Dollar warehouse inspection reports	Link
1410142	Public alerted to potentially contaminated products | News | thewestsidejournal.com	Link
1411772	FDA alerts public to potentially contaminated products from Family Dollar Stores in Tennessee	Link
1412364	FDA reports potentially contaminated products from Family Dollar stores in six states	Link
1414004	FDA warns after Family Dollar distribution center found infested with rodents	Link
1415222	FDA recalls certain Family Dollar products in 6 states over rodent infestation at plant	Link
1418450	FDA warns of potential contaminated products from Family Dollar - Lowndes Signal | Lowndes Signal	Link
1418677	Rats overwhelm Family Dollar warehouse; 404 stores closed as part of recall	Link
1435020	FDA alerts public to potentially-contaminated products from Family Dollar stores	Link
1474587	Arkansas attorney general files suit against Family Dollar Stores, Dollar Tree after rodent infestation at distribution site	Link

Notes: Today, the U.S. Food and Drug Administration is alerting the public that several categories of FDA-regulated products purchased from Jan. 1, 2021, through the present from Family Dollar stores in Alabama, Arkansas, Louisiana, Mississippi, Missouri and Tennessee may be unsafe for consumers to use. The impacted products originated from the company's distribution facility in West Memphis, Arkansas, where an FDA inspection found insanitary conditions, including a rodent infestation, that could cause many of the products to become contaminated. The FDA is working with the company to initiate a voluntary recallExternal Link Disclaimer of the affected products. [...] This alert covers FDA-regulated products purchased from Family Dollar stores in those six states from Jan. 1, 2021, through the present. Some examples of these products include human foods (including dietary supplements (vitamin, herbal and mineral supplements)), cosmetics (skincare products, baby oils, lipsticks, shampoos, baby wipes), animal foods (kibble, pet treats, wild bird seed), medical devices (feminine hygiene products, surgical masks, contact lens cleaning solutions, bandages, nasal care products) and over-the-counter (OTC) medications (pain medications, eye drops, dental products, antacids, other medications for both adults and children). [...]

13 Viraldine, LLC - Center for Drug Evaluation and Research | CDER - Unapproved New Drug Products Related to Coronavirus Disease 2019 (COVID-19) - 2022-03-08

Publication date	2022-03-08
Create date	2022-03-11
Score	2.37
Report id	1422031
Category	Antiseptic
Quality	Diverted/Unregistered
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER Viraldine, LLC MARCS-CMS 625675 — March 07, 2022 Share Tweet Linkedin Email Print Product: Drugs Recipient: Viraldine, LLC 311 Lake Street Elmira , NY 14901 United States infor@viraldine.com Issuing Office: Center for Drug Evaluation and Research | CDER United States Federal Trade Commission WARNING LETTER Date: March 7, 2022 RE: Unapproved New Drug Products Related to Coronavirus Disease 2019 (COVID-19) This is to advise you that the United States Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) reviewed your website at the Internet address https:// viraldine.com/ on December 21, 2021 and March 1, 2022, respectively. The FDA has observed that your website offers non-alcohol-based antiseptic products 1 for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19 2 in people. Based on our review, these products are unapproved new drugs sold in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 355(a). Furthermore, these products are misbranded drugs under sections 502(ee) of the FD&C Act, 21 U.S.C. 352(ee). The introduction or delivery for introduction of these products into interstate commerce is prohibited under sections 301(a) and (d) of the FD&C Act, 21 U.S.C. 331(a) and (d). These violations are described in more detail below. There is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2). The disease caused by the virus has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS. 3 In addition, on March 13, 2020, there was a Presidential declaration of a national emergency in response to COVID-19 that subsequently has been extended. 4 Therefore, FDA is taking urgent measures to protect consumers from certain products that, without approval or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. As described below, you sell products that are intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. We request that you take immediate action to cease the sale of any unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. Some examples of the claims on your labeling that establish

the intended use (as defined in 21 CFR 201.128) of your products and misleadingly represent them as safe and/or effective for the treatment or prevention of COVID-19 include, but may not be limited to, the following: "INTRANASAL POVIDONE-IODINE EFFECTIVELY LIMITS COVID-19 SPREAD, FINDS STUDY HTTPS://PUBMED.NCBI.NL" [from your website https://viraldine.com/faqs-%26-pvp-i-studies] "POVIDONE IODINE (PVP-I) ORO-NASAL SPRAY: AN EFFECTIVE SHIELD FOR COVID-19 PROTECTION FOR HEALTH CARE" [from your website https://viraldine.com/faqs-%26-pvp-istudies] " Results: All concentrations of nasal antiseptics and oral rinse antiseptics evaluated completely inactivated the SARS-CoV-2. Conclusions: Nasal and oral PVP-I antiseptic solutions are effective at inactivating the SARS-CoV-2 at a variety of concentrations after 60-second exposure times. The formulations tested may help to reduce the transmission of SARS-CoV-2 if used for nasal decontamination, oral decontamination, or surface decontamination in known or suspected cases of COVID-19." [from your website https://viraldine.com/faqs-%26-pvp-i-studies] "The researchers came out with the following findings- 1. Povidone-iodine nasal antiseptics at concentrations (0.5%, 1.25%, and 2.5%) completely inactivated SARS-CoV-2 within 15 seconds of contact…" [from your website https://viraldine.com/faqs-%26-pvp-i-studies] "Hence, the authors concluded that 'Povidone-iodine nasal antiseptic solutions at concentrations as low as 0.5% rapidly inactivate SARS-CoV-2 at contact times as short as 15 seconds. Intranasal use of PVP-I has demonstrated safety at concentrations of 1.25% and below and may play an adjunctive role in mitigating viral transmission beyond personal protective equipment.'" [from your website https://viraldine.com/faqs-%26-pvp-i-studies] "SARS-CoV-2 virus was completely inactivated by PVP-I oral antiseptic rinse in vitro, at the lowest concentration of 0.5 % and at the lowest contact time of 15 seconds. . ." [from your website https://viraldine.com/faqs-%26-pvp-i-studies] "Recent evidence has confirmed that 0.5% povidone iodine (PVP-I) mouthrinse/gargle for 30 s can reduce SARS-CoV-2 virus infectivity to below detectable levels. PVP-I can even interrupt SARSCoV-2 attachment to oral and nasopharyngeal tissues and lower the viral particles in the saliva and respiratory droplets. Thus, the use of PVP-I mouthrinse as a prophylactic measure has been advocated across the globe to reduce disease transmission. . . [from your website https://viraldine.com/faqs-%26-pvp-i-studies] "4 Hour Maximum Protection" [from product labels on your website https://viraldine.com/shop] Based on the above claims and statements, your topical antiseptic 5 and oral antiseptic 6 products are "drugs" as defined by section 201(g)(1)(B) of the FD&C Act, 21 U.S.C. 321(g)(1)(B), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or under section 201(g)(1)(C) of the FD&C Act, 21 U.S.C. 321(g)(1)(C), because they are intended to affect the structure or any function of the body. Specifically, 1.5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, 1% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, and .5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY are intended for use as consumer topical antiseptics. 1.5% POVIDONE IODINE USP ANTISEPTIC THROAT SPRAY is intended for use as a consumer oral antiseptic. These consumer topical antiseptics and oral antiseptic products are "new drugs" within the meaning of section 201(p) of the FD&C Act, 21 U.S.C. 321(p), because they are not generally recognized as safe and effective (GRASE) for use under the conditions prescribed, recommended, or suggested in their labeling. New drugs may not be introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in section 505(a) of the FD&C Act, 21 U.S.C. 355(a), unless they are lawfully marketed under section 505G of the FD&C Act (which is not the case for these products, as further described below) or under other exceptions not applicable here. No FDA-approved applications pursuant to section 505 of the FD&C Act, 21 U.S.C. 355, is in effect for these drug products, nor are we aware of any adequate and well-controlled clinical studies in the published literature that support a determination that your drug products are

GRASE for use under the conditions suggested, recommended, or prescribed in their labeling. Accordingly, these drug products are unapproved new drugs marketed in violation of sections 505(a) and 301(d) of the FD&C Act, 21 U.S.C 355(a) and 331(d). We note that OTC topical and oral antiseptic products had been the subject of rulemakings under the Agency's OTC Drug Review. In particular, consumer topical antiseptics were addressed in a tentative final monograph (TFM) entitled "Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Health-Care Antiseptic Drug Products," Proposed Rule, 59 FR 31402 (June 17, 1994) (1994 TFM), as further amended by "Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record," Proposed Rule, 81 FR 42912 (June 30, 2016) (Consumer Antiseptic Rubs Proposed Rule). Over the course of these rulemakings, three active ingredients (benzalkonium chloride, ethyl alcohol (ethanol), and isopropyl alcohol) were classified as Category III for use in consumer antiseptic rub products, meaning that additional safety and effectiveness data are needed to support a determination that a drug product containing one of these active ingredients would be GRASE for use as a consumer antiseptic rub. Oral antiseptics were addressed in a tentative final monograph (TFM) entitled "Oral Health Care Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Oral Antiseptic Drug Products"; Proposed Rule, 59 FR 6084 (February 9, 1994) (Oral Antiseptics Proposed Rule). Over the course of this rulemaking for oral antiseptics, povidone iodine at 0.5%, when labeled for short-term use (not to exceed 7 days), was classified as Category III for use as an OTC oral antiseptic, because additional effectiveness data are needed to support a determination that a product containing this active ingredient would be GRASE for use as an OTC oral antiseptic. Section 505G of the FD&C Act governs nonprescription drugs marketed without an approved application. Under section 505G(a)(3) of the FD&C Act, drugs that were classified as Category III for safety or effectiveness in a TFM that is the most recently applicable proposal or determination for such drug issued under 21 CFR Part 330 – and that were not classified as Category II for safety or effectiveness – are not required to have an approved application under section 505 in order to be marketed, as long as they meet the relevant conditions of use outlined in the applicable TFM, including the active ingredient, and comply with all other applicable requirements. However, your non-alcohol-based antiseptic products do not conform to the 1994 TFM, the Oral Antiseptics Proposed Rule, nor any other TFM, proposed rule, or final rule and do not meet the conditions under section 505G(a)(3) of the FD&C Act for marketing without an approved application under section 505. 7 Specifically, your labeling claims, suggesting that 1.5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, 1% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, .5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, and 1.5% POVIDONE IODINE USP ANTISEPTIC THROAT SPRAY are effective in shortening the duration of infection and preventing infection or disease from the novel coronavirus that causes COVID-19, go beyond merely describing the general intended use of an antiseptic as set forth in the 1994 TFM and the Oral Antiseptics Proposed Rule. 8 In addition, your labeling claims, suggesting that your non-alcohol-based antiseptic products provide up to 4 hours of efficacy against the novel coronavirus that causes COVID-19, are not permitted under the 1994 TFM, the Oral Antiseptics Proposed Rule, or any of the amendments to the TFMs discussed above. Time-specific extended efficacy claims, especially when related to serious-disease related pathogens, may lead to a false sense of security for the general public that may result in infrequent hand washing or the substitution of these products for protective gloves and clothing, which are the principal methods for protecting against the spread of diseases caused by pathogenic microorganisms. As a result, these products may give users the false impression that they need not rigorously adhere to interventions such as social distanc-

ing and exercising good hygienic practices that have been demonstrated to curb the spread of COVID-19. Users who do not follow these interventions are at increased risk for contracting COVID-19 and for spreading disease if they have been exposed to the virus, thereby prolonging the pandemic and increasing its associated morbidity and mortality. In addition, according to the product labeling, 1.5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, 1% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, and .5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY are intended to be applied inside the nostrils. Consumer antiseptic products intended for administration inside the nostrils are not permitted under the 1994 TFM, as further amended by the Consumer Antiseptic Rubs Proposed Rule. 9 Furthermore, 1.5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, 1% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, .5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, and 1.5% POVIDONE IODINE USP ANTISEPTIC THROAT SPRAY are misbranded under section 502(ee) of the FD&C Act, 21 U.S.C. 352(ee), because they are nonprescription drugs subject to section 505G of the FD&C Act, 21 U.S.C. 355h, but do not comply with the requirements for marketing under that section and are not the subject of an application approved under section 505 of the FD&C Act, 21 U.S.C. 355. You should take immediate action to address the violations cited in this letter. This letter is not meant to be an all-inclusive list of violations that exist in connection with your products or operations. It is your responsibility to ensure that the products you sell are in compliance with the FD&C Act and FDA's implementing regulations. We advise you to review your websites, product labels, and other labeling and promotional materials to ensure that you are not misleadingly representing your products as safe and effective for a COVID-19-related use for which they have not been approved by FDA. Within 48 hours, please send an email to COVID-19-Task-Force-CDER@fda.hhs.gov describing the specific steps you have taken to address these violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. Failure to adequately correct any violations may result in legal action, including, without limitation, seizure and injunction. FDA is advising consumers not to purchase or use certain products that have not been approved, cleared, or authorized by FDA and that are being misleadingly represented as safe and/or effective for the treatment or prevention of COVID-19. Your firm will be added to a published list on FDA's website of firms and websites that have received warning letters from FDA concerning the sale or distribution of COVID-19 related products in violation of the FD&C Act. This list can be found at http://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-covid-19-products . Once you have taken corrective actions to address the sale of your unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, and any appropriate corrective actions have been confirmed by FDA, the published list will be updated to indicate that your firm has taken appropriate corrective action. We note however, removal from the published list should not be interpreted to mean that you have properly addressed all other violations for your products and that you are free to proceed with their continued marketing. This letter notifies you of our concerns and provides you with an opportunity to address them. If you cannot take action to address this matter completely within 48 hours, state the reason for the delay and the time within which you will do so. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration. If you are not located in the United States, please note that products that appear to be misbranded or unapproved new drugs may be detained or refused admission if they are offered for importation into the United States. We may advise the appropriate regulatory officials in the country from which you operate that FDA considers your products referenced above to be unapproved and misbranded products that cannot be legally sold to consumers in the United States. Please direct any in-

quiries to FDA at COVID-19-Task-Force-CDER@fda.hhs.gov. FTC Cease and Desist Demand: In addition, it is unlawful under the FTC Act, 15 U.S.C. § 41 et seq., to advertise that a product can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time they are made. For COVID-19, no such study is currently known to exist for the products identified above. Thus, any coronavirus-related prevention or treatment claims regarding such products are not supported by competent and reliable scientific evidence. You must immediately cease making all such claims. Violations of the FTC Act may result in legal action seeking a Federal District Court injunction and an order may require that you pay back money to consumers. In addition, pursuant to the COVID-19 Consumer Protection Act, Section 1401, Division FF, of the Consolidated Appropriations Act, 2021, P.L. 116-260, marketers who make deceptive claims about the treatment, cure, prevention, or mitigation of COVID-19 are subject to a civil penalty of up to $46,517 per violation and may be required to pay refunds to consumers or provide other relief pursuant to Section 19(b) of the FTC Act, 15 U.S.C. § 57b(b). Within 48 hours, please send an email to Richard Cleland, Assistant Director of the FTC's Division of Advertising Practices, via electronic mail at rcleland@ftc.gov certifying that you have ceased making unsubstantiated claims for the products identified above. If you have any questions regarding compliance with the FTC Act, please contact Mr. Cleland at 202-326-3088. Sincerely, /S/ Donald D. Ashley Director Office of Compliance Center for Drug Evaluation and Research Food and Drug Administration Sincerely, /S/ Serena Viswanathan Associate Director Division of Advertising Practices Federal Trade Commission _____1 Your non-alcohol-based antiseptic drug products include 1.5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, 1% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, .5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, and 1.5% POVIDONE IODINE USP ANTISEPTIC THROAT SPRAY. 2 As explained in the next paragraph, there is currently an outbreak of a respiratory disease named "Coronavirus Disease 2019" (COVID-19). 3 Secretary of Health and Human Services, Determination that a Public Health Emergency Exists. (originally issued on Jan. 31, 2020., and subsequently renewed) available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx). 4 Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at https://trumpwhitehouse.archives.gov/presidential-actions/proclamationdeclaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/). 5 1.5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, 1% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, and .5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY 6 1.5% POVIDONE IODINE USP ANTISEPTIC THROAT SPRAY 7 We note that 1.5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, 1% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, .5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, and 1.5% POVIDONE IODINE USP ANTISEPTIC THROAT SPRAY also do not conform to any temporary policy FDA has implemented during the public health emergency. In March 2020, the Agency published three guidance documents to provide regulatory flexibility to certain firms to help meet the demand for alcohol-based hand sanitizer during the COVID-19 public health emergency (PHE). Because your non-alcohol-based consumer antiseptic products are not consistent with the formulations described in these guidances, they do not fall within any temporary Agency policy not to take action against firms manufacturing hand sanitizer products for violations of section 505 of the FD&C Act. Additionally, on December 31, 2021 these guidances were withdrawn, and firms must cease distribution, by March 31, 2022, of any remaining hand sanitizer products that were prepared under the temporary policies before or on December 31, 2021. See, 86 FR 56960, October 13, 2021. 8 The 1994 TFM covers

consumer antiseptics that are indicated for use to decrease bacteria on the skin. 59 FR at 31443. The Oral Antiseptics Proposed Rule covers oral antiseptics that are indicated for use in first aid to help decrease bacterial contamination in minor cuts, minor scrapes or minor oral irritation caused by dental procedures, dentures, orthodontic appliances, or accidental injury and for use by health care professionals for preparation of the oral mucosa prior to injection, dental surgery, or tooth extraction. 59 FR at 6121-22. 9 The 2016 Consumer Antiseptic Rubs Proposed Rule covered consumer antiseptic products intended for use without water. Under the 1994 TFM, as amended by the 2016 Consumer Antiseptic Rubs Proposed Rule, only consumer topical antiseptic products intended for use on the hands without water are permitted. Products intended for other areas of the body such as the nose are not permitted. Content current as of: 03/08/2022 Regulated Product(s) Drugs More Warning Letters Warning Letters About Warning and Close-Out Letters

Click here to see the Original Article

Table 25: Places for report 1422031

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Elmira	42.0898	-76.80773
Americas	United States	United States	39.76	-98.5

Table 26: Drugs for report 1422031

Medicine Name	Medicine Class	Action	ATC Code
povidone-iodine	Iodine products	antiseptics and disinfectants	D08AG02
povidone-iodine	Medicated dressings with antiinfectives	medicated dressings	D09AA09
povidone-iodine	Medicated shampoos	other dermatological preparations	D11AC06
povidone-iodine	Other antiinfectives and antiseptics	antiinfectives and antiseptics, excl. combinations with corticosteroids	G01AX11
povidone-iodine	Antiseptics	throat preparations	R02AA15
povidone-iodine	Other antiinfectives	antiinfectives	S01AX18

Notes: This is to advise you that the United States Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) reviewed your website at the Internet address https://viraldine.com/ on December 21, 2021 and March 1, 2022, respectively. The FDA has observed that your website offers non-alcohol-based antiseptic products1 for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-192 in people. Based on our review, these products are unapproved new drugs sold in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 355(a).

Furthermore, these products are misbranded drugs under sections 502(ee) of the FD&C Act, 21 U.S.C. 352(ee). The introduction or delivery for introduction of these products into interstate commerce is prohibited under sections 301(a) and (d) of the FD&C Act, 21 U.S.C. 331(a) and (d). These violations are described in more detail below. [...] "Results: All concentrations of nasal antiseptics and oral rinse antiseptics evaluated completely inactivated the SARS-CoV-2. Conclusions: Nasal and oral PVP-I antiseptic solutions are effective at inactivating the SARS-CoV-2 at a variety of concentrations after 60-second exposure times. The formulations tested may help to reduce the transmission of SARS-CoV-2 if used for nasal decontamination, oral decontamination, or surface decontamination in known or suspected cases of COVID-19." [from your website https://viraldine.com/faqs-%26-pvp-i-studies] [...]

Annex C

C.4. Sanitisers and disinfectants

Medicine Quality Monitoring Globe

September 7, 2022

This is a summary of the information available in the Medicine Quality Monitoring Globe for the search terms selected between the dates selected. For more information on the terminology used, caveats and the work of the medicine quality group please see the information at: https://www.iddo.org/medicine-quality

Non-Curated reports are those that have been automatically flagged as relevant by the system but have not been manually curated by the curators.

We would be grateful for any feedback on this summary and for the details of any reports that we may have missed.

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Filters applied for this report

Search	("wipes" OR "disinfectant" OR "sanitizer" OR "sanitizing" OR "iodoform" OR "sanitiser")
Start date	2022-01-01
End date	2022-03-31
Language	en
Report type	incident
Curation status	validated
Number of Reports	12

1 ‘Increase risk of cancer’: Health Canada recalls more hand sanitizers

Publication date	2022-02-22
Create date	2022-02-24
Score	19.30
Report id	1408093
Category	Antiseptic
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: ‘Increase risk of cancer’: Health Canada recalls more hand sanitizers Toronto Star

Click here to see the Original Article

Table 1: Places for report 1408093

Region Name	Country	Location	Latitude	Longitude
Americas	Canada	Canada	60.10867	-113.64258

Table 2: Drugs for report 1408093

Medicine Name	Medicine Class	Action	ATC Code
ethanol	Other antiseptics and disinfectants	antiseptics and disinfectants	D08AX08
ethanol	Antidotes	all other therapeutic products	V03AB16
ethanol	Nerve depressants	all other therapeutic products	V03AZ01

Table 3: Other Stories

ID	Title	Link
1419036	’STOP USING IMMEDIATELY’: Shoppers Drug Mart recall involving makeup remover, Sport Chek recall regarding socks and Dollarama recall of hand sanitizers trigger Health Canada warnings to shoppers	Link

Notes: Canada's health agency has added three more hand sanitizer products to its growing list of 48 recalled items which began in the spring of 2021.

Health Canada has recalled the following products: Alcohol Antiseptic 80 per cent (v/v) Topical Solution Hand Sanitizer and Fighting Spirit sanitizer due to possible health risks resulting from "undeclared" elevated levels of acetaldehyde. Both were sold by The Newfoundland Distillery Company.

A third item, Rapid Protectant Hand Sanitizer Gel, is also being recalled due to improper labelling, including "missing risk statements and missing information for vulnerable populations." The product is sold by D&L Distribution and Logistic Services Inc. [...]

2 Health Canada Is Recalling A Slew Of Hand Sanitizers & You Should Definitely Check Yours

Publication date	2022-01-10
Create date	2022-01-18
Score	18.43
Report id	1365051
Category	Antiseptic
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Health Canada Is Recalling A Slew Of Hand Sanitizers & You Should Definitely Check Yours Narcity Canada

Click here to see the Original Article

Table 4: Places for report 1365051

Region Name	Country	Location	Latitude	Longitude
Americas	Canada	Canada	60.10867	-113.64258

Table 5: Drugs for report 1365051

Medicine Name	Medicine Class	Action	ATC Code
ethanol	Other antiseptics and disinfectants	antiseptics and disinfectants	D08AX08
ethanol	Antidotes	all other therapeutic products	V03AB16
ethanol	Nerve depressants	all other therapeutic products	V03AZ01

Notes: Health Canada has just issued a recall on 19 different hand sanitizers, so you'll probably want to make sure your products aren't on the list.

On Friday, October 8, the government agency issued a recall notice that includes products from four different companies. [...]

3 Frozen Wheels, LLC - 619443 - 12/20/2021 - 2022-02-01

Publication date	2022-02-01
Create date	2022-02-03
Score	13.71
Report id	1387296
Category	Antiseptic
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Drug Product/Adulterated

Click here to see the Original Article

Table 6: Places for report 1387296

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Miami	25.77427	-80.19366

Table 7: Drugs for report 1387296

Medicine Name	Medicine Class	Action	ATC Code
ethanol	Other antiseptics and disinfectants	antiseptics and disinfectants	D08AX08
ethanol	Antidotes	all other therapeutic products	V03AB16
ethanol	Nerve depressants	all other therapeutic products	V03AZ01

Notes: [...] The results of FDA laboratory testing of batches of "Greenfrog HAND SANITIZER," "Cleansepure," and "Antibacterial Gel, 70% Ethanol Concentration" drug products detained at the border demonstrate that these drug products are adulterated within the meaning of section 501(d)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act), 21 U.S.C. 351(d)(2), in that a substance was substituted wholly or in part therefor.1 Introduction or delivery for introduction of such products into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a). These violations are described in more detail below. [...]

4 Federal lawsuit claims Triple Five company and Ghermezian family members sold counterfeit hand sanitizer in 2020 - RiverheadLOCAL

Publication date	2022-02-11
Create date	2022-02-17
Score	13.28
Report id	1398834
Category	Antiseptic
Quality	Falsified
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Federal lawsuit claims Triple Five company and Ghermezian family members sold counterfeit hand sanitizer in 2020 - RiverheadLOCAL RiverheadLOCAL

Click here to see the Original Article

Table 8: Places for report 1398834

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5
Americas	Mexico	Mexico	23	-102

Notes: A Triple Five company and members of the Ghermezian family, whose conglomerate is involved in a $40 million land deal with the Town of Riverhead, have been accused of selling counterfeit hand sanitizer beginning in the early days of the COVID-19 pandemic. According to documents filed yesterday in a civil racketeering lawsuit in federal court, Triple Five Worldwide LLC, David Ghermezian and Yonah Ghermezian participated in a ”scheme” to manufacture, import and market counterfeit hand sanitizer produced in Mexico that was put on the ”do not use” list by the FDA for potential methanol contamination. The FDA instructed the public to ”stop using it immediately… (and) throw it away in a hazardous waste container.” The counterfeit hand sanitizer was marketed using the name, logo and design trademarked by a U.S. company, which was already selling hand sanitizer made in the USA at various retailers across the country, according to the complaint filed yesterday in U.S. District Court for the Southern District of New York. [...]

5 Spurious sanitizers, COVID -19 test kits worth Rs 37L seized in Krishna

Publication date	2022-02-02
Create date	2022-02-10
Score	12.59
Report id	1388981
Category	Antiseptic, Medical device for screening/diagnosis/monitoring
Quality	Falsified
Source	Clandestine laboratory
Curation	Manually curated
Incident or General	Incident

Snippet: Spurious sanitizers, COVID -19 test kits worth Rs 37L seized in Krishna NewsMeter

Click here to see the Original Article

Table 9: Places for report 1388981

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Krishna	16.66667	81

Table 10: Drugs for report 1388981

Medicine Name	Medicine Class	Action	ATC Code
	Antiseptics	throat preparations	R02AA

Notes: Drugs Control Administration (DCA) has seized spurious hand sanitizers and COVID -19 test kits worth Rs 37 lakh in the Krishna district. On credible information, DCA officials raided Vaishnavi Garments aka Vaishnavi Enterprises at Subbaramaiah Street and found spurious hand sanitizers and COVID-19 test kits worth Rs 37 lakh. During the investigation, they found that Vaishnavi Enterprises did not possess any drug licence. [...]

6 Hand sanitisers sold in Johannesburg contained traces of toxic ingredients

Publication date	2022-03-26
Create date	2022-04-04
Score	11.44
Report id	1440571
Category	Antiseptic
Quality	Substandard
Source	Street vendors
Curation	Manually curated
Incident or General	Incident

Snippet: Hand sanitisers sold in Johannesburg contained traces of toxic ingredients HeraldLIVE

Click here to see the Original Article

Table 11: Places for report 1440571

Region Name	Country	Location	Latitude	Longitude
Southern Africa	South Africa	Johannesburg	-26.20227	28.04363

Notes: A new study has revealed that many hand sanitiser brands sold in Johannesburg in the early stages of the Covid-19 pandemic contained traces of toxic ingredients and less alcohol than required. [...] The researchers collected 94 samples of hand sanitiser from shops and street vendors between March and June 2020.

"While more (56%) brands of hand sanitiser in this study contained the recommended concentration of alcohol, there were also many (44%) substandard and possibly subpotent preparations," the study found.

"The study also found that only 30% (10 gels and 9 liquids) of the analysed hand sanitisers contained 80% alcohol.

"Even though alcohol concentrations higher than 80% are known to be less potent against bacteria because proteins are not easily denatured in the absence of water, this bodes well for disinfection against SARS-CoV-2 as ethanol at 80% is highly effective against enveloped viruses." Researchers also established that some hand sanitisers contained toxic ingredients. "This is worrying because even if a hand sanitiser contains enough alcohol as recommended or contains ingredients that enhance its virucidal activity in case of low alcohol content ... the presence of toxic ingredients renders the preparation harmful and unfit for human use," they said. [...]

7 Wound Care Gel Recalled by a Manufacturer in California Due to Bacterial Contamination Concerns - Benzing

Publication date	2022-03-17
Create date	2022-03-22
Score	7.63
Report id	1431653
Category	Antiseptic
Quality	Substandard
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Wound Care Gel Recalled by a Manufacturer in California Due to Bacterial Contamination Concerns - Benzing Benzinga

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Table 12: Places for report 1431653

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5

Notes: The U.S. Food & Drug Administration (FDA) recently posted information about a manufacturer of FDA-registered products in California that announced a voluntary recall of one lot of a wound care gel. The recall was initiated because of concerns over potential microbial contamination with Bacillus cereus. The gel was distributed to 61 physician clinics in 17 states. [...] "Fortunately, at the time of the recall posting, the manufacturer had not had any reports of adverse events related to the product," said Michael Chapman, Laboratory Manager at LA Testing's Huntington Beach facility. "At LA Testing, we are dedicated to helping manufacturers, distributors, retailers, and importers avoid these types of costly product recalls, and the health risks associated with contaminated products reaching consumers. With multiple laboratories in California, LA Testing provides microbial and chemical testing for a broad spectrum of contaminants, including Bacillus cereus. We also provide services such as shelf life testing, contamination source tracking, and sterility and sanitation validation." [...]

8 Agropharma Laboratories, Inc. - Office of Pharmaceutical Quality Operations, Division II - CGMP/Finished Pharmaceuticals/Adulterated - 2022-03-29

Publication date	2022-03-29
Create date	2022-04-04
Score	7.61
Report id	1442890
Category	Antiseptic
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER Agropharma Laboratories, Inc. MARCS-CMS 623475 — March 25, 2022 Share Tweet Linkedin Email Print Delivery Method: VIA Electronic Mail Product: Drugs Recipient: Recipient Name Mr. Jorge Gonzalez Camp Recipient Title President Agropharma Laboratories, Inc. Urb Industrial Salinas Carr 701 Salinas 00751 Puerto Rico tato@oleincorp.com agropharma_lab@yahoo.com Issuing Office: Office of Pharmaceutical Quality Operations, Division II United States DATE: 3/25/2022 Case #: 623475 WARNING LETTER Dear Mr. Gonzalez Camp: The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Agropharma Laboratories, Inc., FEI 3000203462, at Carr 701 Km 0.4, Playa Salinas Industrial Park, Salinas, Puerto Rico, from October 21 to November 3, 2021. This warning letter summarizes significant violations of Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals. See Title 21, Code of Federal Regulations (CFR), parts 210 and 211 (21 CFR parts 210 and 211). Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug products are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B). We reviewed your December 6, 2021, response to our Form FDA 483 in detail. Although you mentioned that you engaged the services of a consultant to help you complete a detailed evaluation of the observations and provide responses, you did not provide specific information or evidence of corrective actions to the observations identified during the inspection on our Form FDA 483. During our inspection, our investigators observed specific violations including, but not limited to, the following. 1. Your firm's quality control unit failed to exercise its responsibility to ensure drug products manufactured are in compliance with CGMP, and meet established specifications for identity, strength, quality, and purity (21 CFR 211.22). Your firm manufactures over-the-counter antiseptics indicated for open wounds, as well as hand sanitizers 1 labeled for use by healthcare personnel. Your Quality Unit (QU) did not provide adequate oversight for the manufacture of your drug products. For example, your QU failed to ensure the following: Adequate testing of your incoming components for identity, purity, strength, and other appropriate quality attributes (21 CFR 211.84(d)(1) and (2)). Adequate testing and appropriate specifications

for your finished drug products (21 CFR 211.165(a)). Adequate procedures describing process validation, investigations, deviations, equipment cleaning, and change management (21 CFR 211.22(d)). Adherence to your ongoing stability program (21 CFR 211.166(a)). Performance of annual product reviews (21 CFR 211.180(e)). Your firm's quality systems are inadequate. See FDA's guidance document Quality Systems Approach to Pharmaceutical CGMP Regulations for help in implementing quality systems and risk management approaches to meet the requirements of CGMP regulations 21 CFR parts 210 and 211, at https://www.fda.gov/media/71023/download . In response to this letter, provide a comprehensive assessment and remediation plan to ensure that your QU is given the authority and resources to function effectively. The assessment should also include, but not be limited to: A determination of whether procedures used by your firm are robust and appropriate. Provisions for QU oversight throughout your operations to evaluate adherence to appropriate practices. A complete and final review of each batch and its related information before the QU disposition decision Oversight and approval of investigations and discharging of all other QU duties to ensure identity, strength, quality, and purity of all drug products. 2. Your firm failed to maintain the buildings used in the manufacture, processing, packing, or holding of a drug product in a clean and sanitary condition (21 CFR 211.56(a)). Drug manufacturing areas at your facility were in disrepair. For example, our investigator observed facility damage such as broken walls in the production area, filth, and pooling water in close proximity to open manufacturing equipment. In response to this letter, provide your corrective action and preventive action (CAPA) plan to implement routine, vigilant operations management oversight of facilities and equipment. This plan should ensure, among other things, prompt detection of equipment/facilities performance issues, effective execution of repairs, adherence to appropriate preventive maintenance schedules, timely technological upgrades to the equipment/facility infrastructure, and improved systems for ongoing management review. 3. Your firm failed to establish written procedures for production and process control designed to assure that the drug products you manufacture have the identity, strength, quality, and purity they purport or are represented to possess (21 CFR 211.100(a)). Your firm has not established that your processes used to manufacture drug products are validated. Additionally, your firm uses water from your water system as a component to manufacture your drug products; however, you have not established that the water system is adequately designed, controlled, maintained, and monitored to ensure that it consistently produced water suitable for its intended use. Your firm lacks a process validation program. Process validation evaluates the soundness of design and state of control of a process throughout its lifecycle. Each significant stage of a manufacturing process must be designed appropriately and ensure the quality of raw material inputs, in-process materials, and finished drugs. Process qualification studies determine whether an initial state of control has been established. Successful process qualification studies are necessary before commercial distribution. Thereafter, ongoing vigilant oversight of process performance and product quality is necessary to ensure that you maintain a stable manufacturing operation throughout the product lifecycle. See FDA's guidance document Process Validation: General Principles and Practices for general principles and approaches that FDA considers appropriate elements of process validation, at https://www.fda.gov/media/71021/download . In response to this letter, provide the following: A detailed summary of your validation program for ensuring a state of control throughout the product lifecycle, along with associated procedures. Describe your program for process performance qualification, and ongoing monitoring of both intra-batch and inter-batch variation to ensure a continuing state of control. A timeline for performing appropriate process performance qualification for each of your marketed drug products. Include your process performance protocol(s), and written procedures for qualification of equipment and facilities. Provide a detailed program for designing, validating, maintaining, controlling and monitoring each of our manufacturing processes

that includes vigilant monitoring of intra-batch and inter-batch variation to ensure an ongoing state of control. Also, include your program for qualification of your equipment and facility. A comprehensive, independent assessment of your water system design, control, and maintenance. A thorough remediation plan to install and operate a suitable water system. Include a robust ongoing control, maintenance, and monitoring program to ensure the remediated system design consistently produces water adhering to Purified Water, USP monograph specifications and appropriate microbial limits. Regarding the latter, ensure that your total microbial count limit for water is appropriate in view of the intended use of the products produced by your firm. A detailed risk assessment addressing the potential effects of the observed water system failures on the quality of all drug product lots currently in U.S. distribution or within expiry. Specify actions that you will take in response to the risk assessment, such as customer notifications and product recalls. Drug Production Ceased We acknowledge your commitment to cease production of drugs at this facility. However, your firm continues to be registered as a manufacturer. In response to this letter, clarify whether you intend to resume manufacturing any drugs at this facility or another in the future. If you plan to resume manufacturing drugs, ensure that adequate corrective actions are in place and notify this office to schedule a meeting before resuming your operations. Based upon the nature of the violations we identified at your firm, if your firm intends to resume manufacturing drugs for the U.S. market, we strongly recommend engaging a consultant qualified as set forth in 21 CFR 211.34 to assist your firm in meeting CGMP requirements. Your use of a consultant does not relieve your firm's obligation to comply with CGMP. Your firm's executive management remains responsible for resolving all deficiencies and systemic flaws to ensure ongoing CGMP compliance. Repeat Violations and Observations at Facility In a previous Untitled Letter (11-SJN-UTL-02) dated October 13, 2010, and in subsequent inspections, FDA cited similar CGMP violations and observations. Repeated failures demonstrate that executive management oversight and control over the manufacture of drugs is inadequate. Conclusion The violations cited in this letter are not intended to be an all-inclusive list of violations that exist at your facility. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations. Correct any violations promptly. Failure to promptly and adequately address these violations may result in regulatory or legal action without further notice including, without limitation, seizure, and injunction. Unresolved violations may also prevent other Federal agencies from awarding contracts. Failure to address violations may also cause FDA to withhold issuance of Export Certificates. FDA may withhold approval of new applications or supplements listing your firm as a drug manufacturer until any violations are completely addressed and we confirm your compliance with CGMP. We may re-inspect to verify that you have completed corrective actions to address any violations. This letter notifies you of our findings and provides you an opportunity to address the above deficiencies. After you receive this letter, respond to this office in writing within 15 working days. Specify what you have done to address any violations and to prevent their recurrence. In response to this letter, you may provide additional information for our consideration as we continue to assess your activities and practices. If you cannot complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion. Your written notification should refer to case # 623475 . Please electronically submit your reply, on company letterhead, to Dayna I. Martinez, Compliance Officer, at ORAPHARM2_RESPONSES@fda.hhs.gov. In addition, please submit a signed copy of your response to dayna.matinez@fda.hhs.gov and orapharm2actingdcb@fda.hhs.gov If you have questions regarding the contents of this letter, you may contact Dayna I. Martinez via phone at (787) 729-8608 or email at dayna.martinez@fda.hhs.gov Sincerely, /S/ Monica R. Maxwell Program Division Director Office of Pharmaceutical Quality Operations, Division II Cc: Ms. Marianela Maldonado Resident Agent Agropharma Laboratories, Inc. P.O. Box 1150 Salinas, Puerto

Rico 00751-1150 mmaldonado@oleincorp.com _____1 Due to an increased demand for alcohol-based hand sanitizers during the COVID-19 pandemic, FDA published the Guidance for Industry: Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) on March 19, 2020, and subsequently updated the guidance several times. The guidance was withdrawn effective December 31, 2021 (86 Fed Reg at 56960). This guidance communicated the Agency's temporary policy that we did not intend to take action against firms for CGMP violations under section 501(a)(2)(B) of the FD&C Act if such firms prepared alcohol-based hand sanitizers for consumer use (or for use as a health care personnel hand rub) during the public health emergency, provided certain circumstances described in the guidance are present. These circumstances included preparation of hand sanitizer products using only the ingredients and formulas set forth in the guidance. A review of the formulations of the drug products indicates that such products were not prepared consistent with FDA's temporary policy set forth in the guidance. Because Agropharma's hand sanitizer drug products were not consistent with the formulations described in these guidances, they did not fall within any temporary Agency policy not to take action against firms manufacturing hand sanitizer drug products for violations of section 505 of the FD&C Act. Content current as of: 03/29/2022 Regulated Product(s) Drugs More Warning Letters Warning Letters About Warning and Close-Out Letters

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Table 13: Places for report 1442890

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5
Americas	United States	Salinas	36.67774	-121.6555

Table 14: Drugs for report 1442890

Medicine Name	Medicine Class	Action	ATC Code
	Antiseptics	throat preparations	R02AA

Notes: This warning letter summarizes significant violations of Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals. See Title 21, Code of Federal Regulations (CFR), parts 210 and 211 (21 CFR parts 210 and 211).

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug products are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B). [...]

9 FDA Alerts the Public to Potentially Contaminated Products from Family Dollar Stores in Six States | FDA

Publication date 2022-02-18

Create date 2022-02-21

Score 4.86

Report id 1404932

Category Other, Medical device used for cure/mitigation/treatment, Herbal medicine, Medical devices for disease prevention, Vitamin, Ophthalmic medicines, Analgesic, Nutritional supplement

Quality Substandard

Source Manufacturer

Curation Manually curated

Incident or General Incident

Snippet: FDA Alerts the Public to Potentially Contaminated Products from Family Dollar Stores in Six States | FDA FDA.gov

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Table 15: Places for report 1404932

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Arkansas	34.75037	-92.50044
Americas	United States	Mississippi	32.75041	-89.75036
Americas	United States	Louisiana	31.00047	-92.0004
Americas	United States	Alabama	32.75041	-86.75026
Americas	United States	Tennessee	35.75035	-86.25027
Americas	United States	Missouri	38.25031	-92.50046

Table 16: Drugs for report 1404932

Medicine Name	Medicine Class	Action	ATC Code
			A12
			A11
	Vitamins	i.v. solution additives	B05XC
		antacids	A02A
			N02

Table 17: Other Stories

ID	Title	Link
1404962	FDA Alerts the Public to Potentially Contaminated Products from Family Dollar Stores in Six States - 2022-02-18	Link
1405004	FDA warns of contaminated products from Family Dollar stores in six states including Arkansas	Link
1405009	FDA says Family Dollar stores could have potentially contaminated products	Link
1405048	PUBLIC WARNING: Multiple Family Dollar items contaminated after major rat infestation	Link
1405110	Family Dollar products in the Mid-South could be contaminated due to rodent infestation, FDA says	Link
1405141	FDA warns rodent infestation could affect some Family Dollar products in Missouri	Link
1405241	Hundreds of rodents found inside Family Dollar facility	Link
1405243	Family Dollar items possibly contaminated by live and dead rodents, FDA warns	Link
1405352	FDA warns rodent infestation could affect products in Alabama, Tennessee	Link
1405483	FDA warns rodent infestation could affect products in Arkansas, Louisiana	Link
1405535	FDA issues warning after Family Dollar distribution center found infested with rodents	Link
1405538	1,110 rodents found in Family Dollar Arkansas warehouse: FDA	Link
1405582	1,110 rodents found in Family Dollar Arkansas warehouse: FDA - New York Daily News	Link
1405645	Look for Potentially Contaminated Products from Family Dollar Stores in Six States	Link
1405723	Family Dollar issues voluntary recall for possible rodent contamination of items	Link
1405724	Over 1,000 dead rodents found at Family Dollar distribution center	Link
1406298	Family Dollar Shutters 400 Stores After Recall	Link
1406344	FDA issues Alert about Potentially Contaminated Products from Family Dollar Stores in Six States	Link
1406887	Family Dollar Closes 400 Stores, Recalls Products After FDA Finds Dead Rats in Warehouse	Link
1407495	US Food and Drug Administration (FDA) issues recall of Family Dollar products following rodent infestation	Link
1407788	FDA Warns of Rat Feces, Dead Birds in Family Dollar Products	Link
1408146	Dollar Store Recall Hits Six States	Link
1408841	FDA inspectors found rodents, 'putrid odor' at Arkansas Family Dollar distribution facility	Link

Table 17: Other Stories(continued)

ID	Title	Link
1409563	Arkansas Department of Health releases Family Dollar warehouse inspection reports	Link
1410142	Public alerted to potentially contaminated products | News | thewestsidejournal.com	Link
1411772	FDA alerts public to potentially contaminated products from Family Dollar Stores in Tennessee	Link
1412364	FDA reports potentially contaminated products from Family Dollar stores in six states	Link
1414004	FDA warns after Family Dollar distribution center found infested with rodents	Link
1415222	FDA recalls certain Family Dollar products in 6 states over rodent infestation at plant	Link
1418450	FDA warns of potential contaminated products from Family Dollar - Lowndes Signal | Lowndes Signal	Link
1418677	Rats overwhelm Family Dollar warehouse; 404 stores closed as part of recall	Link
1435020	FDA alerts public to potentially-contaminated products from Family Dollar stores	Link
1474587	Arkansas attorney general files suit against Family Dollar Stores, Dollar Tree after rodent infestation at distribution site	Link

Notes: Today, the U.S. Food and Drug Administration is alerting the public that several categories of FDA-regulated products purchased from Jan. 1, 2021, through the present from Family Dollar stores in Alabama, Arkansas, Louisiana, Mississippi, Missouri and Tennessee may be unsafe for consumers to use. The impacted products originated from the company's distribution facility in West Memphis, Arkansas, where an FDA inspection found insanitary conditions, including a rodent infestation, that could cause many of the products to become contaminated. The FDA is working with the company to initiate a voluntary recallExternal Link Disclaimer of the affected products. [...] This alert covers FDA-regulated products purchased from Family Dollar stores in those six states from Jan. 1, 2021, through the present. Some examples of these products include human foods (including dietary supplements (vitamin, herbal and mineral supplements)), cosmetics (skincare products, baby oils, lipsticks, shampoos, baby wipes), animal foods (kibble, pet treats, wild bird seed), medical devices (feminine hygiene products, surgical masks, contact lens cleaning solutions, bandages, nasal care products) and over-the-counter (OTC) medications (pain medications, eye drops, dental products, antacids, other medications for both adults and children). [...]

10 Iotech International, LLC - Center for Drug Evaluation and Research | CDER - Unapproved New Drug and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19) - 2022-03-17

Publication date	2022-03-17
Create date	2022-03-22
Score	4.16
Report id	1431684
Category	Antiseptic
Quality	Diverted/Unregistered
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER Iotech International, LLC MARCS-CMS 617715 — March 15, 2022 Share Tweet Linkedin Email Print Product: Drugs Recipient: Recipient Name Herb Moskowitz, DDS Iotech International, LLC 6560 E. Rogers Circle Boca Raton , FL 33487 United States herbmoskowitz@iotechinternational.com Issuing Office: Center for Drug Evaluation and Research | CDER United States Federal Trade Commission WARNING LETTER DATE: March 15, 2022 Unapproved New Drug and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19) This is to advise you that the United States Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) reviewed your website at the Internet address www.iotechinternational.com on July 30 and September 9, 2021; and March 9, 2022, respectively. We have also reviewed your Facebook and Instagram social media website at the Internet addresses, https://www.facebook.com/iotechintl/ and https://www.instagram.com/iotech.international/, respectively, where you direct consumers to your website, www.iotechinternational.com, to purchase your products. The FDA has observed that your website offers "ioRinse" (also referred to as "ioRinse™ RTU") and "ioCleanse Molecular iodine Hand Cleanser" for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19 1 in people. Based on our review, these products are unapproved new drugs sold in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 355(a). Furthermore, these products are misbranded drugs under section 502(ee) of the FD&C Act, 21 U.S.C. § 352 (ee). The introduction or delivery for introduction of such products into interstate commerce is prohibited under sections 301(a) and (d) of the FD&C Act, 21 U.S.C. § 331 (a) and (d). These violations are described in more detail below. There is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2). The disease caused by the virus has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS. 2 In addition, on March 13, 2020, there was a

Presidential declaration of a national emergency in response to COVID-19 that subsequently has been extended. 3 Therefore, FDA is taking urgent measures to protect consumers from certain products that, without approval or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. As described below, you sell products that are intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. We request that you take immediate action to cease the sale of any unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. Examples of the claims observed on the "ioRinse" and "ioCleanse Molecular iodine Hand Cleanser" product labeling that provide evidence of the intended uses (as defined in 21 CFR 201.128) of your products, and misleadingly represent them as safe and/or effective for the treatment or prevention of COVID-19 include but may not be limited to, the following: • "A New Super Class of Anti-microbials that kill #coronavirus . . . @iotech.international developed novel Anti-microbials that kill #coronavirus and surpass Chlorihexidine Gluconate in Efficacy. Safe . . . Highly engineered products created by a dentist and chemists. Order today: @iotech.international" [from a March 10, 2020 post on your Instagram webpage, https://www.instagram.com/iotech.international/] • "The aim of the present study was to evaluate and compare the efficacy and cytotoxicity of four different mouthwashes containing 1.5% hydrogen peroxide, 0.2% povidone, 0.12% chlorhexidine and 100 ppm molecular iodine for the ability to inactivate severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) . . . Conclusion: The spread of infection through aerosol and splatter has long been considered one of the main concerns in the dental community. A preprocedural rinse with 100 ppm molecular iodine will play a vital role in combating COVID-19 pandemic by preventing the spread of infection." [from an article entitled "Comparative Analysis of Antiviral Efficacy of Four Different Mouthwashes against Severe Acute Respiratory Syndrome Coronavirus 2: An In Vitro Study" that you provide a link to on your website and that accompanies your products] • "Iotech International's formula 100-S [containing molecular iodine] displayed the greatest antiviral activity of all the tested rinses, completely inactivating SARS-COV-2 within 30 seconds." [from an article entitled "Comparative Analysis of Antiviral Efficacy of Four Different Mouthwashes against Severe Acute Respiratory Syndrome Coronavirus 2: An In Vitro Study" that you provide a link to on your website and that accompanies your products] • "Introducing ioCleanse . . . Non-Staining IoCleanse Hand Cleanser contains the most powerful form of iodine, Molecular Iodine . . . Successfully tested to destroy normal Coronavirus (strain #229E) within seconds. . . . Clinically Proven: Iodine is more effective as an ANTIVIRAL AGENT than Alcohol Sanitizers" [from an April 18, 2020 post on your Facebook webpage, https://www.facebook.com/iotechintl/] Based on the above claims, "ioRinse" and "ioCleanse Molecular iodine Hand Cleanser" are drugs as defined by section 201(g)(1)(B) of the FD&C Act, 21 U.S.C. § 321(g)(1)(B), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and/or under section 201(g)(1)(C) of the FD&C Act, 21 U.S.C. 321(g)(1)(C), because they are intended to affect the structure or any function of the body. Specifically, "ioRinse" and "ioCleanse Molecular iodine Hand Cleanser" are intended for use as an oral antiseptic rinse and as a consumer topical antiseptic, respectively. This oral antiseptic rinse and topical antiseptic are "new drugs" within the meaning of section 201(p) of the FD&C Act, 21 U.S.C. 321(p), because they are not generally recognized as safe and effective (GRASE) for use under the conditions prescribed, recommended, or suggested in their labeling. New drugs may not be introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in section 505(a) of the FD&C Act, 21 U.S.C. 355(a), unless they are lawfully marketed under section 505G of the FD&C Act (which is not the case for these products, as further described below) or under other exceptions not applicable here. No FDA-approved applications pursuant to section 505 of the FD&C Act, 21 U.S.C. 355, is in effect for these drug products, nor are we aware of any adequate

and well-controlled clinical studies in the published literature that support a determination that "ioRinse" and "ioCleanse Molecular iodine Hand Cleanser" are GRASE for use under the conditions suggested, recommended, or prescribed in their labeling. Accordingly, these drug products are unapproved new drugs marketed in violation of sections 505(a) and 301(d) of the FD&C Act, 21 U.S.C 355(a) and 331(d). 4 We note that over-the-counter (OTC) topical antiseptic products, like "ioCleanse Molecular iodine Hand Cleanser," had been the subject of rulemaking under the Agency's OTC Drug Review. In particular, such products were addressed in a tentative final monograph (TFM) entitled "Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Health-Care Antiseptic Drug Products," Proposed Rule, 59 FR 31402 (June 17, 1994) (1994 TFM), as further amended by Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record," Proposed Rule, 81 FR 42912 (June 30, 2016) (Consumer Antiseptic Rubs Proposed Rule). Over the course of these rulemakings, three active ingredients (benzalkonium chloride, ethyl alcohol (ethanol), and isopropyl alcohol) were classified as Category III for use in consumer antiseptic rub products, meaning that additional safety and effectiveness data are needed to support a determination that a drug product containing one of these active ingredients would be GRASE for use as a consumer antiseptic rub. Oral antiseptics like "ioRinse" were addressed in a TFM entitled "Oral Health Care Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Oral Antiseptic Drug Products"; Proposed Rule, 59 FR 6084 (February 9, 1994) (Oral Antiseptics Proposed Rule). The Oral Antiseptics Proposed Rule classified a number of active ingredients, including iodine, as Category III for use by consumers in antiseptic-containing drug products applied topically to the oral cavity to help prevent infection in minor cuts, scrapes or oral irritation caused by dental procedures, dentures, orthodontic appliances, or accidental injury, because additional effectiveness data are needed to support a determination that a drug product containing one of these active ingredients would be GRASE for use as an OTC oral antiseptic (59 FR 6084 at 6121-6122). Section 505G of the FD&C Act addresses nonprescription drugs marketed without an approved application. Under section 505G(a)(3) of the FD&C Act, drugs that were classified as Category III for safety or effectiveness in a TFM that is the most recently applicable proposal or determination for such drug issued under 21 CFR Part 330 – and that were not classified as Category II for safety or effectiveness – are not required to have an approved application under section 505 in order to be marketed, as long as they meet the relevant conditions of use outlined in the applicable TFM and comply with all other applicable requirements. However, your "ioRinse" and "ioCleanse Molecular iodine Hand Cleanser" products do not conform to the 1994 TFM, the Oral Antiseptics Proposed Rule, or any other TFM, proposed rule, or final rule and do not meet the conditions under section 505G(a)(3) of the FD&C Act for marketing without an approved application under section 505. Specifically, your labeling claims 5 suggesting that your oral antiseptic rinse and topical antiseptic products are effective in inactivating and thus preventing infection or disease from the novel coronavirus that causes COVID-19 go beyond merely describing the general intended uses of an antiseptic as set forth in the Oral Antiseptic Proposed Rule and the 1994 TFM, as amended by the 2016 Consumer Antiseptic Rubs Proposed Rule, respectively. 6 In addition, your "ioCleanse Molecular iodine Hand Cleanser" product contains an active ingredient, molecular iodine, which was not one of the three active ingredients classified as Category III in the 1994 TFM. Although molecular iodine is not explicitly identified as an active ingredient on the label of your "ioCleanse Molecular iodine Hand Cleanser" products, your label and labeling clearly represent molecular iodine as an active ingredient, which is defined as a component of a drug intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to

affect the structure or function of the body (see 21 CFR 201.66(b)(2)). Your labeling includes statements such as, "ioTECH International is the leading molecular iodine research and manufacturing company dispensing a patented, breakthrough germicidal product line branded as ioRinse and ioCleanse." In addition, "ioRinse" and "ioCleanse Molecular iodine Hand Cleanser" products are misbranded under section 502(ee) of the FD&C Act, 21 U.S.C. 352(ee), because they are nonprescription drugs subject to section 505G of the FD&C Act, 21 U.S.C. 355h, but do not comply with the requirements for marketing under that section and are not the subject of an application approved under section 505 of the FD&C Act, 21 U.S.C. 355. You should take immediate action to address the violations cited in this letter. This letter is not meant to be an all-inclusive list of violations that exist in connection with your products or operations. It is your responsibility to ensure that the products you sell are in compliance with the FD&C Act and FDA's implementing regulations. We advise you to review your websites, product labels, and other labeling and promotional materials to ensure that you are not misleadingly representing your products as safe and effective for a COVID-19-related use for which they have not been approved by FDA and that you do not make claims that misbrand the products in violation of the FD&C Act. Within 48 hours, please send an email to COVID-19-Task-Force-CDER@fda.hhs.gov describing the specific steps you have taken to address these violations. Include an explanation of each step being taken to prevent the recurrence of any violations, as well as copies of related documentation. Failure to adequately correct any violations may result in legal action, including, without limitation, seizure and injunction. FDA is advising consumers not to purchase or use certain products that have not been approved, cleared, or authorized by FDA and that are being misleadingly represented as safe and/or effective for the treatment or prevention of COVID-19. Your firm will be added to a published list on FDA's website of firms and websites that have received warning letters from FDA concerning the sale or distribution of COVID-19 related products in violation of the FD&C Act. This list can be found at http://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-covid-19-products . Once you have taken actions to address the sale of your unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, and any appropriate corrective actions have been confirmed by FDA, the published list will be updated to indicate that your firm has taken such corrective actions. We note however, removal from the published list should not be interpreted to mean that you have properly addressed all other violations for your products and that you are free to proceed with their continued marketing. This letter notifies you of our concerns and provides you with an opportunity to address them. If you cannot take action to address this matter completely within 48 hours, state the reason for the delay and the time within which you will do so. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration. If you are not located in the United States, please note that products that appear to be misbranded or unapproved new drugs may be detained or refused admission if they are offered for importation into the United States. We may advise the appropriate regulatory officials in the country from which you operate that FDA considers your product(s) referenced above to be unapproved and misbranded products that cannot be legally sold to consumers in the United States. Please direct any inquiries to FDA at COVID-19-Task-Force-CDER@fda.hhs.gov . FTC Cease and Desist Demand: In addition, it is unlawful under the FTC Act, 15 U.S.C. § 41 et seq., to advertise that a product can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time they are made. For COVID-19, no such study is currently known to exist for the products identified above. Thus, any coronavirus-related prevention or treatment claims regarding such products are not supported by competent and reliable scientific evidence.

You must immediately cease making all such claims. Violations of the FTC Act may result in legal action seeking a Federal District Court injunction and an order may require that you pay back money to consumers. In addition, pursuant to the COVID-19 Consumer Protection Act, Section 1401, Division FF, of the Consolidated Appropriations Act, 2021, P.L. 116-260, marketers who make deceptive claims about the treatment, cure, prevention, or mitigation of COVID-19 are subject to a civil penalty of up to $46,517 per violation and may be required to pay refunds to consumers or provide other relief pursuant to Section 19(b) of the FTC Act, 15 U.S.C. § 57b(b). Within 48 hours, please send an email to Richard Cleland, Assistant Director of the FTC's Division of Advertising Practices, via electronic mail at rcleland@ftc.gov certifying that you have ceased making unsubstantiated claims for the products identified above. If you have any questions regarding compliance with the FTC Act, please contact Mr. Cleland at 202-326-3088. Sincerely, /S/ Donald D. Ashley Director Office of Compliance Center for Drug Evaluation and Research Food and Drug Administration Sincerely, /S/ Serena Viswanathan Associate Director Division of Advertising Practices Federal Trade Commission cc: jgolden@goldendentalsolutions.com Curt Lawler, Goldendent LLC 27115 Gratiot Ave. Ste B Roseville, MI 48066 _____1 As explained in the next paragraph, there is currently an outbreak of a respiratory disease named "Coronavirus Disease 2019" (COVID-19). 2 Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx . 3 Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/ . 4 We note that "ioRinse" and "ioCleanse Molecular iodine Hand Cleanser" also do not conform to any temporary policy FDA has implemented during the public health emergency. In March 2020, the Agency published three guidance documents to provide regulatory flexibility to certain firms to help meet the demand for alcohol-based hand sanitizer during the COVID-19 public health emergency (PHE). Because your non-alcohol-based consumer antiseptic products are not consistent with the formulations described in these guidances, they do not fall within any temporary Agency policy not to take action against firms manufacturing hand sanitizer products for violations of section 505 of the FD&C Act. Additionally, on December 31, 2021 these guidances were withdrawn, and firms must cease distribution, by March 31, 2022, of any remaining hand sanitizer products that were prepared under the temporary policies before or on December 31, 2021. See, 86 FR 56960, October 13, 2021. 5 The FD&C Act defines labeling in broad terms, such that labeling means all labels and "other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article (see section 201(m) of the FD&C Act (21 U.S.C. 321(m)). This definition does not require labeling to be physically attached to a drug product. 6 The 1994 TFM covers health care antiseptics that are indicated for use to help reduce bacteria that potentially can cause disease and health care and consumer antiseptics that are indicated for use to decrease bacteria on the skin. 59 FR at 31443. Content current as of: 03/17/2022 Regulated Product(s) Drugs More Warning Letters Warning Letters About Warning and Close-Out Letters

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Table 18: Places for report 1431684

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Boca Raton	26.35869	-80.0831

Table 19: Drugs for report 1431684

Medicine Name	Medicine Class	Action	ATC Code
	Antiseptics	throat preparations	R02AA

Notes: [...] The FDA has observed that your website offers ”ioRinse” (also referred to as ”ioRinse™ RTU”) and ”ioCleanse Molecular iodine Hand Cleanser” for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-191 in people. Based on our review, these products are unapproved new drugs sold in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 355(a). Furthermore, these products are misbranded drugs under section 502(ee) of the FD&C Act, 21 U.S.C. § 352 (ee). The introduction or delivery for introduction of such products into interstate commerce is prohibited under sections 301(a) and (d) of the FD&C Act, 21 U.S.C. § 331 (a) and (d). These violations are described in more detail below. [...]

11 Viraldine, LLC - Center for Drug Evaluation and Research | CDER - Unapproved New Drug Products Related to Coronavirus Disease 2019 (COVID-19) - 2022-03-08

Publication date	2022-03-08
Create date	2022-03-11
Score	4.09
Report id	1422031
Category	Antiseptic
Quality	Diverted/Unregistered
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER Viraldine, LLC MARCS-CMS 625675 — March 07, 2022 Share Tweet Linkedin Email Print Product: Drugs Recipient: Viraldine, LLC 311 Lake Street Elmira , NY 14901 United States infor@viraldine.com Issuing Office: Center for Drug Evaluation and Research | CDER United States Federal Trade Commission WARNING LETTER Date: March 7, 2022 RE: Unapproved New Drug Products Related to Coronavirus Disease 2019 (COVID-19) This is to advise you that the United States Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) reviewed your website at the Internet address https:// viraldine.com/ on December 21, 2021 and March 1, 2022, respectively. The FDA has observed that your website offers non-alcohol-based antiseptic products 1 for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19 2 in people. Based on our review, these products are unapproved new drugs sold in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 355(a). Furthermore, these products are misbranded drugs under sections 502(ee) of the FD&C Act, 21 U.S.C. 352(ee). The introduction or delivery for introduction of these products into interstate commerce is prohibited under sections 301(a) and (d) of the FD&C Act, 21 U.S.C. 331(a) and (d). These violations are described in more detail below. There is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2). The disease caused by the virus has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS. 3 In addition, on March 13, 2020, there was a Presidential declaration of a national emergency in response to COVID-19 that subsequently has been extended. 4 Therefore, FDA is taking urgent measures to protect consumers from certain products that, without approval or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. As described below, you sell products that are intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. We request that you take immediate action to cease the sale of any unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. Some examples of the claims on your labeling that establish

the intended use (as defined in 21 CFR 201.128) of your products and misleadingly represent them as safe and/or effective for the treatment or prevention of COVID-19 include, but may not be limited to, the following: "INTRANASAL POVIDONE-IODINE EFFECTIVELY LIMITS COVID-19 SPREAD, FINDS STUDY HTTPS://PUBMED.NCBI.NL" [from your website https://viraldine.com/faqs-%26-pvp-i-studies] "POVIDONE IODINE (PVP-I) ORO-NASAL SPRAY: AN EFFECTIVE SHIELD FOR COVID-19 PROTECTION FOR HEALTH CARE" [from your website https://viraldine.com/faqs-%26-pvp-istudies] " Results: All concentrations of nasal antiseptics and oral rinse antiseptics evaluated completely inactivated the SARS-CoV-2. Conclusions: Nasal and oral PVP-I antiseptic solutions are effective at inactivating the SARS-CoV-2 at a variety of concentrations after 60-second exposure times. The formulations tested may help to reduce the transmission of SARS-CoV-2 if used for nasal decontamination, oral decontamination, or surface decontamination in known or suspected cases of COVID-19." [from your website https://viraldine.com/faqs-%26-pvp-i-studies] "The researchers came out with the following findings- 1. Povidone-iodine nasal antiseptics at concentrations (0.5%, 1.25%, and 2.5%) completely inactivated SARS-CoV-2 within 15 seconds of contact…" [from your website https://viraldine.com/faqs-%26-pvp-i-studies] "Hence, the authors concluded that 'Povidone-iodine nasal antiseptic solutions at concentrations as low as 0.5% rapidly inactivate SARS-CoV-2 at contact times as short as 15 seconds. Intranasal use of PVP-I has demonstrated safety at concentrations of 1.25% and below and may play an adjunctive role in mitigating viral transmission beyond personal protective equipment.'" [from your website https://viraldine.com/faqs-%26-pvp-i-studies] "SARS-CoV-2 virus was completely inactivated by PVP-I oral antiseptic rinse in vitro, at the lowest concentration of 0.5 % and at the lowest contact time of 15 seconds. . ." [from your website https://viraldine.com/faqs-%26-pvp-i-studies] "Recent evidence has confirmed that 0.5% povidone iodine (PVP-I) mouthrinse/gargle for 30 s can reduce SARS-CoV-2 virus infectivity to below detectable levels. PVP-I can even interrupt SARSCoV-2 attachment to oral and nasopharyngeal tissues and lower the viral particles in the saliva and respiratory droplets. Thus, the use of PVP-I mouthrinse as a prophylactic measure has been advocated across the globe to reduce disease transmission. . . [from your website https://viraldine.com/faqs-%26-pvp-i-studies] "4 Hour Maximum Protection" [from product labels on your website https://viraldine.com/shop] Based on the above claims and statements, your topical antiseptic 5 and oral antiseptic 6 products are "drugs" as defined by section 201(g)(1)(B) of the FD&C Act, 21 U.S.C. 321(g)(1)(B), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or under section 201(g)(1)(C) of the FD&C Act, 21 U.S.C. 321(g)(1)(C), because they are intended to affect the structure or any function of the body. Specifically, 1.5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, 1% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, and .5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY are intended for use as consumer topical antiseptics. 1.5% POVIDONE IODINE USP ANTISEPTIC THROAT SPRAY is intended for use as a consumer oral antiseptic. These consumer topical antiseptics and oral antiseptic products are "new drugs" within the meaning of section 201(p) of the FD&C Act, 21 U.S.C. 321(p), because they are not generally recognized as safe and effective (GRASE) for use under the conditions prescribed, recommended, or suggested in their labeling. New drugs may not be introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in section 505(a) of the FD&C Act, 21 U.S.C. 355(a), unless they are lawfully marketed under section 505G of the FD&C Act (which is not the case for these products, as further described below) or under other exceptions not applicable here. No FDA-approved applications pursuant to section 505 of the FD&C Act, 21 U.S.C. 355, is in effect for these drug products, nor are we aware of any adequate and well-controlled clinical studies in the published literature that support a determination that your drug products are

GRASE for use under the conditions suggested, recommended, or prescribed in their labeling. Accordingly, these drug products are unapproved new drugs marketed in violation of sections 505(a) and 301(d) of the FD&C Act, 21 U.S.C 355(a) and 331(d). We note that OTC topical and oral antiseptic products had been the subject of rulemakings under the Agency's OTC Drug Review. In particular, consumer topical antiseptics were addressed in a tentative final monograph (TFM) entitled "Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Health-Care Antiseptic Drug Products," Proposed Rule, 59 FR 31402 (June 17, 1994) (1994 TFM), as further amended by "Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record," Proposed Rule, 81 FR 42912 (June 30, 2016) (Consumer Antiseptic Rubs Proposed Rule). Over the course of these rulemakings, three active ingredients (benzalkonium chloride, ethyl alcohol (ethanol), and isopropyl alcohol) were classified as Category III for use in consumer antiseptic rub products, meaning that additional safety and effectiveness data are needed to support a determination that a drug product containing one of these active ingredients would be GRASE for use as a consumer antiseptic rub. Oral antiseptics were addressed in a tentative final monograph (TFM) entitled "Oral Health Care Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Oral Antiseptic Drug Products"; Proposed Rule, 59 FR 6084 (February 9, 1994) (Oral Antiseptics Proposed Rule). Over the course of this rulemaking for oral antiseptics, povidone iodine at 0.5%, when labeled for short-term use (not to exceed 7 days), was classified as Category III for use as an OTC oral antiseptic, because additional effectiveness data are needed to support a determination that a product containing this active ingredient would be GRASE for use as an OTC oral antiseptic. Section 505G of the FD&C Act governs nonprescription drugs marketed without an approved application. Under section 505G(a)(3) of the FD&C Act, drugs that were classified as Category III for safety or effectiveness in a TFM that is the most recently applicable proposal or determination for such drug issued under 21 CFR Part 330 – and that were not classified as Category II for safety or effectiveness – are not required to have an approved application under section 505 in order to be marketed, as long as they meet the relevant conditions of use outlined in the applicable TFM, including the active ingredient, and comply with all other applicable requirements. However, your non-alcohol-based antiseptic products do not conform to the 1994 TFM, the Oral Antiseptics Proposed Rule, nor any other TFM, proposed rule, or final rule and do not meet the conditions under section 505G(a)(3) of the FD&C Act for marketing without an approved application under section 505. 7 Specifically, your labeling claims, suggesting that 1.5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, 1% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, .5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, and 1.5% POVIDONE IODINE USP ANTISEPTIC THROAT SPRAY are effective in shortening the duration of infection and preventing infection or disease from the novel coronavirus that causes COVID-19, go beyond merely describing the general intended use of an antiseptic as set forth in the 1994 TFM and the Oral Antiseptics Proposed Rule. 8 In addition, your labeling claims, suggesting that your non-alcohol-based antiseptic products provide up to 4 hours of efficacy against the novel coronavirus that causes COVID-19, are not permitted under the 1994 TFM, the Oral Antiseptics Proposed Rule, or any of the amendments to the TFMs discussed above. Time-specific extended efficacy claims, especially when related to serious-disease related pathogens, may lead to a false sense of security for the general public that may result in infrequent hand washing or the substitution of these products for protective gloves and clothing, which are the principal methods for protecting against the spread of diseases caused by pathogenic microorganisms. As a result, these products may give users the false impression that they need not rigorously adhere to interventions such as social distanc-

ing and exercising good hygienic practices that have been demonstrated to curb the spread of COVID-19. Users who do not follow these interventions are at increased risk for contracting COVID-19 and for spreading disease if they have been exposed to the virus, thereby prolonging the pandemic and increasing its associated morbidity and mortality. In addition, according to the product labeling, 1.5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, 1% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, and .5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY are intended to be applied inside the nostrils. Consumer antiseptic products intended for administration inside the nostrils are not permitted under the 1994 TFM, as further amended by the Consumer Antiseptic Rubs Proposed Rule. 9 Furthermore, 1.5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, 1% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, .5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, and 1.5% POVIDONE IODINE USP ANTISEPTIC THROAT SPRAY are misbranded under section 502(ee) of the FD&C Act, 21 U.S.C. 352(ee), because they are nonprescription drugs subject to section 505G of the FD&C Act, 21 U.S.C. 355h, but do not comply with the requirements for marketing under that section and are not the subject of an application approved under section 505 of the FD&C Act, 21 U.S.C. 355. You should take immediate action to address the violations cited in this letter. This letter is not meant to be an all-inclusive list of violations that exist in connection with your products or operations. It is your responsibility to ensure that the products you sell are in compliance with the FD&C Act and FDA's implementing regulations. We advise you to review your websites, product labels, and other labeling and promotional materials to ensure that you are not misleadingly representing your products as safe and effective for a COVID-19-related use for which they have not been approved by FDA. Within 48 hours, please send an email to COVID-19-Task-Force-CDER@fda.hhs.gov describing the specific steps you have taken to address these violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. Failure to adequately correct any violations may result in legal action, including, without limitation, seizure and injunction. FDA is advising consumers not to purchase or use certain products that have not been approved, cleared, or authorized by FDA and that are being misleadingly represented as safe and/or effective for the treatment or prevention of COVID-19. Your firm will be added to a published list on FDA's website of firms and websites that have received warning letters from FDA concerning the sale or distribution of COVID-19 related products in violation of the FD&C Act. This list can be found at http://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-covid-19-products . Once you have taken corrective actions to address the sale of your unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, and any appropriate corrective actions have been confirmed by FDA, the published list will be updated to indicate that your firm has taken appropriate corrective action. We note however, removal from the published list should not be interpreted to mean that you have properly addressed all other violations for your products and that you are free to proceed with their continued marketing. This letter notifies you of our concerns and provides you with an opportunity to address them. If you cannot take action to address this matter completely within 48 hours, state the reason for the delay and the time within which you will do so. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration. If you are not located in the United States, please note that products that appear to be misbranded or unapproved new drugs may be detained or refused admission if they are offered for importation into the United States. We may advise the appropriate regulatory officials in the country from which you operate that FDA considers your products referenced above to be unapproved and misbranded products that cannot be legally sold to consumers in the United States. Please direct any in-

quiries to FDA at COVID-19-Task-Force-CDER@fda.hhs.gov. FTC Cease and Desist Demand: In addition, it is unlawful under the FTC Act, 15 U.S.C. § 41 et seq., to advertise that a product can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time they are made. For COVID-19, no such study is currently known to exist for the products identified above. Thus, any coronavirus-related prevention or treatment claims regarding such products are not supported by competent and reliable scientific evidence. You must immediately cease making all such claims. Violations of the FTC Act may result in legal action seeking a Federal District Court injunction and an order may require that you pay back money to consumers. In addition, pursuant to the COVID-19 Consumer Protection Act, Section 1401, Division FF, of the Consolidated Appropriations Act, 2021, P.L. 116-260, marketers who make deceptive claims about the treatment, cure, prevention, or mitigation of COVID-19 are subject to a civil penalty of up to $46,517 per violation and may be required to pay refunds to consumers or provide other relief pursuant to Section 19(b) of the FTC Act, 15 U.S.C. § 57b(b). Within 48 hours, please send an email to Richard Cleland, Assistant Director of the FTC's Division of Advertising Practices, via electronic mail at rcleland@ftc.gov certifying that you have ceased making unsubstantiated claims for the products identified above. If you have any questions regarding compliance with the FTC Act, please contact Mr. Cleland at 202-326-3088. Sincerely, /S/ Donald D. Ashley Director Office of Compliance Center for Drug Evaluation and Research Food and Drug Administration Sincerely, /S/ Serena Viswanathan Associate Director Division of Advertising Practices Federal Trade Commission

_____1 Your non-alcohol-based antiseptic drug products include 1.5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, 1% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, .5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, and 1.5% POVIDONE IODINE USP ANTISEPTIC THROAT SPRAY. 2 As explained in the next paragraph, there is currently an outbreak of a respiratory disease named "Coronavirus Disease 2019" (COVID-19). 3 Secretary of Health and Human Services, Determination that a Public Health Emergency Exists. (originally issued on Jan. 31, 2020., and subsequently renewed) available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx). 4 Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at https://trumpwhitehouse.archives.gov/presidential-actions/proclamationdeclaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/). 5 1.5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, 1% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, and .5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY 6 1.5% POVIDONE IODINE USP ANTISEPTIC THROAT SPRAY 7 We note that 1.5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, 1% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, .5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, and 1.5% POVIDONE IODINE USP ANTISEPTIC THROAT SPRAY also do not conform to any temporary policy FDA has implemented during the public health emergency. In March 2020, the Agency published three guidance documents to provide regulatory flexibility to certain firms to help meet the demand for alcohol-based hand sanitizer during the COVID-19 public health emergency (PHE). Because your non-alcohol-based consumer antiseptic products are not consistent with the formulations described in these guidances, they do not fall within any temporary Agency policy not to take action against firms manufacturing hand sanitizer products for violations of section 505 of the FD&C Act. Additionally, on December 31, 2021 these guidances were withdrawn, and firms must cease distribution, by March 31, 2022, of any remaining hand sanitizer products that were prepared under the temporary policies before or on December 31, 2021. See, 86 FR 56960, October 13, 2021. 8 The 1994 TFM covers

consumer antiseptics that are indicated for use to decrease bacteria on the skin. 59 FR at 31443. The Oral Antiseptics Proposed Rule covers oral antiseptics that are indicated for use in first aid to help decrease bacterial contamination in minor cuts, minor scrapes or minor oral irritation caused by dental procedures, dentures, orthodontic appliances, or accidental injury and for use by health care professionals for preparation of the oral mucosa prior to injection, dental surgery, or tooth extraction. 59 FR at 6121-22. 9 The 2016 Consumer Antiseptic Rubs Proposed Rule covered consumer antiseptic products intended for use without water. Under the 1994 TFM, as amended by the 2016 Consumer Antiseptic Rubs Proposed Rule, only consumer topical antiseptic products intended for use on the hands without water are permitted. Products intended for other areas of the body such as the nose are not permitted. Content current as of: 03/08/2022 Regulated Product(s) Drugs More Warning Letters Warning Letters About Warning and Close-Out Letters

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Table 20: Places for report 1422031

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Elmira	42.0898	-76.80773
Americas	United States	United States	39.76	-98.5

Table 21: Drugs for report 1422031

Medicine Name	Medicine Class	Action	ATC Code
povidone-iodine	Iodine products	antiseptics and disinfectants	D08AG02
povidone-iodine	Medicated dressings with antiinfectives	medicated dressings	D09AA09
povidone-iodine	Medicated shampoos	other dermatological preparations	D11AC06
povidone-iodine	Other antiinfectives and antiseptics	antiinfectives and antiseptics, excl. combinations with corticosteroids	G01AX11
povidone-iodine	Antiseptics	throat preparations	R02AA15
povidone-iodine	Other antiinfectives	antiinfectives	S01AX18

Notes: This is to advise you that the United States Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) reviewed your website at the Internet address https://viraldine.com/ on December 21, 2021 and March 1, 2022, respectively. The FDA has observed that your website offers non-alcohol-based antiseptic products1 for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-192 in people. Based on our review, these products are unapproved new drugs sold in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 355(a).

Furthermore, these products are misbranded drugs under sections 502(ee) of the FD&C Act, 21 U.S.C. 352(ee). The introduction or delivery for introduction of these products into interstate commerce is prohibited under sections 301(a) and (d) of the FD&C Act, 21 U.S.C. 331(a) and (d). These violations are described in more detail below. [...] "Results: All concentrations of nasal antiseptics and oral rinse antiseptics evaluated completely inactivated the SARS-CoV-2. Conclusions: Nasal and oral PVP-I antiseptic solutions are effective at inactivating the SARS-CoV-2 at a variety of concentrations after 60-second exposure times. The formulations tested may help to reduce the transmission of SARS-CoV-2 if used for nasal decontamination, oral decontamination, or surface decontamination in known or suspected cases of COVID-19." [from your website https://viraldine.com/faqs-%26-pvp-i-studies] [...]

12 CardioQuip, LLC - Center for Devices and Radiological Health - CGMP/QSR/Medical Devices/PMA/Adulterated - 2022-03-08

Publication date	2022-03-08
Create date	2022-03-11
Score	0.60
Report id	1421934
Category	Medical device for screening/diagnosis/monitoring
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER CardioQuip, LLC MARCS-CMS 621738 — February 11, 2022 Share Tweet Linkedin Email Print Delivery Method: VIA Electronic Mail Product: Medical Devices Recipient: Recipient Name Douglas E. Platt Recipient Title CEO CardioQuip, LLC 8422 Calibration Ct. College Station , TX 77845 United States dplatt@cardioquip.com Issuing Office: Center for Devices and Radiological Health United States WARNING LETTER CMS: 621738 February 11, 2022 Dear Mr. Platt, During an inspection of your firm located in College Station, TX from August 19, 2021 through September 17, 2021, an Investigator from the United States Food and Drug Administration (FDA) observed that your firm manufactures a cardiac heater-cooler product in various configurations. Under section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h)(1), each of these products is a device because it is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. We received a written response from you dated October 4, 2021, concerning our investigator's observations noted on the Form FDA 483 (FDA 483), List of Inspectional Observations, that was issued to your firm. We address this response below, in relation to each of the noted concerns. These concerns include, but are not necessarily limited to, the following: Your firm currently holds a 510(k) clearance (K102147) for the CardioQuip Modular Cooler-Heater Model MCH-1000 device ("MCH-1000 Device"), which was issued on November 19, 2010. However, since the time it was cleared, the MCH-1000 Device has been, in multiple ways, significantly changed or modified in design, components, method of manufacture, or intended use within the meaning of 21 CFR 807.81(a)(3). Specifically, your firm has made significant changes that include, among other things, the addition of an optional airflow hood, a dripless external hose kit, and thermoelectric cooling technology in certain MCH models. The addition of an optional airflow hood is intended to reduce the risk of infection via aerosolization of contaminated water. The airflow hood impacts how potentially contaminated water droplets are dispersed in the operating room. The addition of a dripless antimicrobial external hose kit modifies the same risk by attempting to mitigate biofilm and water-borne

pathogen buildup in the hose kit. The final significant change outlined in this warning letter, the addition of thermoelectric cooling technology, is a major operating principle change as the original 510(k) (K102147) was cleared with the use of optional compressor cooling and not thermoelectric cooling. These and other changes could significantly affect the safety or effectiveness of the device within the meaning of 21 CFR 807.81(a)(3). Accordingly, your firm was required to submit a new premarket notification submission under section 510(k) of the Act, 21 U.S.C. § 360(k), to FDA at least 90 days before you proposed to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of the modified Modular Cooler-Heater devices ("Modified MCH Devices"). (See 21 CFR 807.81(a)(3).) You did not submit any new 510(k) in association with the Modified MCH Devices despite your statement made October 4, 2021, in your written response, that your firm is (b)(4) The Modified MCH Devices are therefore misbranded under section 502(o) the Act, 21 U.S.C. § 352(o), because your firm did not timely notify FDA of its intent to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of the Modified MCH Devices, as required by section 510(k) of the Act. Our inspection revealed that the Modular Cooler-Heater (MCH) devices are also adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption under section 520(g) of the Act, 21 U.S.C. § 360j(g). For a device requiring premarket approval, the notification required by section 510(k) of the Act, 21 U.S.C. § 360(k), is deemed satisfied when a PMA is pending before the agency. 21 CFR 807.81(b). The kind of information that your firm needs to submit in order to obtain approval or clearance for the device is described on the Internet at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm . The FDA will evaluate the information that your firm submits and decide whether the product may be legally marketed. Our inspection also revealed that these devices are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. These deficiencies include, but are not limited to, the following: 1. Failure to establish and maintain adequate procedures to control the design of the device in order to ensure that specified design requirements are met, as required by 21 CFR 820.30(a). Specifically, your firm has not adequately controlled and documented the design of your MCH devices. Specifically, a. Your firm has not adequately conducted design validation for your MCH devices as required by 21 CFR 820.30(g) or validated changes as required by 21 CFR 820.30(i). For example, i. Your firm changed your specification for microbial load measured by heterotrophic plate count (HPC) from (b)(4) CFU/ml to (b)(4) CFU/ml and removed requirements for (b)(4) testing. Your firm did not validate this change to ensure that it meets the intended uses for the device. ii. On March 3, 2020, your firm added an optional airflow hood to your MCH devices intended to redirect the flow of exhaust air downward. Your firm did not validate this change to ensure that it meets the intended use of the device. Your firm's validation of this change only addressed impact to temperature of the unit. The change validation did not address impact to potential microbiological infection to patients. iii. Your firm modified the external tubing of your device between November 23, 2015 and November 11, 2016 to change to a PVC antimicrobial tubing. However, your firm did not adequately document or validate this change. Your firm conducted microbial testing between November 24, 2015 and February 3, 2016 as a water quality comparison when using the old hose and the antimicrobial hose. However, your firm's testing was not conducted to an approved protocol that identified full test methods, sample methods, acceptance criteria, or support for

sample sizes. iv. On July 29, 2016, you effected a change to the MCH-1000 Mini allowing for optional refrigeration technology using (b)(4) technology. This change was not validated. b. Your firm has not adequately conducted risk analysis for your MCH devices, as required by 21 CFR 820.30(g). Specifically, your firm added a new hazard of "Bacteria such as m. chimaera or other biological agents being aerosolized into patient environments" to your MCH-10ARH Risk Assessment document on August 6, 2021; however, your firm has been aware of this hazard since at least 2018. Additionally, this hazard has not been considered as part of your design activities, see item "a" above. c. Your firm failed to establish and maintain adequate procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient, as required by 21 CFR 820.30(c). For example, some of your design inputs are ambiguous and do not align with known risks and user needs. i. Design input #001-DI-02, titled "Cleanability," states " (b)(4) " and documents the Target Specification as " (b)(4) ". This design input does not establish a specific target criteria for cleanliness. ii. Design input #001-DI-10, titled "Device Stability," states " (b)(4) " and documents the Target Specification as " (b)(4) ". This design input does not define "easily". iii. Design input #001-DI-32, titled "Air Exhaust Vent on Cooling Unit," states " (b)(4) ," and documents the Target Specification as " (b)(4) ." This design input does not address potential impact on exhaust air disruption of the cleanroom environment which is one of your firm's identified risks. 2. Failure to ensure that when the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedure, as required by 21 CFR 820.75(a). Specifically, Your firm has not validated your cleaning processes recommended in your product manuals and utilized during servicing of your devices. Your firm conducted HPC testing on water samples collected pre- and post-cleaning in February 2016 and March 2017; however, these tests do not have the necessary information to support that the process consistently meets specification. For example, the records do not identify sample collection methods, sample sizes, disinfectant residue, or acceptance criteria. We acknowledge your firm has initiated CAPA 63 to address deficiencies with process validations to include your cleaning processes. However, your firm has not provided evidence you have completed an adequate validation of your cleaning processes. Additionally, your response does not include a systemic review of your processes to verify that all processes requiring validation have been validated. 3. Failure to establish and maintain procedures for implementing corrective and preventive action, as required by 21 CFR 820.100(a). For example, a. Your firm initiated CAPA 77 in response to an increase of complaints for device contamination with NTM on December 14, 2020. Your firm closed this CAPA on June 2, 2021. However, the CAPA does not show your firm accurately investigated the cause of this quality problem. Your CAPA records state your firm has not linked your device to patient infection; however, your firm has reported events in which you confirmed your device was linked to infection. Additionally, your firm identified revisions to your cleaning procedures as a corrective action for this CAPA. However, your firm has not validated these cleaning procedures despite the closure of this CAPA. b. Your firm initiated CAPA 63, on August 6, 2020, to address lack of validation of your MCH cleaning processes. Your firm has not yet validated your cleaning process despite this CAPA being open for over 15 months. c. Your firm initiated CAPA 2018-027 on January 29, 2018 to address complaints associated with leaking MCH devices. Your firm determined the cause of this issue involved tolerance stacking with certain device specifications when manufactured at the edges of your specification limits. Your firm determined to add a bushing to the device to address this issue. However, the CAPA record does not include documentation to show this change was affected or verification activities to show this corrected the quality problem. Additionally, the CAPA states this corrective action was not feasible on the MCH 1000(m) and it does not identify what corrective actions if any

were taken for those devices. Lastly, your CAPA record states the effectiveness checks for this CAPA would include monitoring of complaints over time; however, there is no record of this having been conducted in relation to this CAPA. This CAPA was closed on, or about, August 15, 2018. 4. Failure to maintain complaint files and establish and maintain adequate procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). Specifically, Your firm's "Complaint Procedure", CQ-SOP-12 Ver 11, dated January 7, 2021 is inadequate. Specifically, your procedure does not provide adequate details to ensure complaints are processed in a uniform and timely manner. Your complaint procedures do not define what methods of investigation may be used when conducting investigations under 21 CFR 820.198(e). Additionally, section 7.9 of your procedure requires a complaint committee to review complaints against your risk analysis procedures. However, the procedure does not provide clear instruction on the frequency and scheduling of these reviews. For example, a. Your firm received 11 complaints on July 28, 2021 in which a hospital reported finding bacterial contamination on several of your MCH devices. Your firm's complaint records assert these isolates did not match the environmental and patient isolates and therefore further investigation was not conducted. However, your firm did not investigate the level of contamination or the cause of the contamination. All of these complaints were subsequently reported under 21 CFR 803. b. Your firm received complaint DI-13886 on January 29, 2021 which alleged biofilm buildup in the tubing of a MCH device. The risk assessment section of this complaint record states, "No change in risk as the device did not malfunction and no new risk identified." However, your firm's current risk matrix "MCH-1000" dated June 11, 2021 does not identify biofilm growth. Additionally, risks associated with bacterial contamination were not added until April 1, 2021. Your complaint record is unclear as to what risk evaluations were conducted as part of this complaint's risk assessment. c. Your firm received complaint DI-13930 on March 15, 2021 involving an alleged patient infection. This complaint does not include an Investigation Questionnaire which your firm provides to some complainants to obtain information associated with the alleged event. Your firm's Director of Quality and Regulatory acknowledged this was an oversight. "Complaint Procedure", CQ-SOP-12 Ver 11, dated January 7, 2021 does not address the use of your "Investigation Questionnaire" form. Our inspection also revealed that your firm's MCH devices are misbranded under section 502(t)(2) of the Act, 21 U.S.C.§ 352(t)(2), in that your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 803 - Medical Device Reporting. Significant concerns include the following: 1. Failure to submit a report to FDA no later than 30 calendar days after the day that the firm received or otherwise became aware of information, from any source, that reasonably suggests that a device that the firm markets has malfunctioned and this device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur, as required by 21 CFR 803.50(a)(2). a. For example, the information included for #DI-14346 reasonably suggests that your firm's MCH malfunctioned in that the water level sensor did not function as designed. Such malfunction resulted in a fire inside the unit that burned out device components. The service form states that the PVC assemblies were burnt out and inoperable due to the fire inside the unit. The fire department was called. A device malfunction that results in fire, and burning of the device components, represents a malfunction that would be likely to cause or contribute to a death or serious injury, if it were to recur. As such, the referenced complaint meets the definition of a reportable malfunction, as defined in 21 CFR 803.3. The date your firm became aware of the event was October 28, 2020. However, no MDR for the referenced complaint has been received by FDA. We have reviewed your firm's response dated October 4, 2021. While acknowledging the "need" for your firm to make "improvements," your response contains insufficient detail or supporting records to show these corrective actions will be ade-

quate to address any violations or planned timeframes for their completion. We request that your firm immediately cease any activities that result in the misbranding or adulteration of the MCH devices, such as their commercial distribution as discussed above. We further request in response to this letter you provide a more comprehensive corrective action plan. Please include supporting records to show completion of your corrective actions and timeframes for ongoing corrections. Additionally, we request you continue to provide ongoing updates to these actions monthly through completion of all corrective actions. This letter notifies you of our concerns and provides you with an opportunity to address them. Your firm should take prompt action to correct any violations. If you believe that your products are not in violation of the FD&C Act, please provide your reasoning and any supporting information for our consideration within 15 days. Failure to adequately address the matters discussed in this letter may result in legal action being initiated by the FDA without further notice. These actions may include, but are not necessarily limited to, seizure, injunction, and civil money penalties. Other federal agencies may take your compliance history into account when considering the award of contracts. Should FDA determine that you have Quality System Regulation violations that are reasonably related to premarket approval applications for Class III devices, such devices will not be approved until the violations have been corrected. Should FDA determine that your devices or facilities do not meet the requirements of the FD&C Act, requests for Certificates to Foreign Governments (CFG) may not be granted. More information on processes for persons denied a CFG can be found at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/process-request-review-fdas-decision-not-issue-certain-export-certificates-devices . We ask that you please notify this office in writing within fifteen business days from the date you receive this letter of the specific steps your firm has taken to address the concerns noted in this letter. Include documentation of any corrections and/or corrective action (which must address systemic problems) that your firm has taken. If any corrections and/or corrective actions your firm plans to take will require more time, please include a timetable for implementation of those activities. If any corrections and/or corrective actions your firm plans to take cannot be completed within fifteen business days, state the reason for requiring additional time and the time within which these activities will be completed. Please provide a translation of documentation not in English to facilitate our review. We will communicate with you regarding your firm's response(s) and any need to re-inspect your firm's facility to verify that any appropriate corrections and/or corrective actions have been made. Your firm's response should be sent to: US Food and Drug Administration, Division 3/West, Office of Medical Device and Radiological Health Operations at ORADevices3 FirmResponse@fda.hhs.gov. Please identify your response with FEI 3007899424. If you have any questions about the contents of this letter, please contact Compliance Officer Jeff R. Wooley at 214-253-5251, or via e-mail at Jeffrey.wooley@fda.hhs.gov. Finally, you should know that this letter is not intended to provide an all-inclusive list of any deficiencies at your firm's facility or associated with your firm's devices. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific concerns noted in this letter and in the Inspectional Observations, FDA 483, issued at the close of the inspection may be indicative of, or in addition to, other issues with your firm's devices, manufacturing, and quality management systems. Your firm should investigate and determine the causes of any deficiencies and take prompt actions to correct any violations and bring the products into compliance. Sincerely, /S/ Bram Zuckerman, M.D. Director OHT 2: Office of Cardiovascular Devices Office of Product Evaluation and Quality Center for Devices and Radiological Health /S/ Shari J. Shambaugh Program Division Director Office of Medical Device and Radiological Health, Division 3 Content current as of: 03/08/2022 Regulated Product(s) Medical Devices More Warning Letters Warning Letters About Warning and Close-Out Letters

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Table 22: Places for report 1421934

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Texas	31.25044	-99.25061

Table 23: Other Stories

ID	Title	Link
1424371	FDA issues CardioQuip, Wickimed warning letters for adulterated devices	Link
1424377	FDA issues CardioQuip, Wickimed warning letters for adulterated devices	Link

Notes: [...] You did not submit any new 510(k) in association with the Modified MCH Devices despite your statement made October 4, 2021, in your written response, that your firm is (b)(4) The Modified MCH Devices are therefore misbranded under section 502(o) the Act, 21 U.S.C. § 352(o), because your firm did not timely notify FDA of its intent to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of the Modified MCH Devices, as required by section 510(k) of the Act.

Our inspection revealed that the Modular Cooler-Heater (MCH) devices are also adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption under section 520(g) of the Act, 21 U.S.C. § 360j(g). [...]

Annex C

C.5. COVID-19 medicines

Medicine Quality Monitoring Globe

September 7, 2022

This is a summary of the information available in the Medicine Quality Monitoring Globe for the search terms selected between the dates selected. For more information on the terminology used, caveats and the work of the medicine quality group please see the information at: https://www.iddo.org/medicine-quality

Non-Curated reports are those that have been automatically flagged as relevant by the system but have not been manually curated by the curators.

We would be grateful for any feedback on this summary and for the details of any reports that we may have missed.

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Filters applied for this report

Search ((”tranilast” OR ”interleukin-2” OR ”INC424” OR ”TNKase” OR ”nitazoxanide” OR ”LY3832479” OR ”baloxavir” OR ”interleukin-7” OR ”Kineret” OR ”ritonavir” OR ”Crizanlizumab” OR ”Apixaban” OR ”cyclosporin” OR ”losartan” OR ”ATI-450” OR ”nitrogen monoxide” OR ”tirofiban” OR ”Ebselen” OR ”corbistadine” OR ”atorvastatin” OR ”Eicosapentaenoic” OR ”nitrite” OR ”Riamilovir” OR ”black cumin” OR ”NK-1R” OR ”Pemziviptadil” OR ”colchicine” OR ”Lithium” OR ”Vancomycin” OR ”Broncho-Vaxom” OR ”ramipril” OR ”Teicoplanin” OR ”tofacitinib” OR ”budesonide” OR ”Paracetamol” OR ”dipyridamole” OR ”levamisole” OR ”atovaquone” OR ”Senicapoc” OR ”covid drug” OR ”enoxaparin” OR ”Brequinar” OR ”povidone-iodine” OR ”levilimab” OR ”degarelix” OR ”LY3819253” OR ”Sofusbovir” OR ”masitinib” OR ”Omega-3” OR ”INM005” OR ”RBT-9” OR ”deferoxamine” OR ”canakinumab” OR ”Ramelteon” OR ”chlorpromazine” OR ”selinexor” OR ”Piclidenoson” OR ”DAS181” OR ”M5049” OR ”Ibudilast” OR ”CM4620-IE” OR ”GNS561” OR ”zanubrutinib” OR ”Cenicriviroc” OR ”sofosbovir” OR ”Trimethoprim” OR ”vadadustat” OR ”AVM0703” OR ”Rabeprazole” OR ”Moxifloxacin” OR ”cobicistat” OR ”BAT2020” OR ”ABX464” OR ”XAV-19” OR ”thalidomide” OR ”bamlanivimab” OR ”GX-19” OR ”corticosteroid” OR ”Tradipitant” OR ”cotrimoxazole” OR ”HuMax-Inflam” OR ”Apilimod” OR ”DUR-928” OR ”escin” OR ”PF-06650833” OR ”octagam” OR ”Antroquinonol” OR ”pacritinib” OR ”Imatinib” OR ”ribavirin” OR ”ambrisentan” OR ”baricitinib” OR ”imatinib” OR ”CD24Fc” OR ”Sulodexide” OR ”AlloStim” OR ”DFV890” OR ”Emapalumab” OR ”sitagliptin” OR ”Metformin” OR ”prednisone” OR ”ulinastatin” OR ”naltrexone” OR ”abidor” OR ”niclosamide” OR ”BIO101” OR ”GS-441524” OR ”argatroban” OR ”Leukine” OR ”xiyanping” OR ”peginterferon” OR ”pembrolizumab” OR ”HuMax” OR ”Lambda” OR ”dornase” OR ”Itraconazole” OR ”telemedicine” OR ”Adenosine” OR ”nirmatrelvir” OR ”Curosurf” OR ”clarithromycin” OR ”bromhexine” OR ”Xpovio” OR ”ebastine” OR ”amoxicillin/clavulanate” OR ”PD-1 mAb” OR ”EPA” OR ”oseltamivir” OR ”Betamethasone” OR ”favipiravir” OR ”mefloquine” OR ”bismuth” OR ”CM4620” OR ”ifenprodil” OR ”Levofloxacin” OR ”REGN10987” OR ”Candesartan” OR ”secukinumab” OR ”Trihexyphenidyl” OR ”Daclatasvir” OR ”pinavir” OR ”tocilizumab” OR ”co-amoxiclav” OR ”EG-HPCP-03a” OR ”hydroxychloroquine” OR ”Polyoxidonium” OR ”STI-5656” OR ”Artesunate” OR ”triazavirine” OR ”Disulfiram” OR ”cholecalciferol” OR ”INO-4800” OR ”PG1” OR ”zinc” OR ”oxytocin” OR ”gimsilumab” OR ”suramin” OR ”rhG-CSF” OR ”desferoxamine” OR ”TD-0903” OR ”OM-85” OR ”Bucillamine” OR ”pirfenidone” OR ”Acetaminophen” OR ”adamumab” OR ”sulfamethoxazole” OR ”BI 764198” OR ”RPH-104” OR ”COVID-19 drug” OR ”alpha lipoic” OR ”almitrine” OR ”melphalan” OR ”dapagliflozin” OR ”NBT-NM108” OR ”TMJ2” OR ”Icosapent” OR ”Ceftriaxone” OR ”isoprinosine” OR ”IMU-838” OR ”tridecactide” OR ”chloroquine” OR ”CSL324” OR ”Lian Hua Qing Weng” OR ”Kevzara” OR ”valsartan” OR ”meplazumab” OR ”Namilumab” OR ”Prednisolone” OR ”sargramostim” OR ”estradiol” OR ”cyclosporine” OR ”Aprepitant” OR ”silymarin” OR ”linagliptin” OR ”Noscapine” OR ”Gemtuzumab” OR ”methylprednisolone” OR ”fluvoxamine” OR ”Coroquard” OR ”mavrilimumab” OR ”anakinra” OR ”ozanimod” OR ”mepolizumab” OR ”acetylsalicylic” OR ”darunavir” OR ”novaferon” OR ”YinHu Qing-Wen” OR ”OM85” OR ”camrelizumab” OR ”Cosentyx” OR ”estrogen” OR ”dexmedetomidine” OR ”LL-37” OR ”Dantonic” OR ”rivaroxaban” OR ”adalimumab” OR ”apremilast” OR ”polyinosinic-polycytidylic” OR ”farpiravir” OR ”montelukast” OR ”Ibuprofen” OR ”IFX-1” OR ”Iodine” OR ”Molnupiravir” OR ”Pioglitazone” OR ”verapamil” OR ”Rapamycin” OR ”Brexanolone” OR ”Eltrombopag” OR ”ravulizumab” OR ”hydrocortisone” OR ”auxora” OR ”tinzaparin” OR ”Vascepa” OR ”omalizumab” OR ”Ty-

bost" OR "Actemra" OR "dociparastat" OR "NA-831" OR "ascorbic acid" OR "MAS825" OR "C21" OR "RoActemra" OR "eculizumab" OR "Bivalirudin" OR "povidon-iodine" OR "ivermectin" OR "Pamrevlumab" OR "danoprevir" OR "Neurokinin" OR "sirolimus" OR "Fostamatinib" OR "resveratrol" OR "Icatibant" OR "bromelain" OR "dexamethasone" OR "TJ003234" OR "iloprost" OR "tacrolimus" OR "astegolimab" OR "interferon" OR "plitidepsin" OR "metenkefalin" OR "azoximer" OR "lopinavir" OR "Tazobactam" OR "carrimycin" OR "CM-4620" OR "CYT107" OR "Heparin" OR "Pyronaridine-Artesunate" OR "Itolizumab" OR "zilucoplan" OR "oxpentifylline" OR "AT-001" OR "Abivertinib" OR "doxycycline" OR "Nigella Sativa" OR "AZD1222" OR "leronlimab" OR "Enalapril" OR "nangibotide" OR "Piperacillin" OR "bevacizumab" OR "lactoferrin" OR "UTTR1147A" OR "Caesalpinia spinosa" OR "mometasone" OR "hydroxychloroquin" OR "Febuxostat" OR "lanadelumab" OR "Thymalfasin" OR "huaier extract" OR "Levoflozacin" OR "Pentoxifylline" OR "tozumab" OR "NP-120" OR "Alvelestat" OR "captopril" OR "merimepodib" OR "Iota-Carrageenan" OR "Lianhua Qingwen" OR "GLS-1200" OR "aescinate" OR "tranexamic" OR "Ledipasvir" OR "ISIS 721744" OR "procalcitonin" OR "SNDX-6352" OR "sirukumab" OR "Enzalutamide" OR "carriomycin" OR "amphotericin" OR "bemiparin" OR "T89" OR "Spironolactone" OR "sotrovimab" OR "fingolimod" OR "aspirin" OR "Remdesivir" OR "TJM2" OR "pyridostigmine" OR "Prolastin" OR "EC-18" OR "poractant" OR "isotretinoin" OR "telmisartan" OR "lenzilumab" OR "avdoralimab" OR "duvelisib" OR "BIO 300" OR "bicalutamide" OR "Ilaris" OR "atlizumab" OR "desferrioxamine" OR "LB1148" OR "Regkirona" OR "vitamin D3" OR "Clopidogrel" OR "CD24" OR "tetrandrine" OR "Lansoprazole" OR "Ruconest" OR "amoxicillin" OR "Trifluoperazine" OR "Ganovo" OR "nitric Oxide" OR "chlorine dioxide" OR "olokizumab" OR "lucinactant" OR "galidesivir" OR "TXA127" OR "Maraviroc" OR "conestat" OR "CA S001" OR "vazegepant" OR "REGN10933" OR "Propranolol" OR "Viagra" OR "Fisetin" OR "Ronapreve" OR "Previfenon" OR "omega 3" OR "regdanvimab" OR "thymosin" OR "Prasugrel" OR "retinoic acid" OR "Ceftaroline" OR "sevoflurane" OR "amoxicillin/clavulanic acid" OR "oestrogen" OR "leflunomide" OR "virazole" OR "PLN-74809" OR "ATYR1923" OR "Olumiant" OR "dalargin" OR "Alinia" OR "methotrexate" OR "dapansutrile" OR "artemisinin" OR "ibrutinib" OR "aescin" OR "CERC-002" OR "fludase" OR "isoflurane" OR "XPro1595" OR "LY-CoV555" OR "CAS0001" OR "immunoglobulin" OR "nafamostat" OR "Crocetinate" OR "Diphenhydramine" OR "BIO 101" OR "AZD1656" OR "PTC299" OR "amodiaquine" OR "casirivimab" OR "BGB-DXP593" OR "opaganib" OR "melatonin" OR "huaier granule" OR "HuMax-IL8" OR "Paxlovid" OR "famotidine" OR "GLS-1027" OR "Trimodulin" OR "tenofovir" OR "Primaquine" OR "AMY-101" OR "covid medicine" OR "umifenovir" OR "EDP1815" OR "Lagevrio" OR "Vitamin B12" OR "Gamunex-C" OR "Bardoxolone" OR "AstroStem-V" OR "LAU-7b" OR "Vitamin E" OR "Vitamin B" OR "RTB101" OR "COVID-19 medicine" OR "curcumin" OR "fondaparinux" OR "Edoxaban" OR "L-Citrulline" OR "ciclesonide" OR "azithromycin" OR "remdesivir" OR "Diltiazem" OR "Methylene blue" OR "clazakizumab" OR "BCX4430" OR "Pyronaridine" OR "Quercetin" OR "Toremifene" OR "COVI-AMG" OR "etoposide" OR "DWJ1248" OR "defibrotide" OR "AT-527" OR "prazosin" OR "triazavirin" OR "BIO300" OR "Ensifentrine" OR "coronavirus medicine" OR "Anti-IL-8" OR "dihydroartemisinin" OR "vitamin c" OR "25-hydroxyvitamin D3" OR "coronavirus drug" OR "formoterol" OR "indomethacin" OR "Rayaldee" OR "ciclosporin" OR "naproxen" OR "fluoxetine" OR "Infliximab" OR "Tenecteplase" OR "ruxolitinib" OR "Molgramostim" OR "vitamin D" OR "simvastatin" OR "alteplase" OR "sildenafil" OR "isoquercetin" OR "GC4419" OR "ketamine" OR "Razuprotafib" OR "camostat" OR "Arbidol" OR "Mont-

morrillonite" OR "acalabrutinib" OR "nivolumab" OR "aviptadil" OR "PUL-042" OR "diammonium" OR "Clevudine" OR "nitrogen oxide" OR "BMS-986253" OR "siltuximab" OR "interleukin 2" OR "jakotinib" OR "nintedanib" OR "Axatilimab" OR "garadacimab" OR "Treamid" OR "ASC09" OR "emtricitabine" OR "LY-CoV016" OR "Pulmozyme" OR "Prostaglandin" OR "ciclosporine" OR "hydrogen peroxide" OR "sarilumab" OR "Losmapimod" OR "azvudine" OR "BLD-2660" OR "EIDD-2801" OR "MSTT1041A" OR "Desidustat" OR "abidole" OR "omeprazole" OR "progesterone" OR "Decitabine" OR "tocopherol" OR "berberine" OR "Xevudy" OR "APL-9" OR "colomycin" OR "XC221" OR "amiodarone" OR "lenalidomide" OR "imdevimab" OR "ixekizumab" OR "VentaProst" OR "acetylcysteine" OR "LY3127804" OR "Atazanavir" OR "TL-895" OR "dalteparin" OR "Thimerosal" OR "Xue-Bi-Jing" OR "GC376" OR "Angiotensin" OR "gs-441542" OR "Risankizumab" OR "co-trimoxazole") OR (("Medicine" OR "Plasma" OR "Treatment" OR "Medication" OR "Monoclonal antibodies" OR "Antibody therapy" OR "Antibody cocktail") AND ("COVID-19" OR "COVID" OR "SARS-CoV-2" OR "Coronavirus" OR "CV19" OR "CV-19" OR "SARS" OR "CoV-2")))

Start date	2022-01-01
End date	2022-03-31
Language	en
Report type	incident
Curation status	validated
Number of Reports	68

1 Viraldine, LLC - Center for Drug Evaluation and Research | CDER - Unapproved New Drug Products Related to Coronavirus Disease 2019 (COVID-19) - 2022-03-08

Publication date	2022-03-08
Create date	2022-03-11
Score	98.34
Report id	1422031
Category	Antiseptic
Quality	Diverted/Unregistered
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER Viraldine, LLC MARCS-CMS 625675 — March 07, 2022 Share Tweet Linkedin Email Print Product: Drugs Recipient: Viraldine, LLC 311 Lake Street Elmira , NY 14901 United States infor@viraldine.com Issuing Office: Center for Drug Evaluation and Research | CDER United States Federal Trade Commission WARNING LETTER Date: March 7, 2022 RE: Unapproved New Drug Products Related to Coronavirus Disease 2019 (COVID-19) This is to advise you that the United States Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) reviewed your website at the Internet address https:// viraldine.com/ on December 21, 2021 and March 1, 2022, respectively. The FDA has observed that your website offers non-alcohol-based antiseptic products 1 for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19 2 in people. Based on our review, these products are unapproved new drugs sold in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 355(a). Furthermore, these products are misbranded drugs under sections 502(ee) of the FD&C Act, 21 U.S.C. 352(ee). The introduction or delivery for introduction of these products into interstate commerce is prohibited under sections 301(a) and (d) of the FD&C Act, 21 U.S.C. 331(a) and (d). These violations are described in more detail below. There is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2). The disease caused by the virus has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS. 3 In addition, on March 13, 2020, there was a Presidential declaration of a national emergency in response to COVID-19 that subsequently has been extended. 4 Therefore, FDA is taking urgent measures to protect consumers from certain products that, without approval or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. As described below, you sell products that are intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. We request that you take immediate action to cease the sale of any unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. Some examples of the claims on your labeling that establish

the intended use (as defined in 21 CFR 201.128) of your products and misleadingly represent them as safe and/or effective for the treatment or prevention of COVID-19 include, but may not be limited to, the following: "INTRANASAL POVIDONE-IODINE EFFECTIVELY LIMITS COVID-19 SPREAD, FINDS STUDY HTTPS://PUBMED.NCBI.NL" [from your website https://viraldine.com/faqs-%26-pvp-i-studies] "POVIDONE IODINE (PVP-I) ORO-NASAL SPRAY: AN EFFECTIVE SHIELD FOR COVID-19 PROTECTION FOR HEALTH CARE" [from your website https://viraldine.com/faqs-%26-pvp-istudies] " Results: All concentrations of nasal antiseptics and oral rinse antiseptics evaluated completely inactivated the SARS-CoV-2. Conclusions: Nasal and oral PVP-I antiseptic solutions are effective at inactivating the SARS-CoV-2 at a variety of concentrations after 60-second exposure times. The formulations tested may help to reduce the transmission of SARS-CoV-2 if used for nasal decontamination, oral decontamination, or surface decontamination in known or suspected cases of COVID-19." [from your website https://viraldine.com/faqs-%26-pvp-i-studies] "The researchers came out with the following findings- 1. Povidone-iodine nasal antiseptics at concentrations (0.5%, 1.25%, and 2.5%) completely inactivated SARS-CoV-2 within 15 seconds of contact…" [from your website https://viraldine.com/faqs-%26-pvp-i-studies] "Hence, the authors concluded that 'Povidone-iodine nasal antiseptic solutions at concentrations as low as 0.5% rapidly inactivate SARS-CoV-2 at contact times as short as 15 seconds. Intranasal use of PVP-I has demonstrated safety at concentrations of 1.25% and below and may play an adjunctive role in mitigating viral transmission beyond personal protective equipment.'" [from your website https://viraldine.com/faqs-%26-pvp-i-studies] "SARS-CoV-2 virus was completely inactivated by PVP-I oral antiseptic rinse in vitro, at the lowest concentration of 0.5 % and at the lowest contact time of 15 seconds. . ." [from your website https://viraldine.com/faqs-%26-pvp-i-studies] "Recent evidence has confirmed that 0.5% povidone iodine (PVP-I) mouthrinse/gargle for 30 s can reduce SARS-CoV-2 virus infectivity to below detectable levels. PVP-I can even interrupt SARSCoV-2 attachment to oral and nasopharyngeal tissues and lower the viral particles in the saliva and respiratory droplets. Thus, the use of PVP-I mouthrinse as a prophylactic measure has been advocated across the globe to reduce disease transmission. . . [from your website https://viraldine.com/faqs-%26-pvp-i-studies] "4 Hour Maximum Protection" [from product labels on your website https://viraldine.com/shop] Based on the above claims and statements, your topical antiseptic 5 and oral antiseptic 6 products are "drugs" as defined by section 201(g)(1)(B) of the FD&C Act, 21 U.S.C. 321(g)(1)(B), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or under section 201(g)(1)(C) of the FD&C Act, 21 U.S.C. 321(g)(1)(C), because they are intended to affect the structure or any function of the body. Specifically, 1.5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, 1% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, and .5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY are intended for use as consumer topical antiseptics. 1.5% POVIDONE IODINE USP ANTISEPTIC THROAT SPRAY is intended for use as a consumer oral antiseptic. These consumer topical antiseptics and oral antiseptic products are "new drugs" within the meaning of section 201(p) of the FD&C Act, 21 U.S.C. 321(p), because they are not generally recognized as safe and effective (GRASE) for use under the conditions prescribed, recommended, or suggested in their labeling. New drugs may not be introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in section 505(a) of the FD&C Act, 21 U.S.C. 355(a), unless they are lawfully marketed under section 505G of the FD&C Act (which is not the case for these products, as further described below) or under other exceptions not applicable here. No FDA-approved applications pursuant to section 505 of the FD&C Act, 21 U.S.C. 355, is in effect for these drug products, nor are we aware of any adequate and well-controlled clinical studies in the published literature that support a determination that your drug products are

GRASE for use under the conditions suggested, recommended, or prescribed in their labeling. Accordingly, these drug products are unapproved new drugs marketed in violation of sections 505(a) and 301(d) of the FD&C Act, 21 U.S.C 355(a) and 331(d). We note that OTC topical and oral antiseptic products had been the subject of rulemakings under the Agency's OTC Drug Review. In particular, consumer topical antiseptics were addressed in a tentative final monograph (TFM) entitled "Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Health-Care Antiseptic Drug Products," Proposed Rule, 59 FR 31402 (June 17, 1994) (1994 TFM), as further amended by "Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record," Proposed Rule, 81 FR 42912 (June 30, 2016) (Consumer Antiseptic Rubs Proposed Rule). Over the course of these rulemakings, three active ingredients (benzalkonium chloride, ethyl alcohol (ethanol), and isopropyl alcohol) were classified as Category III for use in consumer antiseptic rub products, meaning that additional safety and effectiveness data are needed to support a determination that a drug product containing one of these active ingredients would be GRASE for use as a consumer antiseptic rub. Oral antiseptics were addressed in a tentative final monograph (TFM) entitled "Oral Health Care Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Oral Antiseptic Drug Products"; Proposed Rule, 59 FR 6084 (February 9, 1994) (Oral Antiseptics Proposed Rule). Over the course of this rulemaking for oral antiseptics, povidone iodine at 0.5%, when labeled for short-term use (not to exceed 7 days), was classified as Category III for use as an OTC oral antiseptic, because additional effectiveness data are needed to support a determination that a product containing this active ingredient would be GRASE for use as an OTC oral antiseptic. Section 505G of the FD&C Act governs nonprescription drugs marketed without an approved application. Under section 505G(a)(3) of the FD&C Act, drugs that were classified as Category III for safety or effectiveness in a TFM that is the most recently applicable proposal or determination for such drug issued under 21 CFR Part 330 – and that were not classified as Category II for safety or effectiveness – are not required to have an approved application under section 505 in order to be marketed, as long as they meet the relevant conditions of use outlined in the applicable TFM, including the active ingredient, and comply with all other applicable requirements. However, your non-alcohol-based antiseptic products do not conform to the 1994 TFM, the Oral Antiseptics Proposed Rule, nor any other TFM, proposed rule, or final rule and do not meet the conditions under section 505G(a)(3) of the FD&C Act for marketing without an approved application under section 505. 7 Specifically, your labeling claims, suggesting that 1.5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, 1% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, .5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, and 1.5% POVIDONE IODINE USP ANTISEPTIC THROAT SPRAY are effective in shortening the duration of infection and preventing infection or disease from the novel coronavirus that causes COVID-19, go beyond merely describing the general intended use of an antiseptic as set forth in the 1994 TFM and the Oral Antiseptics Proposed Rule. 8 In addition, your labeling claims, suggesting that your non-alcohol-based antiseptic products provide up to 4 hours of efficacy against the novel coronavirus that causes COVID-19, are not permitted under the 1994 TFM, the Oral Antiseptics Proposed Rule, or any of the amendments to the TFMs discussed above. Time-specific extended efficacy claims, especially when related to serious-disease related pathogens, may lead to a false sense of security for the general public that may result in infrequent hand washing or the substitution of these products for protective gloves and clothing, which are the principal methods for protecting against the spread of diseases caused by pathogenic microorganisms. As a result, these products may give users the false impression that they need not rigorously adhere to interventions such as social distanc-

ing and exercising good hygienic practices that have been demonstrated to curb the spread of COVID-19. Users who do not follow these interventions are at increased risk for contracting COVID-19 and for spreading disease if they have been exposed to the virus, thereby prolonging the pandemic and increasing its associated morbidity and mortality. In addition, according to the product labeling, 1.5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, 1% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, and .5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY are intended to be applied inside the nostrils. Consumer antiseptic products intended for administration inside the nostrils are not permitted under the 1994 TFM, as further amended by the Consumer Antiseptic Rubs Proposed Rule. 9 Furthermore, 1.5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, 1% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, .5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, and 1.5% POVIDONE IODINE USP ANTISEPTIC THROAT SPRAY are misbranded under section 502(ee) of the FD&C Act, 21 U.S.C. 352(ee), because they are nonprescription drugs subject to section 505G of the FD&C Act, 21 U.S.C. 355h, but do not comply with the requirements for marketing under that section and are not the subject of an application approved under section 505 of the FD&C Act, 21 U.S.C. 355. You should take immediate action to address the violations cited in this letter. This letter is not meant to be an all-inclusive list of violations that exist in connection with your products or operations. It is your responsibility to ensure that the products you sell are in compliance with the FD&C Act and FDA's implementing regulations. We advise you to review your websites, product labels, and other labeling and promotional materials to ensure that you are not misleadingly representing your products as safe and effective for a COVID-19-related use for which they have not been approved by FDA. Within 48 hours, please send an email to COVID-19-Task-Force-CDER@fda.hhs.gov describing the specific steps you have taken to address these violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. Failure to adequately correct any violations may result in legal action, including, without limitation, seizure and injunction. FDA is advising consumers not to purchase or use certain products that have not been approved, cleared, or authorized by FDA and that are being misleadingly represented as safe and/or effective for the treatment or prevention of COVID-19. Your firm will be added to a published list on FDA's website of firms and websites that have received warning letters from FDA concerning the sale or distribution of COVID-19 related products in violation of the FD&C Act. This list can be found at http://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-covid-19-products . Once you have taken corrective actions to address the sale of your unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, and any appropriate corrective actions have been confirmed by FDA, the published list will be updated to indicate that your firm has taken appropriate corrective action. We note however, removal from the published list should not be interpreted to mean that you have properly addressed all other violations for your products and that you are free to proceed with their continued marketing. This letter notifies you of our concerns and provides you with an opportunity to address them. If you cannot take action to address this matter completely within 48 hours, state the reason for the delay and the time within which you will do so. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration. If you are not located in the United States, please note that products that appear to be misbranded or unapproved new drugs may be detained or refused admission if they are offered for importation into the United States. We may advise the appropriate regulatory officials in the country from which you operate that FDA considers your products referenced above to be unapproved and misbranded products that cannot be legally sold to consumers in the United States. Please direct any in-

quiries to FDA at COVID-19-Task-Force-CDER@fda.hhs.gov. FTC Cease and Desist Demand: In addition, it is unlawful under the FTC Act, 15 U.S.C. § 41 et seq., to advertise that a product can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time they are made. For COVID-19, no such study is currently known to exist for the products identified above. Thus, any coronavirus-related prevention or treatment claims regarding such products are not supported by competent and reliable scientific evidence. You must immediately cease making all such claims. Violations of the FTC Act may result in legal action seeking a Federal District Court injunction and an order may require that you pay back money to consumers. In addition, pursuant to the COVID-19 Consumer Protection Act, Section 1401, Division FF, of the Consolidated Appropriations Act, 2021, P.L. 116-260, marketers who make deceptive claims about the treatment, cure, prevention, or mitigation of COVID-19 are subject to a civil penalty of up to $46,517 per violation and may be required to pay refunds to consumers or provide other relief pursuant to Section 19(b) of the FTC Act, 15 U.S.C. § 57b(b). Within 48 hours, please send an email to Richard Cleland, Assistant Director of the FTC's Division of Advertising Practices, via electronic mail at rcleland@ftc.gov certifying that you have ceased making unsubstantiated claims for the products identified above. If you have any questions regarding compliance with the FTC Act, please contact Mr. Cleland at 202-326-3088. Sincerely, /S/ Donald D. Ashley Director Office of Compliance Center for Drug Evaluation and Research Food and Drug Administration Sincerely, /S/ Serena Viswanathan Associate Director Division of Advertising Practices Federal Trade Commission

_____1 Your non-alcohol-based antiseptic drug products include 1.5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, 1% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, .5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, and 1.5% POVIDONE IODINE USP ANTISEPTIC THROAT SPRAY. 2 As explained in the next paragraph, there is currently an outbreak of a respiratory disease named "Coronavirus Disease 2019" (COVID-19). 3 Secretary of Health and Human Services, Determination that a Public Health Emergency Exists. (originally issued on Jan. 31, 2020., and subsequently renewed) available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx). 4 Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at https://trumpwhitehouse.archives.gov/presidential-actions/proclamationdeclaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/). 5 1.5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, 1% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, and .5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY 6 1.5% POVIDONE IODINE USP ANTISEPTIC THROAT SPRAY 7 We note that 1.5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, 1% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, .5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, and 1.5% POVIDONE IODINE USP ANTISEPTIC THROAT SPRAY also do not conform to any temporary policy FDA has implemented during the public health emergency. In March 2020, the Agency published three guidance documents to provide regulatory flexibility to certain firms to help meet the demand for alcohol-based hand sanitizer during the COVID-19 public health emergency (PHE). Because your non-alcohol-based consumer antiseptic products are not consistent with the formulations described in these guidances, they do not fall within any temporary Agency policy not to take action against firms manufacturing hand sanitizer products for violations of section 505 of the FD&C Act. Additionally, on December 31, 2021 these guidances were withdrawn, and firms must cease distribution, by March 31, 2022, of any remaining hand sanitizer products that were prepared under the temporary policies before or on December 31, 2021. See, 86 FR 56960, October 13, 2021. 8 The 1994 TFM covers

consumer antiseptics that are indicated for use to decrease bacteria on the skin. 59 FR at 31443. The Oral Antiseptics Proposed Rule covers oral antiseptics that are indicated for use in first aid to help decrease bacterial contamination in minor cuts, minor scrapes or minor oral irritation caused by dental procedures, dentures, orthodontic appliances, or accidental injury and for use by health care professionals for preparation of the oral mucosa prior to injection, dental surgery, or tooth extraction. 59 FR at 6121-22. 9 The 2016 Consumer Antiseptic Rubs Proposed Rule covered consumer antiseptic products intended for use without water. Under the 1994 TFM, as amended by the 2016 Consumer Antiseptic Rubs Proposed Rule, only consumer topical antiseptic products intended for use on the hands without water are permitted. Products intended for other areas of the body such as the nose are not permitted. Content current as of: 03/08/2022 Regulated Product(s) Drugs More Warning Letters Warning Letters About Warning and Close-Out Letters

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Table 1: Places for report 1422031

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Elmira	42.0898	-76.80773
Americas	United States	United States	39.76	-98.5

Table 2: Drugs for report 1422031

Medicine Name	Medicine Class	Action	ATC Code
povidone-iodine	Iodine products	antiseptics and disinfectants	D08AG02
povidone-iodine	Medicated dressings with antiinfectives	medicated dressings	D09AA09
povidone-iodine	Medicated shampoos	other dermatological preparations	D11AC06
povidone-iodine	Other antiinfectives and antiseptics	antiinfectives and antiseptics, excl. combinations with corticosteroids	G01AX11
povidone-iodine	Antiseptics	throat preparations	R02AA15
povidone-iodine	Other antiinfectives	antiinfectives	S01AX18

Notes: This is to advise you that the United States Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) reviewed your website at the Internet address https://viraldine.com/ on December 21, 2021 and March 1, 2022, respectively. The FDA has observed that your website offers non-alcohol-based antiseptic products1 for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-192 in people. Based on our review, these products are unapproved new drugs sold in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 355(a).

Furthermore, these products are misbranded drugs under sections 502(ee) of the FD&C Act, 21 U.S.C. 352(ee). The introduction or delivery for introduction of these products into interstate commerce is prohibited under sections 301(a) and (d) of the FD&C Act, 21 U.S.C. 331(a) and (d). These violations are described in more detail below. [...] "Results: All concentrations of nasal antiseptics and oral rinse antiseptics evaluated completely inactivated the SARS-CoV-2. Conclusions: Nasal and oral PVP-I antiseptic solutions are effective at inactivating the SARS-CoV-2 at a variety of concentrations after 60-second exposure times. The formulations tested may help to reduce the transmission of SARS-CoV-2 if used for nasal decontamination, oral decontamination, or surface decontamination in known or suspected cases of COVID-19." [from your website https://viraldine.com/faqs-%26-pvp-i-studies] [...]

2 Pharmacy2Home/LandiCom Holding LTD - 615137 - 02/03/2022 - 2022-02-15

Publication date	2022-02-15
Create date	2022-02-18
Score	81.56
Report id	1401107
Category	Antiparasitic, Anti-malarial, Antiviral others, Antiretroviral
Quality	Diverted/Unregistered
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: Unapproved and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19)

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Table 3: Places for report 1401107

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5

Table 4: Drugs for report 1401107

Medicine Name	Medicine Class	Action	ATC Code
			J05AB04
oseltamivir	Neuraminidase inhibitors	direct acting antivirals	J05AH02
ivermectin	Other dermatologicals	other dermatological preparations	D11AX22
ivermectin	Avermectines	antinematodal agents	P02CF01
lopinavir and ritonavir	Antivirals for treatment of HIV infections, combinations	direct acting antivirals	J05AR10
chloroquine	Aminoquinolines	antimalarials	P01BA01

Notes: This is to advise you that the United States (U.S.) Food and Drug Administration (FDA)

reviewed your website at the Internet address www.pharmacy2home.com on December 13, 2021. FDA has observed that your website offers drug products for sale in the U.S. and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-191 and a variety of other diseases, such as influenza, certain strains of malaria, liver amebiasis, and rheumatoid arthritis. Based on our review, these products are unapproved new drugs introduced into interstate commerce in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. § 355(a)]. [...] For example, under the "Coronavirus (COVID-19): Chloroquine 500 Mg (Aralen)" heading, www.pharmacy2home.com offers chloroquine phosphate described as "Chloroquine (CoronaVirus Covid-19)" and pictured with the brand name "Lariago-DS." Your website states, "Chloroquine is an antimalarial drug which is primarily prescribed to treat certain strains of malaria. It is sometimes also prescribed for liver amebiasis and Rheumatoid arthritis. Chloroquine is found to help fighting[sic] CoronaVirus Covid-19." [...] Your website www.pharmacy2home.com also offers oseltamivir marketed as "Antiflu 75 mg (Oseltamivir)" manufactured by Cipla under the "Coronavirus (COVID-19): Antiflu 75 mg (Oseltamivir)" heading. Your website states, "Antiflu 75 mg (Oseltamivir) is used to treat symptoms cause by the flu virus (influenza)." In addition, www.pharmacy2home.com offers oseltamivir as part of a "CoronaVirus pack" containing "Ritonavir 50mg + Lopinavir 200mg, Ribavirin 200mg, Oseltamivir 75mg" and states, "For CoronaVirus (COVID-19) a combination treatment of Antiflu 75 mg (Oseltamivir) together with Ribasure (Ribavirin) 200 mg and Hivus-LR (Lopinavir + Ritonavir 200/50 mg)." [...] Additionally, www.pharmacy2home.com offers ivermectin under the header "Ivermectin 12mg (Covid/Corona)" and pictured as "Iverheal 12." Your website states, "Ivermectin is an oral drug which is used in treatment of conditions caused by parasitic infections. Ivermectin was found to help coping with Covid-19 and as prohylactic[sic] to Covid-19 (Corona Virus). It can be used to treat onchocerciasis, as well as similar infections such as ascariasis, strongyloidiasis, trichuriasis, enterobiasis, and filariasis"[...]

3 Extrapharmacy.ru - Center for Drug Evaluation and Research | CDER - Unlawful Sale of Unapproved and Misbranded Drugs to United States Consumers Over the Internet - 2022-02-22

Publication date	2022-02-22
Create date	2022-02-24
Score	59.76
Report id	1407898
Category	Anti-malarial, Antiviral others
Quality	Diverted/Unregistered
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER Extrapharmacy.ru MARCS-CMS 615132 — February 15, 2022 Share Tweet Linkedin Email Print Product: Drugs Recipient: Recipient Name Mikhail Kazankov Extrapharmacy.ru Russia Issuing Office: Center for Drug Evaluation and Research | CDER United States FROM: The United States Food and Drug Administration RE: Notice of Unlawful Sale of Unapproved and Misbranded Drugs to United States Consumers Over the Internet DATE: February 15, 2022 WARNING LETTER This is to advise you that the United States (U.S.) Food and Drug Administration (FDA) reviewed your website at the Internet address www.extrapharmacy.ru on December 13, 2021. FDA has observed that your website offers drug products for sale in the U.S. and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19 1 and a variety of other diseases such as systemic lupus erythematosus, rheumatoid arthritis, and malaria. Based on our review, these products are unapproved new drugs introduced into interstate commerce in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. § 355(a)]. Furthermore, these products are misbranded drugs under section 502 of the FD&C Act [21 U.S.C. § 352]. The introduction or delivery for introduction of these products into interstate commerce is prohibited under sections 301(a) and 301(d) of the FD&C Act [21 U.S.C. § 331(a) and 331(d)]. There is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been named ”severe acute respiratory syndrome coronavirus 2” (SARS-CoV-2). The disease caused by the virus has been named ”Coronavirus Disease 2019” (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS. 2 In addition, on March 13, 2020, there was a Presidential declaration of a national emergency in response to COVID-19. 3 Therefore, FDA is taking urgent measures to protect consumers from certain products that, without approval or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. As described below, FDA has observed that your website offers drug products for sale in the U.S. that are intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. There are inherent risks to consumers who purchase

unapproved new drugs and misbranded drugs. Unapproved new drugs do not carry the same assurances of safety and effectiveness as those drugs subject to FDA oversight. Drugs that have circumvented regulatory safeguards may be contaminated, counterfeit, contain varying amounts of active ingredients, or contain different ingredients altogether. We request that you cease the sale of any unapproved and misbranded products, whether for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, or any other disease for which the drugs you are selling are not approved by FDA for distribution in the U.S. Unapproved New Drugs: Certain products offered for sale by www.extrapharmacy.ru are drugs within the meaning of section 201(g) of the FD&C Act [21 U.S.C. § 321(g)] because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or because they are intended to affect the structure or function of the body. These drugs are also new drugs as defined by section 201(p) of the FD&C Act [21 U.S.C. § 321(p)], because they are not generally recognized as safe and effective for their labeled uses. With certain exceptions not applicable here, new drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in section 505(a) of the FD&C Act [21 U.S.C. § 355(a)]. No approved applications pursuant to section 505 of the FD&C Act are in effect for these products. Accordingly, their introduction or delivery for introduction into interstate commerce violates sections 301(d) [21 U.S.C. § 331(d)] and 505(a) of the FD&C Act. For example, among other drugs offered on your website under the category of Coronavirus/COVID-19, www.extrapharmacy.ru offers hydroxychloroquine marketed as "Plaquenil (Hydroxychloroquine)" manufactured by Sanofi. Your website states, "Plaquenil is an effective remedy for malaria, systemic lupus erythematosus, rheumatoid arthritis." While there are FDA-approved versions of hydroxychloroquine, including "Plaquenil," on the market in the U.S., there are no approved drug applications pursuant to section 505 of the FD&C Act in effect for the "Plaquenil (Hydroxychloroquine)" manufactured by Sanofi and offered by www.extrapharmacy.ru. FDA-approved hydroxychloroquine is labeled for the treatment of uncomplicated malaria, discoid and systemic lupus erythematosus, and acute and chronic rheumatoid arthritis and is only available by prescription. In addition, hydroxychloroquine has not been approved by FDA for use in the prevention, diagnosis, treatment, mitigation, or cure of COVID-19. 4 Your website also offers a product marketed as "Areplivir (Favipiravir)" manufactured by Promomed. Your website states, "Favipiravir inhibits SARS-CoV-2 Virus Causing COVID-19," and provides a dosing regimen "[f]or the treatment of COVID-19." There are no approved drug applications pursuant to section 505 of the FD&C Act in effect for the "Areplivir (Favipiravir)" manufactured by Promomed and offered by www.extrapharmacy.ru. Misbranded Drugs: A drug is misbranded under section 502(f)(1) of the FD&C Act [21 U.S.C. § 352(f)(1)] if its labeling fails to bear adequate directions for use. "Adequate directions for use" means directions under which a layperson can use a drug safely and for the purposes for which it is intended (see 21 CFR 201.5). Prescription drugs, as defined in section 503(b)(1) of the FD&C Act [21 U.S.C. § 353(b)(1)], include those that, because of their toxicity or other potentiality for harmful effect, and/or the method of their use, and/or the collateral measures necessary for their use, are not safe for use except under supervision of a practitioner licensed by law to administer them. Prescription drugs, as defined in section 503(b)(1)(A) of the FD&C Act, can be used safely only at the direction, and under the supervision, of a licensed practitioner. Because the aforementioned drugs are prescription drugs intended for conditions that are not amenable to self-diagnosis and treatment by a layperson, adequate directions cannot be written such that a layperson can use the products safely for their intended uses. Consequently, the labeling for these drugs fails to bear adequate directions for use, causing them to be misbranded under section 502(f)(1) of the FD&C Act. In addition, because these drugs are not approved in the U.S., they are also not exempt under 21

CFR 201.115(a) from the requirements of section 502(f)(1) of the FD&C Act. By offering these drugs for sale to U.S. consumers, www.extrapharmacy.ru is causing the introduction of misbranded drugs into interstate commerce in violation of section 301(a) of the FD&C Act [21 U.S.C. § 331(a)]. FDA is sending this Warning Letter to www.extrapharmacy.ru because of the inherent risk to consumers who purchase misbranded and unapproved new drugs. This letter is not intended to identify all the ways in which your products or operations might be in violation of the law. It is your responsibility to ensure that all products you offer for sale are in compliance with the FD&C Act and its implementing regulations. You should take prompt action to address any violations of the FD&C Act (which may include the offer for sale of similarly misbranded and/or unapproved new drugs other than the drugs noted above). We advise you to review your websites, product labels, and other labeling and promotional materials to ensure that you are not misleadingly representing your products as safe and effective for a use for which they have not been approved by FDA and that you are not distributing misbranded products in violation of the FD&C Act. Within 48 hours, please send an email to FDAInternetPharmacyTaskForce-CDER@fda.hhs.gov and COVID-19-Task-Force-CDER@fda.hhs.gov describing the specific steps you have taken to address any violations and to prevent their recurrence. Include an explanation of each step being taken to remedy and prevent the recurrence of any violations, as well as copies of related documentation. Failure to adequately address this matter may result in legal action, including, without limitation, seizure and injunction, without further notice. If you cannot complete corrective action within 48 hours, state the reason for the delay and the time within which you will complete the corrections. This letter notifies you of our concerns and provides you with an opportunity to address them. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration within 48 hours. If you are not located in the U.S., please note that products that appear to be misbranded or unapproved new drugs may be detained or refused admission. We may advise the appropriate regulatory officials in the country from which you operate that your products referenced above appear to be unapproved and misbranded products that cannot be legally sold to consumers in the U.S. Please direct any inquiries to FDA at FDAInternetPharmacyTaskForce-CDER@fda.hhs.gov and COVID-19-Task-Force-CDER@fda.hhs.gov . Sincerely, /S/ Donald D. Ashley Director Office of Compliance Center for Drug Evaluation and Research Food and Drug Administration

_____1 As explained in the next paragraph, there is currently an outbreak of a respiratory disease named "Coronavirus Disease 2019" (COVID-19). 2 Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx . 3 President Donald J. Trump, Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak. Mar. 13, 2020, 85 FR 15337, available at https://www.federalregister.gov/documents/2020/03/18/2020-05794/declaring-a-national-emergency-concerning-the-novel-coronavirus-disease-covid-19-outbreak . 4 On March 28, 2020, FDA issued an Emergency Use Authorization (EUA), pursuant to section 564 of the FD&C Act [21 U.S.C. § 360bbb-3], to permit the emergency use of hydroxychloroquine sulfate and chloroquine phosphate supplied from the Strategic National Stockpile to treat adults and adolescents who weigh 50 kg or more and are hospitalized with COVID-19 for whom a clinical trial is not available, or participation is not feasible. On April 24, 2020, FDA issued a Drug Safety Communication cautioning against the use of hydroxychloroquine or chloroquine for COVID-19 outside of either: (1) use in a hospital setting pursuant to FDA's EUA; or (2) participation in a clinical trial investigating use of chloroquine or hydroxychloroquine for treatment of COVID-19. FDA issued that Drug Safety Communication to remind patients and health care professionals of the known risk of

serious heart rhythm problems associated with chloroquine and hydroxychloroquine. FDA revoked this EUA on June 15, 2020, based on FDA's continuing review of available scientific evidence, including clinical trial results, that led FDA to determine that the statutory criteria for EUA as outlined in Section 564(c)(2) of the FD&C Act were no longer met. Specifically, FDA determined that chloroquine and hydroxychloroquine are unlikely to be effective in treating COVID-19 for the authorized uses under the EUA and that the known and potential benefits of chloroquine and hydroxychloroquine no longer outweigh the known and potential risks for the formerly authorized uses. Authorizations and Revocation of Emergency Use of Drugs During the COVID-19 Pandemic; Availability, 85 Fed. Reg. 56231 (Sept. 11, 2020) (accessible at https://www.federalregister.gov/documents/2020/09/11/2020-20041/authorizations-and-revocation-of-emergency-use-of-drugs-during-the-covid-19-pandemic-availability). Content current as of: 02/22/2022 Regulated Product(s) Drugs More Warning Letters Warning Letters About Warning and Close-Out Letters

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Table 5: Places for report 1407898

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5
Western Asia	Russian Federation	Russian Federation	60	100

Table 6: Drugs for report 1407898

Medicine Name	Medicine Class	Action	ATC Code
favipiravir	Other antivirals	direct acting antivirals	J05AX27
hydroxychloroquine	Aminoquinolines	antimalarials	P01BA02

Notes: [...] For example, among other drugs offered on your website under the category of Coronavirus/COVID-19, www.extrapharmacy.ru offers hydroxychloroquine marketed as "Plaquenil (Hydroxychloroquine)" manufactured by Sanofi. Your website states, "Plaquenil is an effective remedy for malaria, systemic lupus erythematosus, rheumatoid arthritis." While there are FDA-approved versions of hydroxychloroquine, including "Plaquenil," on the market in the U.S., there are no approved drug applications pursuant to section 505 of the FD&C Act in effect for the "Plaquenil (Hydroxychloroquine)" manufactured by Sanofi and offered by www.extrapharmacy.ru. FDA-approved hydroxychloroquine is labeled for the treatment of uncomplicated malaria, discoid and systemic lupus erythematosus, and acute and chronic rheumatoid arthritis and is only available by prescription. In addition, hydroxychloroquine has not been approved by FDA for use in the prevention, diagnosis, treatment, mitigation, or cure of COVID-19.4

Your website also offers a product marketed as "Areplivir (Favipiravir)" manufactured by Promomed. Your website states, "Favipiravir inhibits SARS-CoV-2 Virus Causing COVID-19," and provides a dosing regimen "[f]or the treatment of COVID-19." There are no approved drug applications pursuant to section 505 of the FD&C Act in effect for the "Areplivir (Favipiravir)" manufactured by Promomed and offered by www.extrapharmacy.ru. [...]

4 rxshopmd.com - Center for Drug Evaluation and Research | CDER - Unlawful Sale of Unapproved and Misbranded Drugs to United States Consumers Over the Internet - 2022-02-22

Publication date	2022-02-22
Create date	2022-02-24
Score	51.30
Report id	1407899
Category	Antiretroviral
Quality	Diverted/Unregistered
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER rxshopmd.com MARCS-CMS 615753 — February 15, 2022 Share Tweet Linkedin Email Print Product: Drugs Recipient: rxshopmd.com Cyprus Issuing Office: Center for Drug Evaluation and Research | CDER United States FROM: The United States Food and Drug Administration RE: Notice of Unlawful Sale of Unapproved and Misbranded Drugs to United States Consumers Over the Internet DATE: February 15, 2022 WARNING LETTER This is to advise you that the United States (U.S.) Food and Drug Administration (FDA) reviewed your website at the Internet address www.rxshopmd.com on December 13, 2021. FDA has observed that your website offers drug products for sale in the U.S. and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19 1 and a variety of other diseases such as HIV. Based on our review, these products are unapproved new drugs introduced into interstate commerce in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. § 355(a)]. Furthermore, these products are misbranded drugs under section 502 of the FD&C Act [21 U.S.C. § 352]. The introduction or delivery for introduction of these products into interstate commerce is prohibited under sections 301(a), 301(d), and 301(k) of the FD&C Act [21 U.S.C. § 331(a), 331(d), and 331(k)]. There is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been named ”severe acute respiratory syndrome coronavirus 2” (SARS-CoV-2). The disease caused by the virus has been named ”Coronavirus Disease 2019” (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS. 2 In addition, on March 13, 2020, there was a Presidential declaration of a national emergency in response to COVID-19. 3 Therefore, FDA is taking urgent measures to protect consumers from certain products that, without approval or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. As described below, FDA has observed that your website offers drug products for sale in the U.S. that are intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. There are inherent risks to consumers who purchase unapproved new drugs and misbranded drugs. Unapproved new drugs do not carry the same assurances of safety and effectiveness as those drugs subject to FDA oversight. Drugs that have

circumvented regulatory safeguards may be contaminated, counterfeit, contain varying amounts of active ingredients, or contain different ingredients altogether. We request that you cease the sale of any unapproved and misbranded products, whether for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, or any other disease for which the drugs you are selling are not approved by FDA for distribution in the U.S. Unapproved New Drugs: Certain products offered for sale by www.rxshopmd.com are drugs within the meaning of section 201(g) of the FD&C Act [21 U.S.C. § 321(g)] because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or because they are intended to affect the structure or function of the body. These drugs are also new drugs as defined by section 201(p) of the FD&C Act [21 U.S.C. § 321(p)], because they are not generally recognized as safe and effective for their labeled uses. With certain exceptions not applicable here, new drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in section 505(a) of the FD&C Act [21 U.S.C. § 355(a)]. No approved applications pursuant to section 505 of the FD&C Act are in effect for these products. Accordingly, their introduction or delivery for introduction into interstate commerce violates sections 301(d) [21 U.S.C. § 331(d)] and 505(a) of the FD&C Act. For example, www.rxshopmd.com offers lopinavir + ritonavir marketed as "Hivus-LR (Lopinavir + Ritonavir 200/50 mg)" manufactured by Aurobindo Pharma Ltd. In the description of "Hivus-LR (Lopinavir + Ritonavir 200/50 mg)," your website states, "The medication known mostly as Kaletra is based on Lopinavir + Ritonavir. It is a HIV medication that is used in a combination therapy. In 2020, it have[sic] been also tested and included in the protocols of treatment of the novel coronavirus COVID-19." Additionally, under the "Generic Hivus-LR (Lopinavir + Ritonavir 200/50 mg) guide" heading, www.rxshopmd.com states, "The medication sold under the brand name Kaletra is used as a part of a complex therapy of HIV and AIDS. Since March 2020, it is also approved for the treatment of the novel coronavirus, COVID-19..." While there are FDA-approved versions of lopinavir + ritonavir, including "Kaletra," on the market in the U.S., there are no approved drug applications pursuant to section 505 of the FD&C Act in effect for the "Hivus-LR (Lopinavir + Ritonavir 200/50 mg)" manufactured by Aurobindo Pharma Ltd. and offered by www.rxshopmd.com. FDA-approved lopinavir + ritonavir is an HIV-1 protease inhibitor indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients, and is only available by prescription. In addition, the combination of lopinavir and ritonavir has not been approved by FDA for use in the prevention, diagnosis, treatment, mitigation, or cure of COVID-19. Misbranded Drugs: A drug is misbranded under section 502(f)(1) of the FD&C Act [21 U.S.C. § 352(f)(1)] if its labeling fails to bear adequate directions for use. "Adequate directions for use" means directions under which a layperson can use a drug safely and for the purposes for which it is intended (see 21 CFR 201.5). Prescription drugs, as defined in section 503(b)(1) of the FD&C Act [21 U.S.C. § 353(b)(1)], include those that, because of their toxicity or other potentiality for harmful effect, and/or the method of their use, and/or the collateral measures necessary for their use, are not safe for use except under supervision of a practitioner licensed by law to administer them. Prescription drugs, as defined in section 503(b)(1)(A) of the FD&C Act, can be used safely only at the direction, and under the supervision, of a licensed practitioner. Because the aforementioned drug is a prescription drug intended for a condition that is not amenable to self-diagnosis and treatment by a layperson, adequate directions cannot be written such that a layperson can use the product safely for the intended use. Consequently, the labeling for this drug fails to bear adequate directions for use, causing it to be misbranded under section 502(f)(1) of the FD&C Act. In addition, because the drug is not approved in the U.S., it is also not exempt under 21 CFR 201.115(a) from the requirements of section 502(f)(1) of the FD&C Act. By offering this drug for sale to U.S. consumers, www.rxshopmd.com is

causing the introduction of a misbranded drug into interstate commerce in violation of section 301(a) of the FD&C Act [21 U.S.C. § 331(a)]. Furthermore, under U.S. law, prescription drugs can be dispensed only pursuant to a prescription from a healthcare practitioner licensed by law to administer prescription drugs. By offering the aforementioned drugs without requiring a prescription, www.rxshopmd.com jeopardizes patient safety and misbrands the drugs under section 503(b)(1) of the FD&C Act. Dispensing a prescription drug without a prescription is an act which results in the drug being misbranded while held for sale, in violation of section 301(k) of the FD&C Act [21 U.S.C. § 331(k)]. FDA is sending this Warning Letter to www.rxshopmd.com because of the inherent risk to consumers who purchase misbranded and unapproved new drugs. This letter is not intended to identify all the ways in which your products or operations might be in violation of the law. It is your responsibility to ensure that all products you offer for sale are in compliance with the FD&C Act and its implementing regulations. You should take prompt action to address any violations of the FD&C Act (which may include the offer for sale of similarly misbranded and/or unapproved new drugs other than the drugs noted above). We advise you to review your websites, product labels, and other labeling and promotional materials to ensure that you are not misleadingly representing your products as safe and effective for a use for which they have not been approved by FDA and that you are not distributing misbranded products in violation of the FD&C Act. Within 48 hours, please send an email to FDAInternetPharmacyTaskForce-CDER@fda.hhs.gov and COVID-19-Task-Force-CDER@fda.hhs.gov describing the specific steps you have taken to address any violations and to prevent their recurrence. Include an explanation of each step being taken to remedy and prevent the recurrence of any violations, as well as copies of related documentation. Failure to adequately address this matter may result in legal action, including, without limitation, seizure and injunction, without further notice. If you cannot complete corrective action within 48 hours, state the reason for the delay and the time within which you will complete the corrections. This letter notifies you of our concerns and provides you with an opportunity to address them. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration within 48 hours. If you are not located in the U.S., please note that products that appear to be misbranded or unapproved new drugs may be detained or refused admission. We may advise the appropriate regulatory officials in the country from which you operate that your products referenced above appear to be unapproved and misbranded products that cannot be legally sold to consumers in the U.S. Please direct any inquiries to FDA at FDAInternetPharmacyTaskForce-CDER@fda.hhs.gov and COVID-19-Task-Force-CDER@fda.hhs.gov. Sincerely, /S/ Donald D. Ashley Director Office of Compliance Center for Drug Evaluation and Research Food and Drug Administration _____1 As explained in the next paragraph, there is currently an outbreak of a respiratory disease named "Coronavirus Disease 2019" (COVID-19). 2 Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx . 3 President Donald J. Trump, Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak. Mar. 13, 2020, 85 FR 15337, available at https://www.federalregister.gov/documents/2020/03/18/2020-05794/declaring-a-national-emergency-concerning-the-novel-coronavirus-disease-covid-19-outbreak . Content current as of: 02/22/2022 Regulated Product(s) Drugs More Warning Letters Warning Letters About Warning and Close-Out Letters

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Table 7: Places for report 1407899

Region Name	Country	Location	Latitude	Longitude
Europe	Cyprus	Republic of Cyprus	35	33
Americas	United States	United States	39.76	-98.5

Table 8: Drugs for report 1407899

Medicine Name	Medicine Class	Action	ATC Code
ritonavir	Protease inhibitors	direct acting antivirals	J05AE03
lopinavir and ritonavir	Antivirals for treatment of HIV infections, combinations	direct acting antivirals	J05AR10

Notes: [...] For example, www.rxshopmd.com offers lopinavir + ritonavir marketed as "Hivus-LR (Lopinavir + Ritonavir 200/50 mg)" manufactured by Aurobindo Pharma Ltd. In the description of "Hivus-LR (Lopinavir + Ritonavir 200/50 mg)," your website states, "The medication known mostly as Kaletra is based on Lopinavir + Ritonavir. It is a HIV medication that is used in a combination therapy. In 2020, it have[sic] been also tested and included in the protocols of treatment of the novel coronavirus COVID-19." Additionally, under the "Generic Hivus-LR (Lopinavir + Ritonavir 200/50 mg) guide" heading, www.rxshopmd.com states, "The medication sold under the brand name Kaletra is used as a part of a complex therapy of HIV and AIDS. Since March 2020, it is also approved for the treatment of the novel coronavirus, COVID-19..." While there are FDA-approved versions of lopinavir + ritonavir, including "Kaletra," on the market in the U.S., there are no approved drug applications pursuant to section 505 of the FD&C Act in effect for the "Hivus-LR (Lopinavir + Ritonavir 200/50 mg)" manufactured by Aurobindo Pharma Ltd. and offered by www.rxshopmd.com. FDA-approved lopinavir + ritonavir is an HIV-1 protease inhibitor indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients, and is only available by prescription. In addition, the combination of lopinavir and ritonavir has not been approved by FDA for use in the prevention, diagnosis, treatment, mitigation, or cure of COVID-19. [...]

5 27 pharma companies in Himachal get notice for failed drug samples

Publication date 2022-02-11

Create date 2022-02-18

Score 50.33

Report id 1397229

Category Other, Cardiovascular medicine, Antacid, Antipyretic, Antiviral others

Quality Substandard

Source Manufacturer

Curation Manually curated

Incident or General Incident

Snippet: 27 pharma companies in Himachal get notice for failed drug samples Hindustan Times

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Table 9: Places for report 1397229

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	State of Himāchal Pradesh	31.91667	77.25

Table 10: Drugs for report 1397229

Medicine Name	Medicine Class	Action	ATC Code
favipiravir	Other antivirals	direct acting antivirals	J05AX27
folic acid	Folic acid and derivatives	vitamin b12 and folic acid	B03BB01
enalapril	ACE inhibitors, plain	ace inhibitors, plain	C09AA02
pantoprazole	Proton pump inhibitors	drugs for peptic ulcer and gastro-oesophageal reflux disease (gord)	A02BC02
atenolol	Beta blocking agents, selective	beta blocking agents	C07AB03
paracetamol	Anilides	other analgesics and antipyretics	N02BE01
ferrous sulfate	Iron bivalent, oral preparations	iron preparations	B03AA07

Table 10: Drugs for report 1397229(continued)

Medicine Name	Medicine Class	Action	ATC Code
ferrous sulfate	Iron in combination with folic acid	iron preparations	B03AD03

Table 11: Other Stories

ID	Title	Link
1399151	Drugs made in HP fail quality test: Himachal Congress chief Kuldeep Rathore questions govt	Link
1399802	Drug Alert: CDSCO flags 27 formulations as not of standard quality - 2022-02-14	Link
1434614	Substandard drugs from HP	Link

Notes: Nine medicines manufactured by Himachal Pradesh-based pharmaceutical companies are among 27 drugs that failed the safety standard test in January. According to a monthly alert issued by the Central Drugs Standard Control Organisation (CDSCO), the drugs that failed the test include Favipiravir that is used in the treatment of Covid-19. The other drugs are used in the treatments of heart attack, gastric, gout and high BP. [...] The remaining 18 drugs that failed the test have been manufactured in units of Uttarakhand, Madhya Pradesh, Punjab, Maharashtra, Telangana and Tamil Nadu. The CDSCO had taken 1,227 samples of drugs of which 1,200 cleared the quality test and 27 failed. [...] Additional Information: ID 1399802 (https://medicaldialogues.in/news/industry/pharma/drug-alert-cdsco-flags-27-formulations-as-not-of-standard-quality-88526): These drug samples including Bochem Healthcare's Ferrous Sulphate & Folic Acid Tablets IP, Zee Laboratories' NITZO -2.6 (Controlled Release Tablets of Nitrogylcerin), Skymap Pharmaceuticals' WARZYME Digestive Enzymes (Pepsin & Fungal Diastase Syrup), Ortin Laboratories' Enalapril Maleate Tablets IP 5 mg, OmBiomedic's Pantoprazole Gastro- Resistant Tablets I.P., Terrace Pharmaceutical's Atenolol Tablets IP 50 mg and others are declared as 'Not of Standard Quality'. In addition, Paracetamol Tablets IP 650 mg manufactured by Zim Laboratories, popular covid drug Favipiravir Tablets 400 mg manufactured by Maxrelief Healthcare are on the list. [...] A few of the reasons why the drug samples tested failed were the failure of the assay, failure of the Sterility test, failure of the dissolution test, failure of disintegration, failure of the Assay of Methylcobalamin & Vitamin D3 assay etc. [...]

6 Ivermectin24h.com - Center for Drug Evaluation and Research | CDER - Unlawful Sale of Misbranded Drugs to United States Consumers Over the Internet - 2022-03-15

Publication date	2022-03-15
Create date	2022-03-21
Score	47.20
Report id	1429442
Category	Antiparasitic
Quality	Diverted/Unregistered
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER Ivermectin24h.com MARCS-CMS 615637 — February 25, 2022 Share Tweet Linkedin Email Print Product: Drugs Recipient: Ivermectin24h.com United States Issuing Office: Center for Drug Evaluation and Research | CDER United States FROM: The United States Food and Drug Administration RE: Notice of Unlawful Sale of Misbranded Drugs to United States Consumers Over the Internet DATE: February 25, 2022 WARNING LETTER This is to advise you that the United States (U.S.) Food and Drug Administration (FDA) reviewed your website at the Internet address www.ivermectin24h.com on December 13, 2021. FDA has observed that your website offers drug products for sale in the U.S. and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19 1 and a variety of other diseases such as malaria, lupus erythematosus, and rheumatoid arthritis. Based on our review, these products are misbranded drugs under section 503(b) of the FD&C Act [21 U.S.C. § 353(b)]. The introduction or delivery for introduction of these products into interstate commerce is prohibited under sections 301(a) and 301(k) of the FD&C Act [21 U.S.C. §§ 331(a) and 331(k)]. There is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been named ”severe acute respiratory syndrome coronavirus 2” (SARS-CoV-2). The disease caused by the virus has been named ”Coronavirus Disease 2019” (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS. 2 In addition, on March 13, 2020, there was a Presidential declaration of a national emergency in response to COVID-19. 3 Therefore, FDA is taking urgent measures to protect consumers from certain products that, without approval or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. As described below, FDA has observed that your website offers drug products for sale in the U.S. that are intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. There are inherent risks to consumers who purchase misbranded drugs. Drugs that have circumvented regulatory safeguards may be contaminated, counterfeit, contain varying amounts of active ingredients, or contain different ingredients altogether. We request that you cease the sale of any misbranded products, whether for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, or

any other disease for which the drugs you are selling are not approved by FDA for distribution in the U.S. Misbranded Drugs: Certain products offered for sale by www.ivermectin24h.com are drugs within the meaning of section 201(g) of the FD&C Act [21 U.S.C. § 321(g)] because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or because they are intended to affect the structure or function of the body. For example, www.ivermectin24h.com offers hydroxychloroquine marketed as "Hydroxychloroquine." Your website's homepage features the question, "Worried about CORONAVIRUS?" accompanied by a "BUY NOW" button. From this "BUY NOW" button, your website directs customers to the product page for the "Hydroxychloroquine" offered by www.ivermectin24h.com. Your website states, "Hydroxychloroquine is a medication that can be used to treat multiple diseases including malaria, Lupus Erythematosus, and Rheumatoid Arthritis." FDA-approved hydroxychloroquine is labeled for the treatment of uncomplicated malaria, discoid and systemic lupus erythematosus, and acute and chronic rheumatoid arthritis and is only available by prescription. In addition, hydroxychloroquine has not been approved by FDA for use in the prevention, diagnosis, treatment, mitigation, or cure of COVID-19. 4 FDA-approved drug products containing hydroxychloroquine (also marketed as Plaquenil) are limited by their approved applications to use under the supervision of a licensed practitioner to administer such drugs. Therefore, hydroxychloroquine is a prescription drug as defined in section 503(b)(1)(A) of the FD&C Act (21 U.S.C. § 353(b)(1)(A)), because, in light of its toxicity or potential for harmful effects, the method of its use, or the collateral measures necessary for its use, it is not safe for use except under the supervision of a practitioner licensed by law to administer such a drug. By offering the aforementioned drug without requiring a prescription, www.ivermectin24h.com jeopardizes patient safety and misbrands the drug under section 503(b)(1) of the FD&C Act. Dispensing a prescription drug without a prescription is an act which results in the drug being misbranded while held for sale, in violation of section 301(k) of the FD&C Act [21 U.S.C. § 331(k)]. By offering this drug for sale to U.S. consumers, www.ivermectin24h.com is also causing the introduction of a misbranded drug into interstate commerce in violation of section 301(a) of the FD&C Act [21 U.S.C. § 331(a)]. FDA is sending this Warning Letter to www.ivermectin24h.com because of the inherent risk to consumers who purchase misbranded drugs. This letter is not intended to identify all the ways in which your products or operations might be in violation of the law. It is your responsibility to ensure that all products you offer for sale are in compliance with the FD&C Act and its implementing regulations. You should take prompt action to address any violations of the FD&C Act (which may include the offer for sale of similarly misbranded drugs other than the drugs noted above). We advise you to review your websites, product labels, and other labeling and promotional materials to ensure that you are not misleadingly representing your products as safe and effective for a use for which they have not been approved by FDA and that you are not distributing misbranded products in violation of the FD&C Act. Within 48 hours, please send an email to FDAInternetPharmacyTaskForce-CDER@fda.hhs.gov and COVID-19-Task-Force-CDER@fda.hhs.gov describing the specific steps you have taken to address any violations and to prevent their recurrence. Include an explanation of each step being taken to remedy and prevent the recurrence of any violations, as well as copies of related documentation. Failure to adequately address this matter may result in legal action, including, without limitation, seizure and injunction, without further notice. If you cannot complete corrective action within 48 hours, state the reason for the delay and the time within which you will complete the corrections. This letter notifies you of our concerns and provides you with an opportunity to address them. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration within 48 hours. If you are not located in the U.S., please note that products that appear to be misbranded drugs may be detained or refused

admission. We may advise the appropriate regulatory officials in the country from which you operate that your products referenced above appear to be misbranded products that cannot be legally sold to consumers in the U.S. Please direct any inquiries to FDA at FDAInternet-PharmacyTaskForce-CDER@fda.hhs.gov and COVID-19-Task-Force-CDER@fda.hhs.gov. Sincerely, /S/ Donald D. Ashley Director Office of Compliance Center for Drug Evaluation and Research Food and Drug Administration _____1 As explained in the next paragraph, there is currently an outbreak of a respiratory disease named "Coronavirus Disease 2019" (COVID-19). 2 Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx . 3 President Donald J. Trump, Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak. Mar. 13, 2020, 85 FR 15337, available at https://www.federalregister.gov/documents/2020/03/18/2020-05794/declaring-a-national-emergency-concerning-the-novel-coronavirus-disease-covid-19-outbreak . 4 On March 28, 2020, FDA issued an Emergency Use Authorization (EUA), pursuant to section 564 of the FD&C Act [21 U.S.C. § 360bbb-3], to permit the emergency use of hydroxychloroquine sulfate and chloroquine phosphate supplied from the Strategic National Stockpile to treat adults and adolescents who weigh 50 kg or more and are hospitalized with COVID-19 for whom a clinical trial is not available, or participation is not feasible. On April 24, 2020, FDA issued a Drug Safety Communication cautioning against the use of hydroxychloroquine or chloroquine for COVID-19 outside of either: (1) use in a hospital setting pursuant to FDA's EUA; or (2) participation in a clinical trial investigating use of chloroquine or hydroxychloroquine for treatment of COVID-19. FDA issued that Drug Safety Communication to remind patients and health care professionals of the known risk of serious heart rhythm problems associated with chloroquine and hydroxychloroquine. FDA revoked this EUA on June 15, 2020, based on FDA's continuing review of available scientific evidence, including clinical trial results, that led FDA to determine that the statutory criteria for EUA as outlined in Section 564(c)(2) of the FD&C Act were no longer met. Specifically, FDA determined that chloroquine and hydroxychloroquine are unlikely to be effective in treating COVID-19 for the authorized uses under the EUA and that the known and potential benefits of chloroquine and hydroxychloroquine no longer outweigh the known and potential risks for the formerly authorized uses. Authorizations and Revocation of Emergency Use of Drugs During the COVID-19 Pandemic; Availability, 85 Fed. Reg. 56231 (Sept. 11, 2020) (available at https://www.federalregister.gov/documents/2020/09/11/2020-20041/authorizations-and-revocation-of-emergency-use-of-drugs-during-the-covid-19-pandemic-availability). Content current as of: 03/15/2022 Regulated Product(s) Drugs More Warning Letters Warning Letters About Warning and Close-Out Letters

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Table 12: Places for report 1429442

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5

Table 13: Drugs for report 1429442

Medicine Name	Medicine Class	Action	ATC Code
hydroxychloroquine	Aminoquinolines	antimalarials	P01BA02

Notes: This is to advise you that the United States (U.S.) Food and Drug Administration (FDA) reviewed your website at the Internet address www.ivermectin24h.com on December 13, 2021. FDA has observed that your website offers drug products for sale in the U.S. and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-191 and a variety of other diseases such as malaria, lupus erythematosus, and rheumatoid arthritis. Based on our review, these products are misbranded drugs under section 503(b) of the FD&C Act [21 U.S.C. § 353(b)]. The introduction or delivery for introduction of these products into interstate commerce is prohibited under sections 301(a) and 301(k) of the FD&C Act [21 U.S.C. §§ 331(a) and 331(k)]. [...] For example, www.ivermectin24h.com offers hydroxychloroquine marketed as "Hydroxychloroquine." Your website's homepage features the question, "Worried about CORONAVIRUS?" accompanied by a "BUY NOW" button. From this "BUY NOW" button, your website directs customers to the product page for the "Hydroxychloroquine" offered by www.ivermectin24h.com. Your website states, "Hydroxychloroquine is a medication that can be used to treat multiple diseases including malaria, Lupus Erythematosus, and Rheumatoid Arthritis." FDA-approved hydroxychloroquine is labeled for the treatment of uncomplicated malaria, discoid and systemic lupus erythematosus, and acute and chronic rheumatoid arthritis and is only available by prescription. In addition, hydroxychloroquine has not been approved by FDA for use in the prevention, diagnosis, treatment, mitigation, or cure of COVID-19.4 [...]

7 39 drug samples including Glenmark Telma H fail to clear CDSCO test, 1 declared misbranded - 2022-03-17

Publication date	2022-03-17
Create date	2022-03-22
Score	46.76
Report id	1431500
Category	Other, Cardiovascular medicine, Uterotonic, Antacid, Antidiabetic, Antibiotic, Dermatological medicine
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: New Delhi: In its latest drug safety alert, the apex drug regulatory body, the Central Drugs Standard Control Organization (CDSCO), has flagged 39 medicine batches for failing to qualify for a random drug sample test for the month of February, while 1 drug sample has been declared misbranded.These drugs samples which are declared not of standard quality include Ortin Laboratory's Lapril-5 (Enalapril Maleate Tablets IP 5 mg), Vitcal - AC (Calcium Acetate Tablets U.S.P.), Zyst-P (Pantoprazole Sodium Tablets IP), Theon Pharmaceutical's Trypsin, Bromelain & Rutoside Trihydrate Tablets, Hindustan Antibiotics' Cetirizine Syrup I.P. 5 mg / 5 ml – 60ml etc.In addition, other popular drug samples that are declared not of standard quality include Misoprostol Tablets I.P. 200 mcg manufactured by Cotec Healthcare, Omeprazole Capsules I.P. 20 mg manufactured by Kausikh Therapeutics, Atorvastatin Tablets IP (OZOVAS-10 TABLETS) manufactured by Ozone Pharmaceuticals. Apart from that, Glenmark's Telma H Tablet, a combination of two medicines, Telmisartan 40 mg and Hydrochlorothiazide 12.5 mg, is also on the list, which is used to manage high blood pressure.Also Read:Drug Alert: CDSCO flags 27 formulations as not of standard qualityThis came after analysis and tests conducted by the CDSCO Drugs Control Department on 1221 samples. Out of these, 1181 samples were found to be of standard quality while 39 of them were declared as Not of Standard Quality (NSQ) and 1 drug was declared misbranded.A few of the reasons why the drug samples tested failed were the failure of the assay, failure of the dissolution test, failure of disintegration, failure of the sterility test, failure of Vitamin D3 assay, failure of assay etc.The samples collected were tested in four laboratories, namely CDL Kolkata, CDTL Mumbai, RDTL Chandigarh, RDTL Guwahati.List of Drugs, Medical Devices and Cosmetics declared as Not of Standard Quality/Spurious/Adulterated/Misbranded, for the Month of February – 2022.Total number of samples tested1221Total number of samples declared as of Standard Quality1181Total number of samples declared as Not of Standard Quality39Total number of samples declared as Spurious0Total number of samples declared as Misbranded1S.No.Name of Drugs/medical device/cosmeticsBatch No./Date of Manufacture/Date ofExpiry/Manufactured ByReason for failureDrawn ByFrom1.Lapril-5 (Enalapril Maleate Tablets IP 5 mg)B. No.: GA21011Mfg dt: 06/2021 Exp dt: 05/2023 Mfd by: M/s. OrtinLaboratories Ltd., 275 & 278, (part),

I.D.A.,Pashamylaram-502307, Sanga Reddy, Dist. Telangana.Assay and DissolutionCDSCOWest Zone MumbaiCDTLMumbai2.Erythromycin EPB. No.: EB0121086AMfg dt: 12/2021 Exp dt: 11/2024Mfd by: M/s. Unimax Chemicals Pvt. Ltd.,E-116, MIDC, Tarapur, Boisar, Dist. Palghar- 401506, Maharashtra.AssayCDSCOWest Zone MumbaiCDTLMumbai3.Vitcal - AC (Calcium Acetate Tablets U.S.P.)B. No.: KQ20003Mfg dt: 07/2020 Exp dt: 06/2022 Mfd by: M/s. OrtinLaboratories Limited,275 & 278 (Part) I.D.A., Pashamylaram- 502307, Sangareddy District, Telangana State, India.DissolutionCDSCOWest Zone MumbaiCDLKolkata4.Trypsin, Bromelain & Rutoside Trihydrate TabletsB. No.: GT200466Mfg dt: 03/2020 Exp dt: 02/2022 Mfd by: M/s. TheonPharmaceuticals Ltd.,Description & DisintegrationCDSCOWest Zone MumbaiCDLKolkataVill. Saini Majra , Teh. Nalagarh, Distt. Solan, Himachal Pradesh-174101.5.Compound Sodium Lactate Injection IP (Ringer Lactate Injection Solution for Injection)B. No.: 107008Mfg dt: 07/2021 Exp dt: 06/2023 Mfd by: M/s. IvesDrugs (India), Pvt. Ltd., Works Ghatabillod, Dist.- Dhar, H.O. 504, Chetak Centre, R.N.T. Marg, Indore, MadhyaPradesh – 452 001.SterilityDrug Control Department OdishaCDLKolkata6.Secremet - 1 (Metformin Hydrochloride Prolonged-Release & GlimepirideTablets I.P.)B. No.: 210110Mfg dt: 02/2021 Exp dt: 01/2023 Mfd by: M/s. BalPharma Limited, PlotNo. 1, 2, 3, & 69,Sector - 4, IIE, SIDCUL, Pantnagar, Rudrapur, Distt.Udham Singh Nagar, Uttarakhand.Assay of GlimepirideCDSCOHyderabadCDLKolkata7.LactospeyB. No.: LSC010 Mfg dt: 04/2020Exp dt: 03/2022Assay of Bifidobacteriu m speciesCDSCOHyderabadCDLKolkataMfd by: M/s. Unique Biotech Ltd.8.Lapril-5 (Enalapril Maleate Tablets I.P.5 mg)B. No.: GA20005Mfg dt: 03/2020 Exp dt: 02/2022Dissolution & AssayCDSCOSouth Zone ChennaiCDLKolkataMfd by: M/s. Ortin Laboratories Ltd., 275 & 278 (Part), I.D.A.Pashamylaram - 502307, Sanga Reddy Dist.Telangana, India.9.Omeprazole Capsules I.P. 20 mgB. No.: K0220016Mfg dt: 02/2020 Exp dt: 01/2022Assay & DissolutionCDSCOSouth Zone ChennaiCDLKolkataMfd by: M/s. Kausikh Therapeutics (P) Ltd., Plot No. 6 & 7, DoorNo. 728, Kakkanji Cross Street, Paraniputhur Road, Gerugambakkam,Chennai - 600 128.10.Omeprazole Capsules I.P. 20 mgB. No.: K0220017Mfg dt: 02/2020 Exp dt: 01/2022Assay & DissolutionCDSCOSouth Zone ChennaiCDLKolkataMfd by: M/s. Kausikh Therapeutics (P) Ltd., Plot No. 6 & 7, DoorNo. 728, Kakkanji Cross Street, Paraniputhur Road, Gerugambakkam, Chennai - 600 128.11.Misoprostol...

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Table 14: Places for report 1431500

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Republic of India	22	79

Table 15: Drugs for report 1431500

Medicine Name	Medicine Class	Action	ATC Code
telmisartan	Angiotensin II receptor blockers (ARBs), plain	angiotensin ii receptor blockers (arbs), plain	C09CA07
misoprostol	Prostaglandins	drugs for peptic ulcer and gastro-oesophageal reflux disease (gord)	A02BB01

Table 15: Drugs for report 1431500(continued)

Medicine Name	Medicine Class	Action	ATC Code
misoprostol	Prostaglandins	uterotonics	G02AD06
pantoprazole	Proton pump inhibitors	drugs for peptic ulcer and gastro-oesophageal reflux disease (gord)	A02BC02
	Antibiotics	intestinal antiinfectives	A07AA
	Antibiotics	agents for treatment of hemorrhoids and anal fissures for topical use	C05AB
	Antibiotics	antifungals for topical use	D01AA
	Antibiotics	antiinfectives and antiseptics, excl. combinations with corticosteroids	G01AA
	Antibiotics	antimycotics for systemic use	J02AA
	Antibiotics	drugs for treatment of tuberculosis	J04AB
	Antibiotics	throat preparations	R02AB
	Antibiotics	antiinfectives	S01AA
trypsin	Enzymes	other hematological agents	B06AA07
trypsin	Proteolytic enzymes	enzymes	D03BA01
atorvastatin	HMG CoA reductase inhibitors	lipid modifying agents, plain	C10AA05
omeprazole	Proton pump inhibitors	drugs for peptic ulcer and gastro-oesophageal reflux disease (gord)	A02BC01
hydrochlorothiazide	Thiazides, plain	low-ceiling diuretics, thiazides	C03AA03
enalapril	ACE inhibitors, plain	ace inhibitors, plain	C09AA02
glimepiride	Sulfonylureas	blood glucose lowering drugs, excl. insulins	A10BB12
calcium acetate	Drugs for treatment of hyperkalemia and hyperphosphatemia	all other therapeutic products	V03AE07
rutoside	Bioflavonoids	capillary stabilizing agents	C05CA01
cetirizine	Piperazine derivatives	antihistamines for systemic use	R06AE07
erythromycin	Antiinfectives for treatment of acne	anti-acne preparations for topical use	D10AF02

Table 15: Drugs for report 1431500(continued)

Medicine Name	Medicine Class	Action	ATC Code
erythromycin	Macrolides	macrolides, lincosamides and streptogramins	J01FA01
erythromycin	Antibiotics	antiinfectives	S01AA17
bromelains	Proteolytic enzymes	enzymes	D03BA03
bromelains	Enzymes	other drugs for disorders of the musculoskeletal system	M09AB03
metformin	Biguanides	blood glucose lowering drugs, excl. insulins	A10BA02

Table 16: Other Stories

ID	Title	Link
1432155	9 Himachal Pradesh firms under scanner for substandard drugs	Link

Notes: In its latest drug safety alert, the apex drug regulatory body, the Central Drugs Standard Control Organization (CDSCO), has flagged 39 medicine batches for failing to qualify for a random drug sample test for the month of February, while 1 drug sample has been declared misbranded.These drugs samples which are declared not of standard quality include Ortin Laboratory's Lapril-5 (Enalapril Maleate Tablets IP 5 mg), Vitcal - AC (Calcium Acetate Tablets U.S.P.), Zyst-P (Pantoprazole Sodium Tablets IP), Theon Pharmaceutical's Trypsin, Bromelain & Rutoside Trihydrate Tablets, Hindustan Antibiotics' Cetirizine Syrup I.P. 5 mg / 5 ml – 60ml etc.In addition, other popular drug samples that are declared not of standard quality include Misoprostol Tablets I.P. 200 mcg manufactured by Cotec Healthcare, Omeprazole Capsules I.P. 20 mg manufactured by Kausikh Therapeutics, Atorvastatin Tablets IP (OZOVAS-10 TABLETS) manufactured by Ozone Pharmaceuticals. Apart from that, Glenmark's Telma H Tablet, a combination of two medicines, Telmisartan 40 mg and Hydrochlorothiazide 12.5 mg, is also on the list, which is used to manage high blood pressure. [...]

8 33 drug samples fail to clear CDSCO test, 2 declared misbranded - 2022-01-23

Publication date	2022-01-23
Create date	2022-01-24
Score	46.39
Report id	1377176
Category	Other, Antiparasitic, Cardiovascular medicine, Anti-malarial, Antacid, Ophthalmic medicines, Antiviral others, Antibiotic, Analgesic, Anxiolytic
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: New Delhi: In its latest drug safety alert, the apex drug regulatory body, the Central Drugs Standard Control Organization (CDSCO), flagged 33 medicine batches for failing to qualify for a random drug sample test for the month of December, while two drug samples have been declared misbranded.These drug samples which are declared not of standard quality include Mascot Health Serie's Colchicine Tablets I.P. 0.5 mg, Innova Captab's VERMIKIND- 12 (Ivermectin Dispersible Tablets), Stadmed's Disilox MPS (Aluminium, Magnesium and Simethicone Oral Suspension I.P.), Skymap Pharmaceuticals' Trimetazidine Modified Release Tablets 35 mg, SGS Pharmaceutical's Metronidazole Tablets IP (METRONIDAZOLE400), Skymap Pharmaceuticals' Omeprazole GastroResistant Capsules IP 20 mg etc.In addition, other popular drug samples that are declared not of standard quality include samples from Sun Pharma's Volini pain relief spray containing Diclofenac Diethylamine; Linseed Oil, Methyl Salicylate & Menthol Topical Spray, and GlaxoSmithKline Pharmaceuticals' Betnovate-N Cream containing Betamethasone, Valerate, and Neomycin.Also Read:22 drug samples fail to qualify CDSCO test, DetailsApart from this, the popular covid drug, Remdesivir For Injection 100 mg/vial (COVIFOR), manufactured by Hetero Labs, is also on the list.Further, the list contains two misbranded drugs: Primaquine Tablets IP and Diazepam Injection I.P. (Diazelab).This came after analysis and tests conducted by the CDSCO Drugs Control Department on 1385 samples. Out of these, 1350 samples were found to be of standard quality, while 33 of them were declared as not of standard quality (NSQ), and 2 drugs were declared misbranded.A few of the reasons why the drug samples tested failed were the failure of the assay, the failure of the dissolution test, the failure of disintegration, and the failure of the identification test.The samples collected were tested in five laboratories, namely CDL Kolkata, CDTL Mumbai, RDTL Chandigarh, RDTL Guwahati, and CDTL Hyderabad.List of Drugs, Medical Devices and Cosmetics declared as Not of Standard Quality/Spurious/Adulterated/Misbranded, for the Month of December – 2021:Total number of samples tested1385Total number of samples declared as of Standard Quality1350Total number of samples declared as Not of Standard Quality33Total number of samples declared as Spurious0Total number of samples declared as Misbranded02S.No.Name of Drugs/medical device/cosmeticsBatch No./Date of Manufacture/Date of Expiry/ManufacturedByReason for failureDrawn ByFrom1.Colchicine 0.5 Tablets

(Colchicine Tablets I.P.0.5 mg)B. No.: MT201577Mfg dt: 07/2020 Exp dt: 06/2022Mfd by: M/s. Mascot Health Series Pvt. Ltd., Plot No. 79, 80,Sector- 6A, IIE, Sidcul,Haridwar - 249403 Uttarakhand.Related SubstancesCDSCO,VisakhapatnamCDLKolkata2.Tuscure Syrup (Chlorpheniramine, Phenylephrine & Dextromethorphan Syrup), 100 mlB. No.: ALA2101 Mfg dt: 01/2021 Exp dt: 12/2022Mfd by: M/s. MMC Healthcare Ltd., No. 34-B, SIDCO Industrial Estate, Thirumazhisai, Chennai -600124.Assay of Phenylepheri ne HydrochlorideCDSCOSouth Zone ChennaiCDLKolkata3.COVIFOR (Remdesivir For Injection100 mg/vial)B. No.: REM121006A Mfg dt: 03/2021Exp dt: 11/2021 Mfd by: M/s. Hetero Labs Limited, Hyderabad, India,Manufactured At:Aspiro Pharma Limited, Survey No. 321, Biotech Park, Phase-III, Karkapatia Village, Markook Mandal, Siddipet Dist., Telagana State – 502 281, India.Particulate Matter, Clarity of Solution, Identification and AssaySub-Zone BaddiCDLKolkata4.VERMIKIND - 12(Ivermectin Dispersible Tablets)B. No.: C3FHT015 Mfg dt: 10/2020 Exp dt: 09/2023 Mfd by: M/s. InnovaCaptab Ltd., 1281/1,Hiltop Industrial Estate, Near EPIP, Phase-1, Jharmajri, Baddi, Distt. Solan, Himachal Pradesh -173205.Uniformity of DispersionCDSCOEast Zone KolkataCDLKolkata5.ZINCOPAC BOOSTTablets (Zinc Acetate Tablets50 mg)B. No.: APT/04418Mfg dt: 05/2021 Exp dt: 04/2023 Mfd by: M/s Amkon-Pharmaceuticals, Plot No. 242, Phase-9, Industrial Area, Mohali,Punjab -160 062.Assay of Elemental ZincCDSCOEast Zone KolkataCDLKolkata6.RESENT(Ondansetron HCl Tablets I.P. 4 mg)B. No.: 3233Mfg dt: 06/2021 Exp dt: 05/2023Mfd by: M/s. Infinitive Pharmaceutical Industries, Plot No.63,G.I.D.C. Industrial Estate, Deesa, Gujarat- 385535.DissolutionCDSCOWest Zone MumbaiCDTLMumbai7.Trypsin Chymotrypsin TabletsB. No.: MT193963Mfg dt: 02/2020 Exp dt: 01/2022Mfd by: M/s. Mascot Health Series Pvt Ltd., Plot No. 79, 80, Sector 6 A, IIE, Sidcul, Haridwar - 249 403Uttarakhand.Disintegration testCDSCOWest Zone MumbaiCDTLMumbai8.Disilox MPS (Aluminium, Magnesium and Simethicone Oral Suspension I.P.)B. No.: C22C105Mfg dt: 06/2021 Exp dt: 05/2024Mfd by: M/s. Stadmed Private Limited, 15, Jawpore Road, Kolkata 700074.Microbial contaminatio n in total aerobic viable count and presence of pathogens(E.coli.)CDSCOSub-Zone GoaCDTLMumbai9.Disilox MPS (Aluminium, Magnesium andB. No.: C22E106Mfg dt: 08/2021 Exp dt: 07/2024Microbial contaminatio n in totalCDSCOSub-Zone...

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Table 17: Places for report 1377176

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Republic of India	22	79

Table 18: Drugs for report 1377176

Medicine Name	Medicine Class	Action	ATC Code
linseed	Bulk-forming laxatives	drugs for constipation	A06AC05
neomycin	Antiinfectives and antiseptics for local oral treatment	stomatological preparations	A01AB08
neomycin	Antibiotics	intestinal antiinfectives	A07AA01

Table 18: Drugs for report 1377176(continued)

Medicine Name	Medicine Class	Action	ATC Code
neomycin	Antiinfectives	irrigating solutions	B05CA09
neomycin	Other antibiotics for topical use	antibiotics for topical use	D06AX04
neomycin	Other aminoglycosides	aminoglycoside antibacterials	J01GB05
neomycin	Antibiotics	throat preparations	R02AB01
neomycin	Antibiotics	antiinfectives	S01AA03
neomycin	Antiinfectives	antiinfectives	S02AA07
	Magnesium	other mineral supplements	A12CC
	Zinc	other mineral supplements	A12CB
ondansetron	Serotonin (5HT3) antagonists	antiemetics and antinauseants	A04AA01
trypsin	Enzymes	other hematological agents	B06AA07
trypsin	Proteolytic enzymes	enzymes	D03BA01
colchicine	Preparations with no effect on uric acid metabolism	antigout preparations	M04AC01
remdesivir	Nucleosides and nucleotides excl. reverse transcriptase inhibitors	direct acting antivirals	J05AB16
trimetazidine	Other cardiac preparations	other cardiac preparations	C01EB15
omeprazole	Proton pump inhibitors	drugs for peptic ulcer and gastro-oesophageal reflux disease (gord)	A02BC01
betamethasone	Corticosteroids acting locally	intestinal antiinflammatory agents	A07EA04
betamethasone	Corticosteroids	agents for treatment of hemorrhoids and anal fissures for topical use	C05AA05
betamethasone	Corticosteroids, potent (group III)	corticosteroids, plain	D07AC01
betamethasone	Corticosteroids, potent, other combinations	corticosteroids, other combinations	D07XC01
betamethasone	Glucocorticoids	corticosteroids for systemic use, plain	H02AB01

Table 18: Drugs for report 1377176(continued)

Medicine Name	Medicine Class	Action	ATC Code
betamethasone	Corticosteroids	decongestants and other nasal preparations for topical use	R01AD06
betamethasone	Glucocorticoids	other drugs for obstructive airway diseases, inhalants	R03BA04
betamethasone	Corticosteroids, plain	antiinflammatory agents	S01BA06
diclofenac	Other dermatologicals	other dermatological preparations	D11AX18
diclofenac	Acetic acid derivatives and related substances	antiinflammatory and antirheumatic products, non-steroids	M01AB05
diclofenac	Antiinflammatory preparations, non-steroids for topical use	topical products for joint and muscular pain	M02AA15
diclofenac	Antiinflammatory agents, non-steroids	antiinflammatory agents	S01BC03
dextromethorphan	Opium alkaloids and derivatives	cough suppressants, excl. combinations with expectorants	R05DA09
chymotrypsin	Enzymes	other hematological agents	B06AA04
chymotrypsin	Other surgical aids	surgical aids	S01KX01
ivermectin	Other dermatologicals	other dermatological preparations	D11AX22
ivermectin	Avermectines	antinematodal agents	P02CF01
metronidazole	Antiinfectives and antiseptics for local oral treatment	stomatological preparations	A01AB17
metronidazole	Other chemotherapeutics	chemotherapeutics for topical use	D06BX01
metronidazole	Imidazole derivatives	antiinfectives and antiseptics, excl. combinations with corticosteroids	G01AF01
metronidazole	Imidazole derivatives	other antibacterials	J01XD01

Table 18: Drugs for report 1377176(continued)

Medicine Name	Medicine Class	Action	ATC Code
metronidazole	Nitroimidazole derivatives	agents against amoebiasis and other protozoal diseases	P01AB01
diazepam	Benzodiazepine derivatives	anxiolytics	N05BA01
primaquine	Aminoquinolines	antimalarials	P01BA03
phenylephrine	Adrenergic and dopaminergic agents	cardiac stimulants excl. cardiac glycosides	C01CA06
phenylephrine	Sympathomimetics, plain	decongestants and other nasal preparations for topical use	R01AA04
phenylephrine	Sympathomimetics, combinations excl. corticosteroids	decongestants and other nasal preparations for topical use	R01AB01
phenylephrine	Sympathomimetics	nasal decongestants for systemic use	R01BA03
phenylephrine	Sympathomimetics excl. antiglaucoma preparations	mydriatics and cycloplegics	S01FB01
phenylephrine	Sympathomimetics used as decongestants	decongestants and antiallergics	S01GA05

Notes: In its latest drug safety alert, the apex drug regulatory body, the Central Drugs Standard Control Organization (CDSCO), flagged 33 medicine batches for failing to qualify for a random drug sample test for the month of December, while two drug samples have been declared misbranded. [...]

9 BOC seizes P30 million worth of counterfeits of paracetamol brands, other medicines

Publication date 2022-01-11

Create date 2022-05-27

Score 40.88

Report id 1357602

Category Other, Antiparasitic, Vitamin, Hormone replacement, Analgesic, Nutritional supplement

Quality Falsified

Source Unspecified outlet

Curation Manually curated

Incident or General Incident

Snippet: BOC seizes P30 million worth of counterfeits of paracetamol brands, other medicines GMA News Online

Click here to see the Original Article

Table 19: Places for report 1357602

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Philippines	Paranaque City	14.48156	121.01749

Table 20: Drugs for report 1357602

Medicine Name	Medicine Class	Action	ATC Code
cefixime	Third-generation cephalosporins	other beta-lactam antibacterials	J01DD08
phenylephrine, combinations	Sympathomimetics	nasal decongestants for systemic use	R01BA53
phenylephrine, combinations	Sympathomimetics used as decongestants	decongestants and antiallergics	S01GA55
			A11
	Vitamins	i.v. solution additives	B05XC
estradiol, combinations	Natural and semisynthetic estrogens, plain	estrogens	G03CA53

Table 20: Drugs for report 1357602(continued)

Medicine Name	Medicine Class	Action	ATC Code
ibuprofen, combinations	Propionic acid derivatives	antiinflammatory and antirheumatic products, non-steroids	M01AE51
ivermectin	Other dermatologicals	other dermatological preparations	D11AX22
ivermectin	Avermectines	antinematodal agents	P02CF01
paracetamol	Anilides	other analgesics and antipyretics	N02BE01
ibuprofen	Other cardiac preparations	other cardiac preparations	C01EB16
ibuprofen	Antiinflammatory products for vaginal administration	other gynecologicals	G02CC01
ibuprofen	Propionic acid derivatives	antiinflammatory and antirheumatic products, non-steroids	M01AE01
ibuprofen	Antiinflammatory preparations, non-steroids for topical use	topical products for joint and muscular pain	M02AA13
ibuprofen	Other throat preparations	throat preparations	R02AX02

Table 21: Other Stories

ID	Title	Link
1360838	BOC seizes P30M worth of fake paracetamol, other medicines	Link
1362827	P30M worth of fake Biogesic, other meds seized; suspect arrested	Link
1364741	Pakistani nabbed, P30-M fake meds seized in Parañaque	Link
1365665	P30M worth of fake Biogesic, other meds seized; suspect arrested| SUNSTAR	Link

Notes: The Bureau of Customs (BOC) on Tuesday said it has seized P30 million worth of counterfeits of popular medicine brands. In a statement, the BOC said that working with the Philippine Drug Enforcement Agency (PDEA), the National Intelligence Coordinating Agency (NICA), the Intelligence Service Armed Forces Of the Philippines (ISAFP), and the Philippine Coast Guard (PCG), it seized the fake items—bearing the names of brands Biogesic, Neozep, Bioflu, Immunpro, Ivermectin, Phenokinon F Injection, Medicol, Planax, Alaxan FR, MX3 and others—on January 5, 2022. Customs said that certification from the Food and Drug Admin-

istration (FDA) and Unilab Pharmaceuticals, the makers of market-leading paracetamol brand Biogesic, stated that the said medicines were counterfeit. The counterfeit medicines were packed in cartons with tags of Chinese characters, it said. [...]

10 Iotech International, LLC - Center for Drug Evaluation and Research | CDER - Unapproved New Drug and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19) - 2022-03-17

Publication date	2022-03-17
Create date	2022-03-22
Score	38.58
Report id	1431684
Category	Antiseptic
Quality	Diverted/Unregistered
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER Iotech International, LLC MARCS-CMS 617715 — March 15, 2022 Share Tweet Linkedin Email Print Product: Drugs Recipient: Recipient Name Herb Moskowitz, DDS Iotech International, LLC 6560 E. Rogers Circle Boca Raton , FL 33487 United States herbmoskowitz@iotechinternational.com Issuing Office: Center for Drug Evaluation and Research | CDER United States Federal Trade Commission WARNING LETTER DATE: March 15, 2022 Unapproved New Drug and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19) This is to advise you that the United States Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) reviewed your website at the Internet address www.iotechinternational.com on July 30 and September 9, 2021; and March 9, 2022, respectively. We have also reviewed your Facebook and Instagram social media website at the Internet addresses, https://www.facebook.com/iotechintl/ and https://www.instagram.com/iotech.international/, respectively, where you direct consumers to your website, www.iotechinternational.com, to purchase your products. The FDA has observed that your website offers "ioRinse" (also referred to as "ioRinse™ RTU") and "ioCleanse Molecular iodine Hand Cleanser" for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19 1 in people. Based on our review, these products are unapproved new drugs sold in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 355(a). Furthermore, these products are misbranded drugs under section 502(ee) of the FD&C Act, 21 U.S.C. § 352 (ee). The introduction or delivery for introduction of such products into interstate commerce is prohibited under sections 301(a) and (d) of the FD&C Act, 21 U.S.C. § 331 (a) and (d). These violations are described in more detail below. There is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2). The disease caused by the virus has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS. 2 In addition, on March 13, 2020, there was a

Presidential declaration of a national emergency in response to COVID-19 that subsequently has been extended. 3 Therefore, FDA is taking urgent measures to protect consumers from certain products that, without approval or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. As described below, you sell products that are intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. We request that you take immediate action to cease the sale of any unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. Examples of the claims observed on the "ioRinse" and "ioCleanse Molecular iodine Hand Cleanser" product labeling that provide evidence of the intended uses (as defined in 21 CFR 201.128) of your products, and misleadingly represent them as safe and/or effective for the treatment or prevention of COVID-19 include but may not be limited to, the following: • "A New Super Class of Anti-microbials that kill #coronavirus . . . @iotech.international developed novel Anti-microbials that kill #coronavirus and surpass Chlorihexidine Gluconate in Efficacy. Safe . . . Highly engineered products created by a dentist and chemists. Order today: @iotech.international" [from a March 10, 2020 post on your Instagram webpage, https://www.instagram.com/iotech.international/] • "The aim of the present study was to evaluate and compare the efficacy and cytotoxicity of four different mouthwashes containing 1.5% hydrogen peroxide, 0.2% povidone, 0.12% chlorhexidine and 100 ppm molecular iodine for the ability to inactivate severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) . . . Conclusion: The spread of infection through aerosol and splatter has long been considered one of the main concerns in the dental community. A preprocedural rinse with 100 ppm molecular iodine will play a vital role in combating COVID-19 pandemic by preventing the spread of infection." [from an article entitled "Comparative Analysis of Antiviral Efficacy of Four Different Mouthwashes against Severe Acute Respiratory Syndrome Coronavirus 2: An In Vitro Study" that you provide a link to on your website and that accompanies your products] • "Iotech International's formula 100-S [containing molecular iodine] displayed the greatest antiviral activity of all the tested rinses, completely inactivating SARS-COV-2 within 30 seconds." [from an article entitled "Comparative Analysis of Antiviral Efficacy of Four Different Mouthwashes against Severe Acute Respiratory Syndrome Coronavirus 2: An In Vitro Study" that you provide a link to on your website and that accompanies your products] • "Introducing ioCleanse . . . Non-Staining IoCleanse Hand Cleanser contains the most powerful form of iodine, Molecular Iodine . . . Successfully tested to destroy normal Coronavirus (strain #229E) within seconds. . . . Clinically Proven: Iodine is more effective as an ANTIVIRAL AGENT than Alcohol Sanitizers" [from an April 18, 2020 post on your Facebook webpage, https://www.facebook.com/iotechintl/] Based on the above claims, "ioRinse" and "ioCleanse Molecular iodine Hand Cleanser" are drugs as defined by section 201(g)(1)(B) of the FD&C Act, 21 U.S.C. § 321(g)(1)(B), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and/or under section 201(g)(1)(C) of the FD&C Act, 21 U.S.C. 321(g)(1)(C), because they are intended to affect the structure or any function of the body. Specifically, "ioRinse" and "ioCleanse Molecular iodine Hand Cleanser" are intended for use as an oral antiseptic rinse and as a consumer topical antiseptic, respectively. This oral antiseptic rinse and topical antiseptic are "new drugs" within the meaning of section 201(p) of the FD&C Act, 21 U.S.C. 321(p), because they are not generally recognized as safe and effective (GRASE) for use under the conditions prescribed, recommended, or suggested in their labeling. New drugs may not be introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in section 505(a) of the FD&C Act, 21 U.S.C. 355(a), unless they are lawfully marketed under section 505G of the FD&C Act (which is not the case for these products, as further described below) or under other exceptions not applicable here. No FDA-approved applications pursuant to section 505 of the FD&C Act, 21 U.S.C. 355, is in effect for these drug products, nor are we aware of any adequate

and well-controlled clinical studies in the published literature that support a determination that "ioRinse" and "ioCleanse Molecular iodine Hand Cleanser" are GRASE for use under the conditions suggested, recommended, or prescribed in their labeling. Accordingly, these drug products are unapproved new drugs marketed in violation of sections 505(a) and 301(d) of the FD&C Act, 21 U.S.C 355(a) and 331(d). 4 We note that over-the-counter (OTC) topical antiseptic products, like "ioCleanse Molecular iodine Hand Cleanser," had been the subject of rulemaking under the Agency's OTC Drug Review. In particular, such products were addressed in a tentative final monograph (TFM) entitled "Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Health-Care Antiseptic Drug Products," Proposed Rule, 59 FR 31402 (June 17, 1994) (1994 TFM), as further amended by Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record," Proposed Rule, 81 FR 42912 (June 30, 2016) (Consumer Antiseptic Rubs Proposed Rule). Over the course of these rulemakings, three active ingredients (benzalkonium chloride, ethyl alcohol (ethanol), and isopropyl alcohol) were classified as Category III for use in consumer antiseptic rub products, meaning that additional safety and effectiveness data are needed to support a determination that a drug product containing one of these active ingredients would be GRASE for use as a consumer antiseptic rub. Oral antiseptics like "ioRinse" were addressed in a TFM entitled "Oral Health Care Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Oral Antiseptic Drug Products"; Proposed Rule, 59 FR 6084 (February 9, 1994) (Oral Antiseptics Proposed Rule). The Oral Antiseptics Proposed Rule classified a number of active ingredients, including iodine, as Category III for use by consumers in antiseptic-containing drug products applied topically to the oral cavity to help prevent infection in minor cuts, scrapes or oral irritation caused by dental procedures, dentures, orthodontic appliances, or accidental injury, because additional effectiveness data are needed to support a determination that a drug product containing one of these active ingredients would be GRASE for use as an OTC oral antiseptic (59 FR 6084 at 6121-6122). Section 505G of the FD&C Act addresses nonprescription drugs marketed without an approved application. Under section 505G(a)(3) of the FD&C Act, drugs that were classified as Category III for safety or effectiveness in a TFM that is the most recently applicable proposal or determination for such drug issued under 21 CFR Part 330 – and that were not classified as Category II for safety or effectiveness – are not required to have an approved application under section 505 in order to be marketed, as long as they meet the relevant conditions of use outlined in the applicable TFM and comply with all other applicable requirements. However, your "ioRinse" and "ioCleanse Molecular iodine Hand Cleanser" products do not conform to the 1994 TFM, the Oral Antiseptics Proposed Rule, or any other TFM, proposed rule, or final rule and do not meet the conditions under section 505G(a)(3) of the FD&C Act for marketing without an approved application under section 505. Specifically, your labeling claims 5 suggesting that your oral antiseptic rinse and topical antiseptic products are effective in inactivating and thus preventing infection or disease from the novel coronavirus that causes COVID-19 go beyond merely describing the general intended uses of an antiseptic as set forth in the Oral Antiseptic Proposed Rule and the 1994 TFM, as amended by the 2016 Consumer Antiseptic Rubs Proposed Rule, respectively. 6 In addition, your "ioCleanse Molecular iodine Hand Cleanser" product contains an active ingredient, molecular iodine, which was not one of the three active ingredients classified as Category III in the 1994 TFM. Although molecular iodine is not explicitly identified as an active ingredient on the label of your "ioCleanse Molecular iodine Hand Cleanser" products, your label and labeling clearly represent molecular iodine as an active ingredient, which is defined as a component of a drug intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to

affect the structure or function of the body (see 21 CFR 201.66(b)(2)). Your labeling includes statements such as, "ioTECH International is the leading molecular iodine research and manufacturing company dispensing a patented, breakthrough germicidal product line branded as ioRinse and ioCleanse." In addition, "ioRinse" and "ioCleanse Molecular iodine Hand Cleanser" products are misbranded under section 502(ee) of the FD&C Act, 21 U.S.C. 352(ee), because they are nonprescription drugs subject to section 505G of the FD&C Act, 21 U.S.C. 355h, but do not comply with the requirements for marketing under that section and are not the subject of an application approved under section 505 of the FD&C Act, 21 U.S.C. 355. You should take immediate action to address the violations cited in this letter. This letter is not meant to be an all-inclusive list of violations that exist in connection with your products or operations. It is your responsibility to ensure that the products you sell are in compliance with the FD&C Act and FDA's implementing regulations. We advise you to review your websites, product labels, and other labeling and promotional materials to ensure that you are not misleadingly representing your products as safe and effective for a COVID-19-related use for which they have not been approved by FDA and that you do not make claims that misbrand the products in violation of the FD&C Act. Within 48 hours, please send an email to COVID-19-Task-Force-CDER@fda.hhs.gov describing the specific steps you have taken to address these violations. Include an explanation of each step being taken to prevent the recurrence of any violations, as well as copies of related documentation. Failure to adequately correct any violations may result in legal action, including, without limitation, seizure and injunction. FDA is advising consumers not to purchase or use certain products that have not been approved, cleared, or authorized by FDA and that are being misleadingly represented as safe and/or effective for the treatment or prevention of COVID-19. Your firm will be added to a published list on FDA's website of firms and websites that have received warning letters from FDA concerning the sale or distribution of COVID-19 related products in violation of the FD&C Act. This list can be found at http://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-covid-19-products . Once you have taken actions to address the sale of your unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, and any appropriate corrective actions have been confirmed by FDA, the published list will be updated to indicate that your firm has taken such corrective actions. We note however, removal from the published list should not be interpreted to mean that you have properly addressed all other violations for your products and that you are free to proceed with their continued marketing. This letter notifies you of our concerns and provides you with an opportunity to address them. If you cannot take action to address this matter completely within 48 hours, state the reason for the delay and the time within which you will do so. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration. If you are not located in the United States, please note that products that appear to be misbranded or unapproved new drugs may be detained or refused admission if they are offered for importation into the United States. We may advise the appropriate regulatory officials in the country from which you operate that FDA considers your product(s) referenced above to be unapproved and misbranded products that cannot be legally sold to consumers in the United States. Please direct any inquiries to FDA at COVID-19-Task-Force-CDER@fda.hhs.gov . FTC Cease and Desist Demand: In addition, it is unlawful under the FTC Act, 15 U.S.C. § 41 et seq., to advertise that a product can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time they are made. For COVID-19, no such study is currently known to exist for the products identified above. Thus, any coronavirus-related prevention or treatment claims regarding such products are not supported by competent and reliable scientific evidence.

You must immediately cease making all such claims. Violations of the FTC Act may result in legal action seeking a Federal District Court injunction and an order may require that you pay back money to consumers. In addition, pursuant to the COVID-19 Consumer Protection Act, Section 1401, Division FF, of the Consolidated Appropriations Act, 2021, P.L. 116-260, marketers who make deceptive claims about the treatment, cure, prevention, or mitigation of COVID-19 are subject to a civil penalty of up to $46,517 per violation and may be required to pay refunds to consumers or provide other relief pursuant to Section 19(b) of the FTC Act, 15 U.S.C. § 57b(b). Within 48 hours, please send an email to Richard Cleland, Assistant Director of the FTC's Division of Advertising Practices, via electronic mail at rcleland@ftc.gov certifying that you have ceased making unsubstantiated claims for the products identified above. If you have any questions regarding compliance with the FTC Act, please contact Mr. Cleland at 202-326-3088. Sincerely, /S/ Donald D. Ashley Director Office of Compliance Center for Drug Evaluation and Research Food and Drug Administration Sincerely, /S/ Serena Viswanathan Associate Director Division of Advertising Practices Federal Trade Commission cc: jgolden@goldendentalsolutions.com Curt Lawler, Goldendent LLC 27115 Gratiot Ave. Ste B Roseville, MI 48066 _____1 As explained in the next paragraph, there is currently an outbreak of a respiratory disease named "Coronavirus Disease 2019" (COVID-19). 2 Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx . 3 Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/ . 4 We note that "ioRinse" and "ioCleanse Molecular iodine Hand Cleanser" also do not conform to any temporary policy FDA has implemented during the public health emergency. In March 2020, the Agency published three guidance documents to provide regulatory flexibility to certain firms to help meet the demand for alcohol-based hand sanitizer during the COVID-19 public health emergency (PHE). Because your non-alcohol-based consumer antiseptic products are not consistent with the formulations described in these guidances, they do not fall within any temporary Agency policy not to take action against firms manufacturing hand sanitizer products for violations of section 505 of the FD&C Act. Additionally, on December 31, 2021 these guidances were withdrawn, and firms must cease distribution, by March 31, 2022, of any remaining hand sanitizer products that were prepared under the temporary policies before or on December 31, 2021. See, 86 FR 56960, October 13, 2021. 5 The FD&C Act defines labeling in broad terms, such that labeling means all labels and "other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article (see section 201(m) of the FD&C Act (21 U.S.C. 321(m)). This definition does not require labeling to be physically attached to a drug product. 6 The 1994 TFM covers health care antiseptics that are indicated for use to help reduce bacteria that potentially can cause disease and health care and consumer antiseptics that are indicated for use to decrease bacteria on the skin. 59 FR at 31443. Content current as of: 03/17/2022 Regulated Product(s) Drugs More Warning Letters Warning Letters About Warning and Close-Out Letters

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Table 22: Places for report 1431684

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Boca Raton	26.35869	-80.0831

Table 23: Drugs for report 1431684

Medicine Name	Medicine Class	Action	ATC Code
	Antiseptics	throat preparations	R02AA

Notes: [...] The FDA has observed that your website offers ”ioRinse” (also referred to as ”ioRinse™ RTU”) and ”ioCleanse Molecular iodine Hand Cleanser” for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-191 in people. Based on our review, these products are unapproved new drugs sold in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 355(a). Furthermore, these products are misbranded drugs under section 502(ee) of the FD&C Act, 21 U.S.C. § 352 (ee). The introduction or delivery for introduction of such products into interstate commerce is prohibited under sections 301(a) and (d) of the FD&C Act, 21 U.S.C. § 331 (a) and (d). These violations are described in more detail below. [...]

11 2 Chinese nationals arrested allegedly for selling counterfeit medicines

Publication date	2022-03-22
Create date	2022-03-28
Score	30.03
Report id	1435936
Category	Herbal medicine, Antibiotic
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: 2 Chinese nationals arrested allegedly for selling counterfeit medicines Manila Bulletin

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Table 24: Places for report 1435936

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Philippines	Mandaue City	10.32361	123.92222

Table 25: Drugs for report 1435936

Medicine Name	Medicine Class	Action	ATC Code
amoxicillin	Penicillins with extended spectrum	beta-lactam antibacterials, penicillins	J01CA04

Table 26: Other Stories

ID	Title	Link
1436866	3 charged for selling fake medicines in Mandaue City| SUNSTAR	Link

Notes: Agents of the National Bureau of Investigation-Central Visayas (NBI 7) arrested two Chinese nationals allegedly for selling counterfeit medicines during a raid of their stores in

Mandaue City. [...] Among the fake medicines seized from the raided stores were Amoxicillin capsules and Lianhua Qingwen Jian, a drug that supposedly treats Covid-19 infection. [...]

12 Health authorities warn public vs illicit sale of molnupiravir

Publication date	2022-01-19
Create date	2022-01-20
Score	21.44
Report id	1369174
Category	Antiviral others
Quality	Falsified
Source	Not applicable
Curation	Manually curated
Incident or General	Incident

Snippet: Health authorities warn public vs illicit sale of molnupiravir ABS-CBN News

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Table 27: Places for report 1369174

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Philippines	Republic of the Philippines	13	122

Notes: Health authorities on Wednesday warned the public about the spread of fake COVID-19 oral treatments such as molnupiravir, advising them not to buy medicines from unauthorized sources, noting the possible health hazards of these drugs.
In a statement, the Department of Health (DOH) said it received reports about ”possible” counterfeit versions of the antiviral drug molnupiravir. [...]

13 DCGI asks States to keep vigil on suspected spurious tocilizumab injections in India

Publication date	2022-01-10
Create date	2022-01-17
Score	20.22
Report id	1357205
Category	Immunosuppressant
Quality	Falsified
Source	Not applicable
Curation	Manually curated
Incident or General	Incident

Snippet: DCGI asks States to keep vigil on suspected spurious tocilizumab injections in India ETHealthworld.com

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Table 28: Places for report 1357205

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Republic of India	22	79

Table 29: Drugs for report 1357205

Medicine Name	Medicine Class	Action	ATC Code
tocilizumab	Interleukin inhibitors	immunosuppressants	L04AC07

Table 30: Other Stories

ID	Title	Link
1358864	Nagpur FDA to keep vigil on sale of fake Tocilizumab	Link
1359366	DCGI directs strict vigil on spurious Tocilizumab Injs distribution in India	Link
1359428	DCGI directs strict vigil on spurious Tocilizumab Injs distribution in India - 2022-01-12	Link
1360190	FDA steps up vigil over tocilizumab distribution	Link

Notes: The Drugs Controller General of India (DCGI) informed the State drug controllers, zonal offices of Central Drugs Standard Control Organisation (CDSCO), and the drug manufacturers in the country to keep a watch and vigil on the distribution and sale of suspected spurious tocilizumab injections, one of the medicines used for management of COVID-19. Following a complaint from Roche Products (India) Pvt Ltd regarding distribution and sale of suspected spurious tocilizumab injections in the country. Roche owns the import and marketing authorisation for tocilizumab injection 80mg/4ml, 200mg/10 ml and 400mg/20ml, under the brand name Actemra, in the country. The products are distributed and marketed by Cipla Ltd. [...]

14 Spurious drugs seized in Mardan

Publication date	2022-01-14
Create date	2022-01-17
Score	18.80
Report id	1363284
Category	Other, Antiseptic, Antibiotic
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Spurious drugs seized in Mardan The News International

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Table 31: Places for report 1363284

Region Name	Country	Location	Latitude	Longitude
Southern Asia	Pakistan	Mardan	34.19794	72.04965

Table 32: Drugs for report 1363284

Medicine Name	Medicine Class	Action	ATC Code
cefradine	First-generation cephalosporins	other beta-lactam antibacterials	J01DB09
piperacillin	Penicillins with extended spectrum	beta-lactam antibacterials, penicillins	J01CA12
tazobactam	Beta-lactamase inhibitors	beta-lactam antibacterials, penicillins	J01CG02
	Antiseptics	throat preparations	R02AA

Notes: [...] He said the team seized spurious, low quality and unregistered drugs during the action. He added that the team seized suspected spurious Tanzo 4.5gm injection, plasodine 450ml solution, Velosef 250/500mg and unregistered bandages. The official said the samples of suspected drugs had been sent to the Drug Testing Laboratory (DTL) for analysis.

15 High demand boosts black market for Covid drug

Publication date	2022-03-07
Create date	2022-03-11
Score	18.23
Report id	1421477
Category	Antiviral others
Quality	Diverted/Unregistered
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: High demand boosts black market for Covid drug VnExpress International

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Table 33: Places for report 1421477

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Viet Nam	Vietnam	16.16667	107.83333

Notes: With drug stores requiring doctor prescriptions to sell Covid-19 drugs containing molnupiravir, patients are turning to get them in the black market. [...] "There are too many sellers, too many prices. Some even offered me wholesale deals, but all transactions are made online and I could not tell which one was credible," Quang said. Finally, he decided to buy a box of Molnupiravir Stella as "it was the one on the newspaper." [...] Anh is selling Vietnam-made drug at VND750,000 per box of 100 pills and VND250,000-300,000 per box of 20 pills. The Indian drug will cost three times higher as it is more effective, she added.

In HCMC, Huy, who advertises himself as a pharmacist with 20 years of experience, is selling molnupiravir to whoever wants it.

He said he has been selling out repeatedly. Huy is offering different brands, with product prices ranging from VND250,000 to VND1.2 million. [...]

16 Police, FDA seize P3.5-M fake medicines in Ozamiz raid

Publication date 2022-03-09

Create date 2022-03-11

Score 17.68

Report id 1422610

Category Other, Cardiovascular medicine, Antispasmodic, Antidiarrhoeal, Anti-inflammatory medicine, Antitussive, Antibiotic

Quality Falsified

Source Unlicensed outlets

Curation Manually curated

Incident or General Incident

Snippet: Police, FDA seize P3.5-M fake medicines in Ozamiz raid pna.gov.ph

Click here to see the Original Article

Table 34: Places for report 1422610

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Philippines	Ozamiz City	8.1481	123.8405

Table 35: Drugs for report 1422610

Medicine Name	Medicine Class	Action	ATC Code
dicycloverine	Synthetic anticholinergics, esters with tertiary amino group	drugs for functional gastrointestinal disorders	A03AA07
carbocisteine	Mucolytics	expectorants, excl. combinations with cough suppressants	R05CB03
amoxicillin	Penicillins with extended spectrum	beta-lactam antibacterials, penicillins	J01CA04
loperamide	Antipropulsives	antipropulsives	A07DA03
mefenamic acid	Fenamates	antiinflammatory and antirheumatic products, non-steroids	M01AG01

Table 35: Drugs for report 1422610(continued)

Medicine Name	Medicine Class	Action	ATC Code
losartan	Angiotensin II receptor blockers (ARBs), plain	angiotensin ii receptor blockers (arbs), plain	C09CA01

Notes: Authorities seized some PHP3.5 million worth of counterfeit medicines in a recent raid in Ozamiz City, police said. [...] Among the confiscated items were two big boxes containing 31,700 capsules of loperamide hydrochloride; another box contained 27,000 tablets of losartan potassium; 31,500 capsules of amoxicillin trihydrate; 13,100 capsules of mefenamic acid; 12,200 tablets of dicycloverine hydrochloride; and 13,400 tablets of carbocisteine. [...] She said the FDA has certified that all of the confiscated medicines were fake, adding that a tip from a pharmaceutical company, which complained that some of its brand names were being sold by the suspect, helped law enforcement agencies pinpoint his location. [...]

17 Public Alert No. 016/2022 – Substandard Cozol Suspension (Manufactured By M/S. Alkemy Pharmaceutical Laboratories (PVT.) Ltd. Hyderabad) Pakistan

Publication date	2022-03-24
Create date	2022-05-09
Score	17.33
Report id	1478349
Category	Antibiotic
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: The National Agency for Food and Drug Administration and Control is notifying the healthcare providers and the public that Drug Regulatory Authority of Pakistan (DRAP) and CDL Karachi Pakistan has declared ”Cozol Suspension” batch E206 as a substandard drug and has been recalled from circulation.

Details of the Affected product

Product Name Active Ingredient

Manf date Expiry Date Batch No Manufacturer Cozol Suspension

Trimethoprim and Sulphhamethoxazole Sep 2021 Aug 2024 E-206 Alkemy Pharmaceutical Laboratories (Pvt.) Ltd. Hyderabad) Pakistan.

All medical products must be obtained from licensed, authentic, and reliable sources. Their authenticity and condition should be carefully checked

NAFDAC requests increased vigilance within the supply chains of institutions/pharmacies/ healthcare facilities likely to be affected by this substandard product batch.

If anyone has used this substandard product batch or suffer an adverse reaction/event having used this product batch, it is advised to seek immediate medical advice from a qualified healthcare professional.

Members of the public already in possession of the above stated product batch are implored to discontinue sale or use and handover stock to the nearest NAFDAC office.

Healthcare professionals and consumers are encouraged to report adverse events or side effects related to the use of the product to the nearest NAFDAC office, NAFDAC PRASCOR (20543 TOLL FREE from all networks), via pharmacovigilance@nafdac.gov.ng or via the NAFDAC ADR e-Reporting platform available at www.nafdac.gov.ng

NAFDAC……..Customer-focused, Agency-minded!!!

Signed Management

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Table 36: Places for report 1478349

Region Name	Country	Location	Latitude	Longitude
Southern Asia	Pakistan	Islamic Republic of Pakistan	30	70

Table 37: Drugs for report 1478349

Medicine Name	Medicine Class	Action	ATC Code
sulfamethoxazole and trimethoprim	Combinations of sulfonamides and trimethoprim, incl. derivatives	sulfonamides and trimethoprim	J01EE01

Notes: The National Agency for Food and Drug Administration and Control is notifying the healthcare providers and the public that Drug Regulatory Authority of Pakistan (DRAP) and CDL Karachi Pakistan has declared ”Cozol Suspension” batch E206 as a substandard drug and has been recalled from circulation. [...]

18 Crackdown on falsified meds in Africa nets 12m illegal products - 2022-03-06

Publication date 2022-03-06

Create date 2022-03-09

Score 16.52

Report id 1420044

Category Other, Erectile dysfunction medicine, Antiepileptic, Medical devices for disease prevention, Anti-inflammatory medicine, Vaccine, Medical device for screening/diagnosis/monitoring, Antibiotic, Analgesic

Quality Diverted/Unregistered

Source Private pharmacy

Curation Manually curated

Incident or General Incident

Snippet: Seizures included 2m anticonvulsant medicines, 300,000 other epilepsy drugs, 208,000 masks and 1,600 rapid COVID tests.

Click here to see the Original Article

Table 38: Places for report 1420044

Region Name	Country	Location	Latitude	Longitude
		Africa	7.1881	21.09375

Table 39: Drugs for report 1420044

Medicine Name	Medicine Class	Action	ATC Code
	Antibiotics	intestinal antiinfectives	A07AA
	Antibiotics	agents for treatment of hemorrhoids and anal fissures for topical use	C05AB
	Antibiotics	antifungals for topical use	D01AA
	Antibiotics	antiinfectives and antiseptics, excl. combinations with corticosteroids	G01AA
	Antibiotics	antimycotics for systemic use	J02AA

Table 39: Drugs for report 1420044(continued)

Medicine Name	Medicine Class	Action	ATC Code
	Antibiotics	drugs for treatment of tuberculosis	J04AB
	Antibiotics	throat preparations	R02AB
	Antibiotics	antiinfectives	S01AA
			J07
			N02

Table 40: Other Stories

ID	Title	Link
1420050	Crackdown on falsified meds in Africa nets 12m illegal products	Link
1426178	Zimbabwe: ZRP, Interpol Operation Nets 2 000 - AllAfrica	Link
1438597	ZRP, Interpol operation nets 2 000	Link

Notes: A pan-African enforcement operation has identified hundreds of suspects and resulted in seizures of more than 12 million illicit health products, including epilepsy medicines. [...] Inspections were carried out at roadblocks, open markets, pharmacies, warehouses and other locations suspected of producing, smuggling, storing or distributing fake pharmaceuticals, with notables seizures including 2 million anticonvulsant medicines, 300,000 other epilepsy drugs, more than 208,000 COVID-19 protection masks and 1,600 rapid COVID tests. Other commonly seized illicit medicines included antibiotics, anti-inflammatories, analgesics and medication used to correct erectile dysfunction, rheumatism and epilepsy, said Interpol. [...] West African operations revealed the use of counterfeit COVID-19 vaccination certificates in several countries, whilst East African operations saw the use of unregulated and unlawful distribution and sale of genuine COVID-19 vaccines. [...]

19 Health Ministry warns of fake drugs for treating C-19

Publication date	2022-02-22
Create date	2022-02-28
Score	16.45
Report id	1408533
Category	Antiviral others
Quality	Falsified
Source	Private pharmacy
Curation	Manually curated
Incident or General	Incident

Snippet: Health Ministry warns of fake drugs for treating C-19 Khmer Times

Click here to see the Original Article

Table 41: Places for report 1408533

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Cambodia	Kingdom of Cambodia	13	105

Notes: Amid the diminishing supply of Molnatris (Molunpiravir 200 mg) capsules, used for home treatment, the Health Ministry is also worried about tainted or counterfeit products and has issued a directive banning the unapproved sale and distribution of Covid-19 drugs. [...] In an exclusive interview with Khmer Times, many witnesses have claimed that they are taking the fake medicine as it is not in the same box or container as the government's recommended medicine.

Among those witnesses, Sary Rachana, who is infected with Omicron and undergoing home treatment, said yesterday that she bought two boxes for $75 each from a pharmacy in Tuol Tompoung commune but the medicine box is orange and she is worried that it will negatively affect her health. Pok Touch, 45, said yesterday that he bought medicine from a pharmacy in Takhmao City for $78 per box. The box is green and he was persuaded that this one is from the United States and is better than the blue one which is recommended by the ministry.

20 Medical Product Alert N°2/2022: Falsified DESREM (Remdesivir)

Publication date	2022-03-09
Create date	2022-03-11
Score	15.98
Report id	1423472
Category	Antiviral others
Quality	Falsified
Source	Not applicable
Curation	Manually curated
Incident or General	Incident

Snippet: Medical Product Alert N°2/2022: Falsified DESREM (Remdesivir) World Health Organization

Click here to see the Original Article

Table 42: Places for report 1423472

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Republic of India	22	79
Americas	Guatemala	Republic of Guatemala	15.5	-90.25

Table 43: Drugs for report 1423472

Medicine Name	Medicine Class	Action	ATC Code
remdesivir	Nucleosides and nucleotides excl. reverse transcriptase inhibitors	direct acting antivirals	J05AB16

Table 44: Other Stories

ID	Title	Link
1423283	WHO warns of counterfeit COVID-19 drugs	Link

Notes: This WHO Medical Product Alert refers to two falsified batches of DESREM Remdesivir

for Injection 100mg/vial. The falsified batches have been identified in Guatemala and India and were reported to WHO in February 2022.

The genuine manufacturer of DESREM, Mylan Laboratories Ltd, has confirmed that the products identified in this Alert are falsified. Laboratory analysis of these falsified products, conducted by the genuine manufacturer, established that they do not contain any of the stated active pharmaceutical ingredient (remdesivir). The vials of these falsified products may be smaller than genuine DESREM and the labels have multiple spelling errors and use the wrong font styles and colours. Although the identified batch numbers are genuine, the expiry dates listed below are falsified.

The products identified in this Alert are falsified on the basis that they deliberately/fraudulently misrepresent their identity, composition, and source. [...]

21 CAG raps J'khand Health Dept for administering expired vaccines to children

Publication date	2022-03-16
Create date	2022-03-22
Score	15.94
Report id	1430802
Category	Other, Vaccine, Antiviral others, Antibiotic
Quality	Substandard
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: CAG raps J'khand Health Dept for administering expired vaccines to children ThePrint

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Table 45: Places for report 1430802

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Republic of India	22	79

Table 46: Drugs for report 1430802

Medicine Name	Medicine Class	Action	ATC Code
amoxicillin	Penicillins with extended spectrum	beta-lactam antibacterials, penicillins	J01CA04
			J07
dexamethasone	Corticosteroids for local oral treatment	stomatological preparations	A01AC02
dexamethasone	Corticosteroids	agents for treatment of hemorrhoids and anal fissures for topical use	C05AA09
dexamethasone	Corticosteroids, moderately potent (group II)	corticosteroids, plain	D07AB19

Table 46: Drugs for report 1430802(continued)

Medicine Name	Medicine Class	Action	ATC Code
dexamethasone	Corticosteroids, moderately potent, other combinations	corticosteroids, other combinations	D07XB05
dexamethasone	Corticosteroids, combinations for treatment of acne	anti-acne preparations for topical use	D10AA03
dexamethasone	Glucocorticoids	corticosteroids for systemic use, plain	H02AB02
dexamethasone	Corticosteroids	decongestants and other nasal preparations for topical use	R01AD03
dexamethasone	Corticosteroids, plain	antiinflammatory agents	S01BA01

Table 47: Other Stories

ID	Title	Link
1430855	National Auditor Rebukes Jharkhand Over Expired Vaccines For Children	Link
1431364	Expired vaccines, unutilised funds: CAG report exposes Jharkhand's health infrastructure	Link

Notes: The Comptroller and Auditor General of India (CAG), in its latest report on Wednesday, rapped the Jharkhand Health Department for administering expired and substandard vaccines to children in some district hospitals. [...] "In district hospital (DH), Ramgarh, 410 doses of Hepatitis-B vaccines with shelf life up to October 2018 were administered to children between November 2018 and January 2019," the CAG said in the audit report tabled in the assembly.

It said that when questioned, the deputy superintendent of the hospital stated in a reply that wrong expiry date was recorded by mistake in the vaccine stock register. [...] Further it pointed out that in DH, Ramgarh, Acyclovir 200 mg tablet (Batch T-15818), supplied (on August 31, 2018) through JMHIDPCL, was reported (on March 15, 2019) as "not of standard quality" by the State Drug Testing Laboratory, Jharkhand.

"However, 140 out of supplied 5,000 tablets of the same batch were distributed (between November 23, 2018 and March 27, 2019) to OPD patients and remaining 4,860 tablets were lying in store as of February 2020," the report mentioned.

Likewise, the report pointed out that CS-cum-CMO (civil surgeon cum chief medical officer) issued (between July 25, 2018 and January 23, 2019) 17,500 vials of Dexamethasone Sodium Phosphate (Dexona) 2 ml injections to DH, Deoghar. [...] The drug inspector, Deoghar collected (on July 30, 2018) samples of the injection of the same batch from the store of CS-cum-CMO which were found (on March 8, 2019) spurious by the Regional Drug Testing Laboratory, Guwahati.

The samples were re-tested by CDL, Kolkata on the orders of the Civil Court, Deoghar and

were again found (on September 11, 2019) ”not of standard quality”, it said.

It was noticed that 4,185 out of 17,500 vials of injections were issued (July 28, 2018 to March 12, 2019) to different wards from the store of DH, Deoghar and were administered to patients till March 2019.

”Audit further noticed that 309 vials were administered (between March 12 and March 31, 2019) even after the injection was detected as spurious by the Regional Drug Testing Laboratory, Guwahati as intimated (on March 12, 2019) by the drug inspector, Deoghar. [...] The CAG said that purchase order for supply of 24.71 lakh tablets of Amoxicillin with Potassium Clavulanate 625 mg valued at Rs 1.11 crore was issued (in March 2017) to a vendor that supplied (in June 2017) 24.47 lakh tablets in five batches, bearing manufacturing date of May 2017 and expiry date of October 2018 along with the quality certificates.

As per the provision of the contract, JMHIDPCL got the sample tested from an empanelled laboratory which found (on July 27, 2017) all the batches ”not of standard quality”. [...]

22 Pfizer, following last year's Chantix recall, pulls blood pressure med in Canada on carcinogen fears

Publication date	2022-03-02
Create date	2022-04-18
Score	13.97
Report id	1446487
Category	Cardiovascular medicine
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Pfizer, following last year's Chantix recall, pulls blood pressure med in Canada on carcinogen fears FiercePharma

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Table 48: Places for report 1446487

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5
Americas	Canada	Canada	60.10867	-113.64258

Table 49: Drugs for report 1446487

Medicine Name	Medicine Class	Action	ATC Code
propranolol	Beta blocking agents, non-selective	beta blocking agents	C07AA05

Notes: "Following last year's wide-ranging Chantix recall, Pfizer is initiating another product pull thanks to higher-than-allowed levels of a likely carcinogen.

Pfizer is pulling 15 lots of its long-acting blood pressure med Inderal from Canadian shelves, citing unacceptable nitrosamine levels across a range of product strengths. The recall specifically covers multiple batches of 60-mg, 80-mg, 120-mg and 160-mg extended-release capsules, the Canadian government said in a recall notice published this week.

The suspect Inderal batches were set to expire as early as Sept. 30, 2022, and as late as Jan. 31, 2024. The beta blocker Inderal, also known as propranolol hydrochloride, is used to treat

high blood pressure and prevent angina pectoris—a condition associated with sharp chest pain and breathing trouble. [...]”

23 Plastikon Healthcare Issues Voluntary Nationwide Recall of Milk of Magnesia Oral Suspension 2400 mg/30 mL, Magnesium Hydroxide 1200mg/Aluminum Hydroxide 1200mg/ Simethicone 120mg per 30 mL, and Acetaminophen 650mg/ 20.3mL, Unit Dose Cu

Publication date	2022-03-24
Create date	2022-03-29
Score	13.48
Report id	1438852
Category	Antacid, Antipyretic
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Plastikon Healthcare Issues Voluntary Nationwide Recall of Milk of Magnesia Oral Suspension 2400 mg/30 mL, Magnesium Hydroxide 1200mg/Aluminum Hydroxide 1200mg/ Simethicone 120mg per 30 mL, and Acetaminophen 650mg/ 20.3mL, Unit Dose Cu FDA.gov

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Table 50: Places for report 1438852

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5
Americas	United States	Lawrence	38.97167	-95.23525

Table 51: Drugs for report 1438852

Medicine Name	Medicine Class	Action	ATC Code
magnesium hydroxide	Magnesium compounds	antacids	A02AA04
magnesium hydroxide	Other urologicals	urologicals	G04BX01
aluminium hydroxide	Aluminium compounds	antacids	A02AB01
paracetamol	Anilides	other analgesics and antipyretics	N02BE01

Table 52: Other Stories

ID	Title	Link
1438889	Plastikon Healthcare Issues Voluntary Nationwide Recall of Milk of Magnesia Oral Suspension 2400 mg/ 30 mL, Magnesium Hydroxide 1200mg/Aluminum Hydroxide 1200mg/Simethicone 120mg per 30 mL, and Acetaminophen 650mg/ 20.3mL, Unit Dose Cups, Due to Microbial C	Link
1440683	FDA: Nationwide recall of Milk of Magnesia, other medicines due to possible contamination	Link
1440776	Over-the-counter laxative, antacid recalled for bacterial contamination	Link
1441321	Contamination found in milk of magnesia and generic Tylenol sent to hospitals, nursing homes	Link
1441762	FDA: Milk of Magnesia recalled due to bacterial contamination	Link
1442136	Pain Relief, Heartburn Medication Recall Announced by FDA — Best Life	Link
1445651	Recall: Major Pharmaceuticals milk of magnesia, pain drug	Link
1472682	Milk of magnesia products being recalled over possible contamination	Link
1580145	Plastikon Healthcare Expands Voluntary Nationwide Recall of Milk of Magnesia Oral Suspension and Magnesium Hydroxide /Aluminum Hydroxide / Simethicone Oral Suspension Due to Microbial Contamination - 2022-08-03	Link
1580154	Plastikon Healthcare Expands Voluntary Nationwide Recall of Milk of Magnesia Oral Suspension and Magnesium Hydroxide /Aluminum Hydroxide / Simethicone Oral Suspension Due to Microbial Contamination	Link

Notes: Lawrence, KS, Plastikon Healthcare, LLC is voluntarily recalling three (3) lots of Milk of Magnesia 2400 mg/30 mL Oral Suspension, one (1) lot of Acetaminophen 650mg/ 20.3mL, and six (6) lots of Magnesium Hydroxide 1200mg/Aluminum Hydroxide 1200mg/Simethicone 120mg per 30 mL to the hospital, clinic and patient level. The products are being recalled due to microbial contamination and failure to properly investigate failed microbial testing. [...] Product indication, lot numbers, expiration dates and NDC information are listed in the table below. The product is packaged for institutional use and is sold to clinics and hospitals nationwide in single use cups with a foil lid. The affected lots were distributed to Major Pharmaceuticals Distribution Center (wholesaler) between 5/1/2020 and 6/28/2021, who shipped to hospitals, nursing homes, and clinics nationwide. The products are private labeled for Major Pharmaceuticals. [...]

24 2 people suffer adverse effects after taking supplements with potent, banned substances: HSA

Publication date	2022-02-28
Create date	2022-03-03
Score	12.98
Report id	1414240
Category	Herbal medicine, Nutritional supplement
Quality	Substandard
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: 2 people suffer adverse effects after taking supplements with potent, banned substances: HSA The Straits Times

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Table 53: Places for report 1414240

Region Name	Country	Location	Latitude	Longitude
Southern Asia	Singapore	Singapore	1.36667	103.8

Table 54: Other Stories

ID	Title	Link
1414310	HSA issues advisory against herbal, slimming capsules after consumers report adverse effects	Link
1414366	Potent medicinal ingredients, banned substance found in 2 health products: HSA	Link
1414367	HSA issued advisory against herbal, slimming capsules after consumers report adverse effects	Link
1414522	2 suffer adverse effects after taking health products with potent ingredients, banned substance: HSA	Link
1489185	'Buying a hope': Why people try dubious pills for pain relief and weight loss	Link

Notes: Two people experienced adverse effects after taking products containing potent undeclared ingredients, the Health Sciences Authority (HSA) said on Tuesday (March 1). The

products are Traditional Herbs Preparation XPE and FS++ Slimming Supplements By JPJ Slim. [...] In its statement, HSA said it found potent adulterants, which include medicinal ingredients and sibutramine, a banned substance, in the products. [...] Upon testing the product, HSA detected six medicinal ingredients: dexamethasone, chlorpheniramine, ibuprofen, lovastatin, chloramphenicol and tetracycline. [...]

25 Cofepris warns about counterfeit oncology drug Keytruda

Publication date	2022-02-09
Create date	2022-02-17
Score	12.83
Report id	1399152
Category	Other
Quality	Falsified
Source	Not applicable
Curation	Manually curated
Incident or General	Incident

Snippet: Cofepris warns about counterfeit oncology drug Keytruda Then24.com

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Table 55: Places for report 1399152

Region Name	Country	Location	Latitude	Longitude
Americas	Mexico	Mexico	23	-102

Table 56: Drugs for report 1399152

Medicine Name	Medicine Class	Action	ATC Code
pembrolizumab	Monoclonal antibodies	other antineoplastic agents	L01XC18

Notes: The Federal Commission for the Protection against Sanitary Risks (Cofepris), warned about the identification of nine falsified batches of the real medicine Keytrude (pembrolizumab), classified as a monoclonal antibody and used to treat patients with metastatic or non-removable melanoma and lung cancer. [...] The lots T009249, S035357, S012080, T021792, LT87333, LT78236, DC68976, DE68005 and VZ01380 were identified as fake. [...]

26 Agra company selling fake vitamin tablets sealed

Publication date	2022-02-03
Create date	2022-02-10
Score	12.55
Report id	1389697
Category	Vitamin
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Agra company selling fake vitamin tablets sealed Devdiscourse

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Table 57: Places for report 1389697

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Agra	27.18333	78.01667

Table 58: Drugs for report 1389697

Medicine Name	Medicine Class	Action	ATC Code
	Vitamin D and analogues	vitamin a and d, incl. combinations of the two	A11CC

Table 59: Other Stories

ID	Title	Link
1390463	Agra based Madhav Pharma sealed for selling fake vitamin tablets	Link
1390487	Agra based Madhav Pharma sealed for selling fake vitamin tablets - 2022-02-04	Link
1417685	Agra company selling fake vitamin tablets sealed	Link

Notes: An Agra-based pharmaceutical company was sealed after being found selling substandard and fake vitamin-D tablets, following information shared by the drugs control department of Delhi, officials said on Thursday. According to an official, the department received

a complaint from Macleods Pharmaceuticals stating they had found that fake tablets were being sold in Delhi with their company name in the last week of December. Following this, the drugs control department here developed intelligence and conducted a raid on January 19 and seized some samples. The seized samples were tested and some of them were found to be sub-standard and some fake, the official said. [...]

27 T&T on alert as fake COVID-19 vaccine pills seized abroad | Loop Trinidad & Tobago

Publication date	2022-03-24
Create date	2022-03-29
Score	12.49
Report id	1438727
Category	Other
Quality	Falsified
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: T&T on alert as fake COVID-19 vaccine pills seized abroad | Loop Trinidad & Tobago Loop News Trinidad & Tobago

Click here to see the Original Article

Table 60: Places for report 1438727

Region Name	Country	Location	Latitude	Longitude
Europe	Ireland	Ireland	53	-8
Americas	Trinidad and Tobago	Republic of Trinidad and Tobago	11	-61
Online	Online	Online	0	0

Table 61: Other Stories

ID	Title	Link
1439932	Ministry warns public against bogus Pfizer vaccine tablets	Link
1439989	MOH warns public about fake COVID-19 vaccine tablets	Link

Notes: The Ministry of Health has alerted the public to counterfeit COVID-19 Prophylactics/ Pfizer Vaccine tablets following a seizure in Ireland. In an advisory today, the Ministry said it was advised of the threat to public health by the Trinidad and Tobago Police Service. It noted that these pills are being touted on several websites and online spaces as a cure/prevention to the COVID-19 virus, but Pfizer does not produce any such tablets. Further, the Ministry said

the tablets have been found to contain sugar and no active ingredient. The Ministry warned that people who take this medication may falsely believe they are protected from COVID-19. In this respect, it said any tablets labelled "Pfizer Vaccine" should be considered as counterfeit. [...]

28 Cofepris warns about counterfeit medicine Xarelto

Publication date	2022-02-18
Create date	2022-02-21
Score	12.42
Report id	1404858
Category	Other
Quality	Falsified
Source	Not applicable
Curation	Manually curated
Incident or General	Incident

Snippet: Cofepris warns about counterfeit medicine Xarelto Then24.com

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Table 62: Drugs for report 1404858

Medicine Name	Medicine Class	Action	ATC Code
rivaroxaban	Direct factor Xa inhibitors	antithrombotic agents	B01AF01

Table 63: Other Stories

ID	Title	Link
1405546	Health authorities alert on counterfeit lots of the Xarelto Medicine in Mexico	Link
1406949	Mexico warns of falsified clotting drug Xarelto - 2022-02-21	Link
1407211	Mexico warns of falsified clotting drug Xarelto	Link

Notes: The Federal Commission for the Protection against Sanitary Risks (Cofepris) warned about the detection of three falsified batches of the medication Xarelto (rivaroxaban). Through a statement, it was reported that inconsistencies were identified in three false batches of the medicine xareltoanticoagulant produced by Bayer de México, which can be verified by any user or business.

These are batches BXJG6V2 and BXJG6V3, which are considered fake and adulterated if they contain 14 tablets, since it is half of those that the medicine original. The packages also present anomalies in colors and fonts.

In the case of lot 765289, the packaging indicates that it has 100 capsules, however, the original drug It has no presentation with that amount. [...]

29 Jamshedpur: 1000 L of banned prohibited drug Oxytocin seized from Jugsalai godown

Publication date	2022-03-06
Create date	2022-03-10
Score	12.36
Report id	1420053
Category	Other
Quality	Diverted/Unregistered
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Jamshedpur: 1000 L of banned prohibited drug Oxytocin seized from Jugsalai godown Avenue Mail

Click here to see the Original Article

Table 64: Places for report 1420053

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Jugsālai	22.77668	86.18351

Table 65: Drugs for report 1420053

Medicine Name	Medicine Class	Action	ATC Code
oxytocin	Oxytocin and analogues	posterior pituitary lobe hormones	H01BB02

Notes: A joint team of drug inspectors and district police confiscated 1000 litres of the prohibited drug Oxytocin from the godown of Vikas Roadways near St. John School at ME Road, Jugsalai, here on Sunday.

Drug Inspector Mohammad Abrar Ansari said the department had got a tip-off about certain people engaged in the trade of fake and prohibited drugs in Jugsalai. The culprits had reportedly brought a large consignment of the banned drug for sale to various customers, he said. [...]

30 Adulterated supplements: 17 per cent of herbal weight loss nutraceuticals sold in UAE contain synthetic drugs

Publication date	2022-02-16
Create date	2022-02-21
Score	12.27
Report id	1403800
Category	Nutritional supplement
Quality	Substandard
Source	Not applicable
Curation	Manually curated
Incident or General	Incident

Snippet: Adulterated supplements: 17 per cent of herbal weight loss nutraceuticals sold in UAE contain synthetic drugs NutraIngredients-Asia

Click here to see the Original Article

Table 66: Places for report 1403800

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Malaysia	Malaysia	2.5	112.5
Americas	United States	United States	39.76	-98.5
Americas	Canada	Canada	60.10867	-113.64258
Southern Asia	India	Republic of India	22	79
Western Asia	United Arab Emirates	United Arab Emirates	23.75	54.5
		Europe	48.69096	9.14062
Eastern Asia	China	People's Republic of China	35	105

Notes: Analysing 137 weight loss supplements, 17.5% of these contained significant concentrations of either sibutramine, phenolphthalein, or fluoxetine, which are active pharmaceutical ingredients on the FDA list of prohibited compounds. [...] Of the 137 weight loss supplements available in UAE, most were in the form of capsules (63.5%), followed by tablets (22.6%), and tea bags (13.9%). Most of the supplements were made in US (48.9%), followed by EU (16.1%), China (5.1%), Malaysia (4.4%), India and UAE with 2.9% each, and Canada (2.2%). About 17.5% did not have a declared country of origin. [...] Among the weight loss supplements, 15.3% contained undeclared sibutramine, 13.9% contained undeclared phenolphthalein, and

5.1% contained undeclared fluoxetine. In total, 17.5% of all supplements contained significant concentrations of either sibutramine, phenolphthalein, or fluoxetine. Sibutramine was found in 21 samples at varying levels of 0.14 to 16,823.3 mg/kg. According to researchers, past research also showed sibutramine was the most frequent illegal additive in herbal weight loss preparations. [...] The second most frequent illegal additive in herbal weight loss products in this research was the laxative phenolphthalein, which was found in 19 samples at levels of 1.9 to 13,218.8 mg/kg. The damaging side effect of phenolphthalein is an increased risk of cancer. The third most frequent illegal additive found in weight loss supplements was fluoxetine, found in seven samples at levels between 12 to 193.97 mg/kg. Fluoxetine is an anti-depressant with side effects of nausea, drowsiness, and tiredness. [...]

31 The Era of Fake Medicines: Investigating counterfeit medicinal products for erectile dysfunction disguised ...

Publication date	2022-02-21
Create date	2022-02-22
Score	11.51
Report id	1406576
Category	Herbal medicine
Quality	Falsified
Source	Not applicable
Curation	Manually curated
Incident or General	Incident

Snippet: The Era of Fake Medicines: Investigating counterfeit medicinal products for erectile dysfunction disguised ... Physician's Weekly

Click here to see the Original Article

Table 67: Places for report 1406576

Region Name	Country	Location	Latitude	Longitude
Online	Online	Online	0	0

Table 68: Other Stories

ID	Title	Link
1407120	The Era of Fake Medicines: Investigating counterfeit medicinal products for erectile dysfunction disguised asherbal supplements.	Link

Notes: Sales of substandard and falsified medical products (SF) are rising rapidly everywhere around the globe. The wide and easy access to these products is an alarming issue to the global health systems and undermined the health of patients, especially with the thrive of online commerce. To tackle this threat to public health, new ways to access these products should be identified and detection technologies should be strengthened. The overarching aim of this study was to investigate if herbal supplements sold online claiming to be natural alternatives to Viagra® were amongst these SF medical products and how effective different analytical techniques are in providing information about these products. 3 products which claimed to be herbal supplements for men sexual performance were purchased from an e-commerce platform. Two

products were received as unregistered generic sildenafil citrate tablets manufactured in India (and thus different to the products information on the website) while one product was received in the same packaging as shown on the website, claiming to be an herbal product. Nevertheless, all products were proven to contain sildenafil citrate, the active pharmaceutical ingredients in Viagra® after the comprehensive analytical tests. The results elucidated that the quality standards for the unregistered generic sildenafil citrate tablets were fulfilled according to the British Pharmacopeia, but the falsified product failed the quality tests and contained approximately 200 mg sildenafil citrate, which is equivalent to 2-fold of the daily maximum dose. [...]

32 5 recent medical device recalls

Publication date 2022-02-04

Create date 2022-02-11

Score 11.41

Report id 1390679

Category Medical device used for cure/mitigation/treatment, Medical device for screening/diagnosis/monitoring

Quality Substandard

Source Manufacturer

Curation Manually curated

Incident or General Incident

Snippet: 5 recent medical device recalls Becker's Hospital Review

Click here to see the Original Article

Table 69: Places for report 1390679

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5

Notes: [...] 2. Philips Respironics recalled 215 Trilogy EVO Ventilators and 51 Trilogy EVO repair kits on Jan. 26 due to potential health risks from polyester-based polyurethane sound abatement foam. The foam may break down and potentially enter the device's air pathway, causing potential inhalation. There have been no reported injuries or deaths.

3. Medtronic recalled over 95,100 units of the HawkOne Directional Atherectomy System on Jan. 21 due to the risk of guidewire within the catheter moving downward or prolapsing when force is applied during use. There have been 163 complaints, 55 injuries and no deaths reported about this device issue.

4. Getinge USA recalled 50 units of the Vaporizer Sevoflurane Maquet Filling for Flow Family Anesthesia Systems on Jan. 19 due to the risk of potential chemical breakdown of sevoflurane, a general surgical anesthetic, which may result in inhalation and/or skin exposure to harmful chemicals. There have been eight complaints regarding this device issue, but no reported deaths or injuries.

5. Cardiovascular Systems recalled 697 units of its Wirion embolic protection devices on Jan. 10 because of complaints of filter breakage during retrieval. There have been reports of nine device malfunctions and no reports of death related to the issue.

33 Five suspects held as FIA busts racket of fake medicines

Publication date 2022-02-05

Create date 2022-02-11

Score 11.32

Report id 1391738

Category Cardiovascular medicine, Respiratory diseases medicine, Antibiotic, Analgesic

Quality Substandard

Source Clandestine laboratory

Curation Manually curated

Incident or General Incident

Snippet: Five suspects held as FIA busts racket of fake medicines The News International

Click here to see the Original Article

Table 70: Places for report 1391738

Region Name	Country	Location	Latitude	Longitude
Southern Asia	Pakistan	Karachi	24.8608	67.0104

Table 71: Drugs for report 1391738

Medicine Name	Medicine Class	Action	ATC Code
cefixime	Third-generation cephalosporins	other beta-lactam antibacterials	J01DD08
spironolactone	Aldosterone antagonists	potassium-sparing agents	C03DA01
nalbuphine	Morphinan derivatives	opioids	N02AF02
amlodipine	Dihydropyridine derivatives	selective calcium channel blockers with mainly vascular effects	C08CA01
ceftriaxone	Third-generation cephalosporins	other beta-lactam antibacterials	J01DD04
salbutamol	Selective beta-2-adrenoreceptor agonists	adrenergics, inhalants	R03AC02
salbutamol	Selective beta-2-adrenoreceptor agonists	adrenergics for systemic use	R03CC02

Table 72: Other Stories

ID	Title	Link
1392453	Five held for manufacturing counterfeit drugs in city	Link

Notes: The Corporate Crime Circle (CCC) of the Federal Investigation Agency (FIA) has arrested five men on charges of selling fake medicines and seized a huge quantity of spurious medicines and material in Karachi. [...] During the raid, a huge quantity of spurious and altered medicines was found. They included Disprin tablets, Cefim Suspension, Cefim DS Suspension, Aldactone tables, Ventoline Expectorant, Kinz Injection, Cefixime Suspension, Inocef Injection (vial) and Norvasc tablets. [...] He further disclosed that the powder in the bottle is "Cefxime", which he has locally purchased from the market to repack it into M/S Hilton Pharmaceuticals' branded bottle of "Cefim & Cefim DS" at the house of Muhammad Moiz in Liaquatabad. He said Sikandar used to pick up the "Cefixime" powder bottles without any labelling from him and returned them in the packing of "Cefim and Cefim DS Suspension". [...] The arrested suspects and the seized medicines were brought to the FIA's CCC police station. A certificate for tests from the Central Drug Laboratory, Karachi, said the drugs were spurious and substandard. [...]

34 Indianapolis CBP Seizes Almost 50 Pounds of Ketamine in Three Days

Publication date	2022-02-10
Create date	2022-02-14
Score	11.28
Report id	1396572
Category	Anaesthetic
Quality	Diverted/Unregistered
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Indianapolis CBP Seizes Almost 50 Pounds of Ketamine in Three Days Customs and Border Protection

Click here to see the Original Article

Table 73: Places for report 1396572

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Indianapolis	39.76838	-86.15804

Table 74: Drugs for report 1396572

Medicine Name	Medicine Class	Action	ATC Code
ketamine	Other general anesthetics	anesthetics, general	N01AX03

Notes: [...] Two days later officers were examining a pair of elephant statues and discovered a white granular powder concealed inside the elephants. Officers tested the powder which tested positive for ketamine. Almost 20 pounds of ketamine was seized.

Finally on February 6, two folding ottomans were examined by officers, and this led to the discovery of white granular powder inside the walls and top of the ottomans. In total, officers discovered 17 pounds of ketamine. [...]

35 Officials Seize Large Cache of Fake COVID Vaccines, Drugs, Test Kits in Varanasi – The Wire Science

Publication date 2022-02-03

Create date 2022-05-11

Score 11.04

Report id 1390161

Category Vaccine, Antiviral others, Medical device for screening/diagnosis/monitoring

Quality Falsified

Source Clandestine laboratory

Curation Manually curated

Incident or General Incident

Snippet: Officials Seize Large Cache of Fake COVID Vaccines, Drugs, Test Kits in Varanasi – The Wire Science The Wire Science

Click here to see the Original Article

Table 75: Places for report 1390161

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Varanasi	25.31668	83.01041
Southern Asia	India	Uttar Pradesh	27.25	80.75
Southern Asia	India	Delhi	28.65195	77.23149

Table 76: Drugs for report 1390161

Medicine Name	Medicine Class	Action	ATC Code
			J07
remdesivir	Nucleosides and nucleotides excl. reverse transcriptase inhibitors	direct acting antivirals	J05AB16

Table 77: Other Stories

ID	Title	Link
1388119	Manufacture of fake corona vaccine stirred up the country, STF confiscated fake goods worth crores	Link

Table 77: Other Stories(continued)

ID	Title	Link
1388191	Uttar Pradesh: Fake Covid vaccine manufacturing unit busted in Varanasi	Link
1388268	5 Arrested By UP STF For Supplying Fake Vaccines, Testing Kits	Link
1388316	Gang making fake Covid vaccines, testing kits busted in Varanasi, 5 held	Link
1388953	Varanasi: Fake vaccine racket busted, 5 arrested	Link
1389061	Fake vaccine unit unearthed in Uttar Pradesh, 5 held	Link
1389177	Be careful! Millions of people have got fake corona vaccine	Link
1389213	Uttar Pradesh: Fake Covid-19 vaccines and testing kits worth Rs 4 crore. seized , 5 arrested	Link
1389245	Uttar Pradesh: Fake Covid-19 vaccines, testing kits worth Rs 4 crore seized, 5 arrested - 2022-02-03	Link
1390198	Fake vaccine racket busted in Varanasi; UP Police arrests five	Link
1391998	Varanasi: Fake COVID-19 vaccines, testing kits confiscated - Goa Chronicle	Link

Notes: In a raid conducted on February 2, the Uttar Pradesh Food and Drug Administration (FDA) has secured a large tranche of spurious COVID-19 vaccines, drugs and rapid antigen test kits from Varanasi. [...] Officials also seized as many as 10,800 kits of 'Standard Q Covid-19 Ag SD BIOSENSOR Rapid Test Kits'. In normal course, the kits are manufactured by SD Biosensor Healthcare Pvt. Ltd., a Gurugram-based company. The seized materials had fake batch numbers and fake expiry dates.

To make these kits, the accused used pregnancy strips. The COVID-19 rapid antigen test kits look similar to pregnancy kits; both are strip-based tests. According to FDA officials, the accused would procure pregnancy kits from the market and simply paste a wrapper of the antigen kit on it. The production cost was Rs 50 per kit but the accused sold it at Rs 500. Officials also recovered 880 vials (2 ml each) of Zydus Cadila's COVID-19 vaccine, ZyCoV-D. Note that Zydus Cadila had initiated its supply of this vaccine to the Centre only on February 2, and that the Centre had planned to begin administering it in Bihar. Yet the spurious doses had already been available in Varanasi. To make the spurious COVID-19 vaccine vials, the accused would fill empty vials with distilled water and slap the company's (Cadila's) wrapper on it. Doing this cost Rs 25 but the selling price was Rs 300.

The drug administration team also recovered 6,000 vials "filled with transparent fluid meant for packing as Covishield with green cap". The accused were allegedly selling the spurious vaccines mostly to private hospitals in the city. They also recovered 1,550 vials of spurious (injectable) remdesivir vials. According to information shared by the raiding team, the accused would fill water mixed with Glucon-D in an empty vial and paste a fake wrapper around it. The manufacturing cost of one such vial would be Rs 100 – and the selling price, Rs 3,000. [...] In all, according to the STF's statement, the police and the FDA officials had together seized four sealing machines, two cartons of empty vials, blue and green sealing caps (for ZyCoV-D and Covishield, respectively), and many fake wrappers. [...]

36 Amid inspection and recall woes, Aurobindo to shut down NJ site in April

Publication date	2022-03-23
Create date	2022-03-29
Score	10.99
Report id	1437366
Category	Antibiotic
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Amid inspection and recall woes, Aurobindo to shut down NJ site in April Endpoints News

Click here to see the Original Article

Table 78: Places for report 1437366

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5
Americas	United States	Jersey City	40.72816	-74.07764

Table 79: Drugs for report 1437366

Medicine Name	Medicine Class	Action	ATC Code
polymyxin B	Antibiotics	intestinal antiinfectives	A07AA05
polymyxin B	Polymyxins	other antibacterials	J01XB02
polymyxin B	Antibiotics	antiinfectives	S01AA18
polymyxin B	Antiinfectives	antiinfectives	S02AA11
polymyxin B	Antiinfectives	antiinfectives	S03AA03
moxifloxacin	Fluoroquinolones	quinolone antibacterials	J01MA14
moxifloxacin	Fluoroquinolones	antiinfectives	S01AE07

Table 80: Other Stories

ID	Title	Link
1439613	Fierce Pharma Asia—Chinese biotech's Pfizer trade secret suit; Lilly, Innovent's FDA rebuff; Aurobindo's New Jersey closure	Link
1440680	Aurobindo to turn out lights at troubled New Jersey plant, putting 99 jobs on the chopping block	Link

Notes: [...] Aurobindo was forced to recall 1.15 million bottles of Moxifloxacin Ophthalmic Solution, an antibiotic used in the treatment of bacterial infections, made out of its New Jersey site due to failed impurities and degradation specifications at the end of February. It also initiated a voluntary recall of a lot of polymyxin B for injection after there was a hair found in a vial within the lot. The antibiotic is used to treat meningitis, pneumonia, sepsis, and urinary tract infections. If the drug is injected with contaminants, it could cause a serious hypersensitivity reaction, the FDA said, that could be life-threatening. [...]

37 BOC seizes P150M worth of fake COVID test kits, goods

Publication date 2022-01-23

Create date 2022-01-24

Score 9.95

Report id 1377074

Category Medical devices for disease prevention, Herbal medicine, Medical device for screening/diagnosis/monitoring

Quality Falsified

Source Unlicensed outlets

Curation Manually curated

Incident or General Incident

Snippet: BOC seizes P150M worth of fake COVID test kits, goods Manila Bulletin

Click here to see the Original Article

Table 81: Places for report 1377074

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Philippines	Manila	14.6042	120.9822

Table 82: Other Stories

ID	Title	Link
1377884	P150 million fake COVID-19 test kits, drugs seized	Link
1378348	P150-M fake antigen test kits, medicines seized from Chinese national	Link
1378696	P150M worth of fake Covid test kits, medicines seized| SUNSTAR	Link
1378946	P150 million worth of fake COVID-19 test kits, meds seized; warehouse owner arrested	Link
1379359	Bureau of Customs seizes fake Covid test kits, medicines worth P150M| SUNSTAR	Link
1380996	PNP intensifies crackdown vs fake COVID-19 test kits, other medical supplies - UNTV News	Link
1383666	Bureau of Customs seizes fake Covid test kits, medicines worth P150M	Link
1385925	P150M worth of fake COVID test kits, other medical products seized	Link

Notes: Operatives of the Bureau of Customs (BOC) confiscated some P150-million worth of fake COVID-19 antigen test kits, face masks, medicines as well as counterfeit products during a raid in a warehouse on Friday, Jan. 21 in a warehouse in Manila. [...] During the inspection, authorities found thousands of Clungene COVID-19 antigen test kits, counterfeit Chinese herbal medicines LianHua and fake 3M N95 face masks. They also found counterfeit Nike, Fila, Converse, Adidas, Louis Vuitton and Gucci bags, wallets, phone accessories, and others. [...]

38 Contaminated ivermectin in controversial Murupara GP's seized import, court hears

Publication date	2022-03-29
Create date	2022-04-06
Score	9.86
Report id	1443486
Category	Antiparasitic
Quality	Substandard
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Contaminated ivermectin in controversial Murupara GP's seized import, court hears Stuff

Click here to see the Original Article

Table 83: Places for report 1443486

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Republic of India	22	79
Melanesia	New Zealand	Tauranga	-37.68611	176.16667

Table 84: Drugs for report 1443486

Medicine Name	Medicine Class	Action	ATC Code
ivermectin	Other dermatologicals	other dermatological preparations	D11AX22
ivermectin	Avermectines	antinematodal agents	P02CF01

Table 85: Other Stories

ID	Title	Link
1443579	Contaminated ivermectin in controversial Murupara doctor's seized import, court hears	Link

Notes: A suspended doctor who sought to treat Covid patients with ivermectin ended up

importing tainted drugs.

Details of the contamination, believed to be bacterial, emerged at Tauranga District Court, where Dr Bernard Conlon is battling the Ministry of Health over the seized medicines.

The products came from India and were seized by Customs at the border, tested by Crown Research Institute ESR, and some were found to be contaminated, the court heard. [...]

39 Public Notification: Wonderful Honey contains hidden drug ingredient - 2022-03-04

Publication date	2022-03-04
Create date	2022-03-09
Score	9.67
Report id	1418594
Category	Nutritional supplement
Quality	Falsified
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: The Food and Drug Administration is advising consumers not to purchase or use Wonderful Honey, a product promoted for sexual enhancement on various websites and possibly in some retail stores. This product was discovered during an examination of imported goods.

Click here to see the Original Article

Table 86: Places for report 1418594

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5
Online	Online	Online	0	0

Notes: [...] FDA laboratory analysis confirmed that Wonderful Honey contains sildenafil, the active ingredient in the FDA-approved prescription drug Viagra, used to treat erectile dysfunction. FDA approval of Viagra is restricted to use under the supervision of a licensed health care professional. This undeclared ingredient may interact with nitrates found in some prescription drugs, such as nitroglycerin, and may lower blood pressure to dangerous levels. People with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. [...]

40 US Customs has seized 21 shipments of drugs at Erlanger port since first of the year

Publication date 2022-02-04

Create date 2022-02-11

Score 9.20

Report id 1390450

Category Other, Erectile dysfunction medicine, Vitamin, Nutritional supplement

Quality Diverted/Unregistered

Source Other

Curation Manually curated

Incident or General Incident

Snippet: US Customs has seized 21 shipments of drugs at Erlanger port since first of the year User-generated content

Click here to see the Original Article

Table 87: Places for report 1390450

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Malaysia	Malaysia	2.5	112.5
Southern Asia	India	Republic of India	22	79
Americas	United States	Cincinnati	39.12711	-84.51439
Eastern Asia	China	People's Republic of China	35	105
Northern Africa	Sudan	Republic of the Sudan	16	30

Table 88: Drugs for report 1390450

Medicine Name	Medicine Class	Action	ATC Code
tadalafil	Drugs used in erectile dysfunction	urologicals	G04BE08
sildenafil	Drugs used in erectile dysfunction	urologicals	G04BE03
			A11
	Vitamins	i.v. solution additives	B05XC

Table 88: Drugs for report 1390450(continued)

Medicine Name	Medicine Class	Action	ATC Code
vardenafil	Drugs used in erectile dysfunction	urologicals	G04BE09

Table 89: Other Stories

ID	Title	Link
1391517	Cincinnati Gets Pounded with $757,000 Worth of Illicit Erectile Dysfunction Drugs, Feds Say	Link

Notes: Since Jan. 1, U.S. Customs and Border Protection officers have seized 21 shipments of improperly imported Viagra, Cialis, and Levitra transiting through the Port of Cincinnati, which is located in Erlanger, near the Cincinnati/Northern Kentucky Airport.

Officers found approximately 32,556 pills of the prescription drugs in shipments of vitamins, supplements, watches, and other medications. The shipments also contained 1,050 packets of jellies and so-called "Miracle Honey," which is laced with sildenafil, the active ingredient in Viagra. [...]

41 Cofepris warns of the sale of fake COVID pills.

Publication date	2022-01-15
Create date	2022-05-31
Score	9.13
Report id	1363858
Category	Antiviral others
Quality	Falsified
Source	Unspecified outlet
Curation	Manually curated
Incident or General	Incident

Snippet: Cofepris warns of the sale of fake COVID pills. The Yucatan Times

Click here to see the Original Article

Table 90: Places for report 1363858

Region Name	Country	Location	Latitude	Longitude
Americas	Mexico	Mexico	23	-102

Table 91: Other Stories

ID	Title	Link
1363222	Mexico sees fake molnupiravir, 1 week after drug approved	Link

Notes: The Federal Commission for Protection against Health Risks warned on Friday about the illegal marketing of the drug molnupiravir, the pill against COVID-19 manufactured by Merck & Co. [...] The agency explained that complaints had been received about products being marketed as molnupiravir, so it reminded no one can sell the drug under the emergency use authorization.

The presentations that are being sold fraudulently are: – Mpiravir, from Merit laboratory, in white box presentation with green and yellow lines. It has an expiration date of October 2023 and contains 40 capsules of 200 milligrams. – Molaz, from Azista, in a white box with orange and purple lines; it contains 200 mg capsules and 40 capsules; it is offered as an over-the-counter product.

42 Louisville CBP Intercepted Over 2000 Pounds of Narcotics in January

Publication date	2022-02-08
Create date	2022-02-18
Score	9.11
Report id	1394224
Category	Other, Anaesthetic
Quality	Diverted/Unregistered
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Louisville CBP Intercepted Over 2000 Pounds of Narcotics in January Customs and Border Protection

Click here to see the Original Article

Table 92: Places for report 1394224

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Louisville	38.25424	-85.75941

Table 93: Drugs for report 1394224

Medicine Name	Medicine Class	Action	ATC Code
ketamine	Other general anesthetics	anesthetics, general	N01AX03

Table 94: Other Stories

ID	Title	Link
1401829	US Customs and Border Protection seized 2,079 pounds of illicit drugs in Jan. at Port of Louisville	Link

Notes: [...] CBP officers seized 282 shipments in January that contained various drugs. The narcotics arrived from India, the United Kingdom, Hong Kong, Mexico, and Canada. CBP seized: 1,113 pounds of Marijuana, 300 pounds of Methamphetamine, 179 pounds of drug pre-

cursors, 137 pounds of Khat, 108 pounds of scheduled narcotics, 103 pounds of cocaine, 75 pounds of Ketamine, and 64 pounds of steroids. [...]

43 BrandShield takes down 850 rogue pharmacies in a year - 2022-03-16

Publication date 2022-03-16

Create date 2022-03-22

Score 9.09

Report id 1430757

Category Other, Alzheimer's medicine, Antidiabetic, Respiratory diseases medicine

Quality Diverted/Unregistered

Source Website(s)

Curation Manually curated

Incident or General Incident

Snippet: Listings that were removed contained medicines for cancer, diabetes, asthma, COVID-19, and Alzheimer's among others.

Click here to see the Original Article

Table 95: Places for report 1430757

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Malaysia	Malaysia	2.5	112.5
Online	Online	Online	0	0
Southern Asia	India	Republic of India	22	79
South-Eastern Asia	Indonesia	Republic of Indonesia	-5	120
South-Eastern Asia	Philippines	Republic of the Philippines	13	122
Southern Asia	Singapore	Singapore	1.36667	103.8

Notes: The brand protection company – which specialises in the monitoring, detection and removal of online threats – also took action against around 14,000 fraudulent e-commerce listings and 4,000 social media posts suspected of peddling falsified medicines.

The listings that were removed contained medicines for cancer, diabetes, asthma, COVID-19, and Alzheimer's among others, with an estimated total value of $1.8m. [...]

44 Metformin Recalled Over Presence of NDMA, a Possible Carcinogen | Health.com

Publication date 2022-01-06

Create date 2022-01-10

Score 9.06

Report id 1352529

Category Antidiabetic

Quality Substandard

Source Manufacturer

Curation Manually curated

Incident or General Incident

Snippet: Metformin Recalled Over Presence of NDMA, a Possible Carcinogen | Health.com Health.com

Click here to see the Original Article

Table 96: Places for report 1352529

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Kansas City	39.09973	-94.57857

Table 97: Drugs for report 1352529

Medicine Name	Medicine Class	Action	ATC Code
metformin	Biguanides	blood glucose lowering drugs, excl. insulins	A10BA02

Notes: [...] Nostrum Laboratories, Inc., announced on January 4 that it is voluntarily recalling one lot of its Metformin HCl Extended Release Tablets, USP 750 mg. The medication is designed to improve blood glucose control in adults with type 2 diabetes, when used alongside a healthy diet and exercise. The affected product is packaged in 100-tablet bottles, has the NDC of 29033-056-01, a lot number of MET200501, and an expiration date of July 2022. So far, the company hasn't received any reports of adverse events related to the recall. [...]

45 Two held for manufacturing fake medicines

Publication date	2022-03-31
Create date	2022-04-08
Score	8.98
Report id	1445496
Category	Antacid, Respiratory diseases medicine
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Two held for manufacturing fake medicines newagebd.net

Click here to see the Original Article

Table 98: Places for report 1445496

Region Name	Country	Location	Latitude	Longitude
Southern Asia	Bangladesh	Bangladesh	24	90

Table 99: Drugs for report 1445496

Medicine Name	Medicine Class	Action	ATC Code
pantoprazole	Proton pump inhibitors	drugs for peptic ulcer and gastro-oesophageal reflux disease (gord)	A02BC02
montelukast	Leukotriene receptor antagonists	other systemic drugs for obstructive airway diseases	R03DC03

Table 100: Other Stories

ID	Title	Link
1514686	Factory of counterfeit medicine busted	Link

Notes: A team of the Detective Branch of police seized fake medicines and arrested two people for manufacturing and distributing them across the country using the forged logos of different well-known brands.

The arrested are Giyas Uddin Ahmed, 47, owner of West Pharmaceutical Ayurvedic medicine factory and his assistant Ali Akkas Sheikh, 45. [...] A team of DB Lalbagh division conducted a raid at a courier service centre of Chawkbazar area in the capital and arrested Ali Akkas Sheikh with large consignments of Monas-10 and Pantonix-20 counterfeit drugs, DMP additional commissioner for DB AKM Hafiz Akter said. [...] Under the guise of the Ayurvedic business, the ring was manufacturing fake medicines. The group had been involved in manufacturing fake medicines and different courier services were used to transport those fake medicines to remote areas of the country.

The group was manufacturing fake medicines using the brand logos of Square Pharmaceuticals, Incepta Pharmaceuticals, Zenith Pharmaceuticals and The Acme Laboratories. The DB team also seized a large cache of fake medicines from the factory. [...]

46 Leader of Dark Web Drug Trafficking Operation Sentenced to Eight Years in Prison and 59 Bitcoin in Forfeiture

Publication date	2022-03-11
Create date	2022-03-14
Score	8.94
Report id	1425662
Category	Opioid
Quality	Falsified
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: Leader of Dark Web Drug Trafficking Operation Sentenced to Eight Years in Prison and 59 Bitcoin in Forfeiture Department of Justice

Click here to see the Original Article

Table 101: Places for report 1425662

Region Name	Country	Location	Latitude	Longitude
Online	Online	Online	0	0
Americas	United States	United States	39.76	-98.5

Table 102: Drugs for report 1425662

Medicine Name	Medicine Class	Action	ATC Code
alprazolam	Benzodiazepine derivatives	anxiolytics	N05BA12

Table 103: Other Stories

ID	Title	Link
1428101	Man convicted of drug charges must forfeit cryptocurrency	Link
1428137	Man Convicted of Running Dark Web Drug Ring Must Forfeit $2M in Cryptocurrency	Link
1428245	Feds to seize $2M in Bitcoin from convicted Brockton drug dealer	Link

Table 103: Other Stories(continued)

ID	Title	Link
1428437	Dark web drug trafficking leader sentenced in Boston, forfeit $2M in Bitcoin	Link

Notes: [...] Binh Thanh Le, 25, of Brockton, was sentenced by U.S. Senior District Court Judge Rya W. Zobel to eight years in prison and three years of supervised release. Le was also ordered to forfeit more than 59 Bitcoin (currently worth in excess of $2 million), $114,680 in cash, $42,390 representing the proceeds from the sale of a 2018 BMW M3, along with other items including a pill press and currency counter. On Sept. 29, 2021, Le pleaded guilty to conspiracy to manufacture, distribute and possess with intent to distribute Methylenedioxymethamphetamine (MDMA), commonly known as ecstasy, Ketamine and Alprazolam (Xanax). [...] Over 19 kilograms of MDMA, almost seven kilograms of Ketamine, nearly one kilogram of cocaine and more than 10,000 counterfeit Xanax pills were seized by authorities during the investigation. Investigators also recovered a computer with the "EastSideHigh" vendor page open, numerous packages containing MDMA and Ketamine, various shipping and packaging materials and a pill press from the office space in Stoughton. [...]

47 Manila cops told to arrest sellers of 'fake' meds

Publication date	2022-01-22
Create date	2022-01-24
Score	8.67
Report id	1375739
Category	Respiratory diseases medicine
Quality	Falsified
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: Manila cops told to arrest sellers of 'fake' meds manilastandard.net

Click here to see the Original Article

Table 104: Places for report 1375739

Region Name	Country	Location	Latitude	Longitude
Online	Online	Online	0	0
South-Eastern Asia	Philippines	Manila	14.6042	120.9822

Table 105: Drugs for report 1375739

Medicine Name	Medicine Class	Action	ATC Code
chlorphenamine	Substituted alkylamines	antihistamines for systemic use	R06AB04
paracetamol	Anilides	other analgesics and antipyretics	N02BE01
phenylephrine	Adrenergic and dopaminergic agents	cardiac stimulants excl. cardiac glycosides	C01CA06
phenylephrine	Sympathomimetics, plain	decongestants and other nasal preparations for topical use	R01AA04
phenylephrine	Sympathomimetics, combinations excl. corticosteroids	decongestants and other nasal preparations for topical use	R01AB01

Table 105: Drugs for report 1375739(continued)

Medicine Name	Medicine Class	Action	ATC Code
phenylephrine	Sympathomimetics	nasal decongestants for systemic use	R01BA03
phenylephrine	Sympathomimetics excl. antiglaucoma preparations	mydriatics and cycloplegics	S01FB01
phenylephrine	Sympathomimetics used as decongestants	decongestants and antiallergics	S01GA05

Notes: Manila Mayor Francisco Isko Moreno Domagoso has directed the Manila Police District (MPD) to crack down on those behind the production of fake medicines that endanger the lives of Filipino consumers, especially the poor who rely on cheap drugs like paracetamol. Moreno's directive came after operatives of the Special Mayor's Reaction Team (SMaRT) arrested Monique Gamboa, an online seller of fake medicines that are supposedly manufactured by Unilab. SMaRT is under the leadership of Police Lt. Col. Rosalino Ibay Jr.

After a test-buy was set up by SMaRT operatives in Sta. Cruz, Manila, Gamboa yielded 18,000 tablets of Bioflu and a box of Neozep tablets amounting to P1.1 million. Criminal charges have been filed against the suspect before the City prosecutor's office. [...]

48 Falsified rare disease drug Soliris found in supply chain - 2022-01-13

Publication date	2022-01-13
Create date	2022-01-17
Score	8.49
Report id	1361171
Category	Immunosuppressant
Quality	Falsified
Source	Distributor/Wholesaler
Curation	Manually curated
Incident or General	Incident

Snippet: Fake batches of the AstraZeneca/Alexion blockbuster were found in Argentina, Uruguay, Estonia and India.

Click here to see the Original Article

Table 106: Places for report 1361171

Region Name	Country	Location	Latitude	Longitude
Americas	Argentina	Argentine Republic	-34	-64
Southern Asia	India	Republic of India	22	79
		South America	-14.60485	-57.65625
		Europe	48.69096	9.14062
Europe	Estonia	Republic of Estonia	59	26
Americas	Uruguay	Oriental Republic of Uruguay	-33	-56

Table 107: Drugs for report 1361171

Medicine Name	Medicine Class	Action	ATC Code
eculizumab	Selective immunosuppressants	immunosuppressants	L04AA25

Table 108: Other Stories

ID	Title	Link
1361176	Falsified rare disease drug Soliris found in supply chain	Link

Notes: Several falsified batches of a medicine claiming to be AstraZeneca/Alexion's rare disease therapy Soliris were discovered in the supply chain in the last few weeks of 2021, according to the World Health organization (WHO).

Various counterfeit copies with different packaging were found in South America, Europe and India, suggesting that there has been a concerted effort by fraudsters to inveigle the fake vials into international supply chains. [...] Falsified copies of the Soliris with the lot number 1012401 and an expiry date of SEP 22 and Spanish packaging have been encountered in Argentina and Uruguay, with another version (Lot No. 1013715, Expiry Feb 2022) also found in Uruguay.

Another lot (No. 1001600, expiry 03/2023) was intercepted in Estonia with English packaging, while in India the batch is in the Turkish language and has the lot number 1001701 and expiry date of 03/2023. [...]

49 Teva recalls one lot of leukemia med after finding particulates in vial

Publication date	2022-03-30
Create date	2022-04-18
Score	8.02
Report id	1446625
Category	Other
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Teva recalls one lot of leukemia med after finding particulates in vial FiercePharma

Click here to see the Original Article

Table 109: Places for report 1446625

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5

Table 110: Other Stories

ID	Title	Link
1446804	Teva Pharmaceuticals Recalls Acute Myeloid Leukemia Drug Over Particulate Matter Contamination	Link

Notes: [...] Teva Pharmaceutical is pulling one lot of its injectable leukemia med IDArubicin hydrochloride in the U.S. after an internal inspection uncovered silica and iron oxide particulate matter in a lone drug vial, the company said in a recall notice published on the FDA's website. The defect hasn't turned up in any other vials, Teva added. [...] The cancer med comes in 5-ml single-dose vials, of which Teva distributed 1,565 from the affected lot. [...] Teva faced a similar ordeal last summer, when it recalled one lot of the cancer med topotecan injection. In that instance, a pharmacy complaint tipped off the company to the presence of a single glass particulate in a vial of the drug. After a sample review, Teva said it turned up two other particles, which it identified as grey silicone and "translucent, colorless cotton fiber." [...] Elsewhere, particulates have presaged major problems for Gilead Sciences in recent months. In December,

the Foster City, California-based drugmaker said it was recalling two batches of the COVID-19 antiviral Veklury, also known as remdesivir. Much like Teva's topotecan pull, a customer complaint flagged the presence of glass particulates, which Gilead then confirmed through its own investigation. Later that same month, the FDA slapped a clinical hold on 10 studies of Gilead's injectable HIV prospect lenacapavir, citing concerns about the compatibility of the solution with the borosilicate vials it's stored in. Gilead flagged the risk that the borosilicate vials could interact with the drug to create "sub-visible" glass particles. [...]

50 Pharma company warns of counterfeit anti-rabies serum Equirab

Publication date	2022-03-09
Create date	2022-03-11
Score	7.44
Report id	1422731
Category	Antiviral others
Quality	Falsified
Source	Not applicable
Curation	Manually curated
Incident or General	Incident

Snippet: Pharma company warns of counterfeit anti-rabies serum Equirab GMA News Online

Click here to see the Original Article

Table 111: Places for report 1422731

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Philippines	Republic of the Philippines	13	122

Table 112: Drugs for report 1422731

Medicine Name	Medicine Class	Action	ATC Code
rabies serum	Immune sera	immune sera	J06AA06

Table 113: Other Stories

ID	Title	Link
1424203	Drugmaker BSV warns of fake rabies serum in Philippines - 2022-03-10	Link
1424220	Drugmaker BSV warns of fake rabies serum in Philippines	Link

Notes: A pharmaceutical company has warned the public against the counterfeit drugs bearing the name of its anti-rabies serum Equirab which is being circulated in the local market. [...]

Along with the FDA, BSV BioScience said they obtained fake samples of Equirab in its 200 IU/ml (1000 IU/5 mL) formulation. [...]

51 Biz establishment caught selling ‘fake paracetamol’| SUNSTAR

Publication date	2022-01-23
Create date	2022-01-24
Score	7.41
Report id	1378479
Category	Antipyretic
Quality	Falsified
Source	Other
Curation	Manually curated
Incident or General	Incident

Snippet: Biz establishment caught selling ‘fake paracetamol’| SUNSTAR Sun.Star

Click here to see the Original Article

Table 114: Places for report 1378479

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Philippines	Bacolod City	10.66667	122.95

Table 115: Drugs for report 1378479

Medicine Name	Medicine Class	Action	ATC Code
paracetamol	Anilides	other analgesics and antipyretics	N02BE01

Table 116: Other Stories

ID	Title	Link
1380697	’Beware of fake paracetamol’	Link

Notes: A business establishment in Bacolod City was reportedly caught selling suspected fake paracetamols a week ago, an official of the Emergency Operations Center-Task Force (EOC-TF) said. [...] Sorongon said they earlier conducted an inspection together with the Food and Drug Administration (FDA) as well as the Department of Trade and Industry (DTI) at the city’s

Libertad area where they caught the employees of the store selling the supposed fake paracetamols. [...]

52 P100K worth of fake paracetamol tablets seized —police

Publication date	2022-01-18
Create date	2022-01-20
Score	7.21
Report id	1367574
Category	Antipyretic
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: P100K worth of fake paracetamol tablets seized —police GMA News Online

Click here to see the Original Article

Table 117: Places for report 1367574

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Philippines	Quezon City	14.6488	121.0509

Table 118: Drugs for report 1367574

Medicine Name	Medicine Class	Action	ATC Code
paracetamol	Anilides	other analgesics and antipyretics	N02BE01

Table 119: Other Stories

ID	Title	Link
1367824	7 nabbed for P2 million antigen tests, fake meds	Link
1368777	Fake paracetamol seized in Caloocan and QC | Philippines Lifestyle News	Link

Notes: Over P100,000 worth of fake paracetamol tablets were confiscated while a delivery rider was arrested, police said. In Maki Pulido's "24 Oras" report, police received a complaint from a victim in Caloocan who had rashes from fake medicine he bought from a motorcycle rider. He added that he was forced to purchase the medicine because branded paracetamol are out

of stock in local drugstores. Subsequently, Caloocan police conducted a ”test buy” wherein they seized medicines that had a fake lot number which means it is not made by authorized manufacturers. Also, the security marks were also bogus. [...]

53 Police arrest 5 linked to Lower Mainland gang conflict in major drug, gun bust

Publication date	2022-02-01
Create date	2022-02-07
Score	7.03
Report id	1387628
Category	Anxiolytic
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Police arrest 5 linked to Lower Mainland gang conflict in major drug, gun bust Globalnews.ca

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Table 120: Places for report 1387628

Region Name	Country	Location	Latitude	Longitude
Americas	Canada	Coquitlam	49.2846	-122.78217

Table 121: Drugs for report 1387628

Medicine Name	Medicine Class	Action	ATC Code
alprazolam	Benzodiazepine derivatives	anxiolytics	N05BA12

Notes: [...] Police also seized large quantities of suspected fentanyl, cocaine, methamphetamine, MDMA, ketamine, Oxy pills, a cutting agent, assorted pills, and 51,000 suspected counterfeit Xanax pills. [...]

54 Valenzuela shutters store selling fake paracetamol

Publication date	2022-01-07
Create date	2022-05-27
Score	6.88
Report id	1353688
Category	Antipyretic
Quality	Falsified
Source	Private pharmacy
Curation	Manually curated
Incident or General	Incident

Snippet: Valenzuela shutters store selling fake paracetamol Philstar.com

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Table 122: Places for report 1353688

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Philippines	City of Valenzuela	14.71667	120.96667

Table 123: Drugs for report 1353688

Medicine Name	Medicine Class	Action	ATC Code
paracetamol	Anilides	other analgesics and antipyretics	N02BE01

Table 124: Other Stories

ID	Title	Link
1354440	Valenzuela closes down store selling fake paracetamol	Link

Notes: The Valenzuela City government yesterday announced it would crack down on stores selling fake medicines amid a rise in demand due to the surge in COVID-19 cases. The city government said it shut down a sari-sari store in Barangay Malinta after it was reportedly found to be selling counterfeit Biogesic tablets. [...] The crackdown came in the wake of reports of people complaining about having difficulty buying cough and cold medicines. [...]

55 Fake medicines found in Laguna, Zamboanga City

Publication date	2022-02-03
Create date	2022-02-10
Score	6.67
Report id	1389812
Category	Antipyretic
Quality	Falsified
Source	Private pharmacy
Curation	Manually curated
Incident or General	Incident

Snippet: Fake medicines found in Laguna, Zamboanga City GMA News Online

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Table 125: Places for report 1389812

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Philippines	Republic of the Philippines	13	122

Table 126: Drugs for report 1389812

Medicine Name	Medicine Class	Action	ATC Code
paracetamol	Anilides	other analgesics and antipyretics	N02BE01

Notes: Consumers are warned to be extra careful in purchasing medicines as authorities confiscated fake medicines from separate operations in Laguna and Zamboanga City, according to a report on "State of the Nation."

advertisement In Laguna, authorities confiscated several boxes that contain suspected fake paracetamol and other kinds of medicines. [...]

56 Drug haul nets nearly 1,200 pills, suspected to be fentanyl

Publication date	2022-02-23
Create date	2022-02-28
Score	6.37
Report id	1409385
Category	Opioid, Anxiolytic
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Drug haul nets nearly 1,200 pills, suspected to be fentanyl WANE

Click here to see the Original Article

Table 127: Places for report 1409385

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Fort Wayne	41.1306	-85.12886

Table 128: Drugs for report 1409385

Medicine Name	Medicine Class	Action	ATC Code
oxycodone	Natural opium alkaloids	opioids	N02AA05
alprazolam	Benzodiazepine derivatives	anxiolytics	N05BA12

Notes: Fort Wayne narcotics officers seized more than 1,000 fake Percocet pills off the streets, potentially saving many lives.
The total haul – 1,178 pills – had a street value of nearly $13,000, according to a probable cause affidavit. Other drugs and several guns were seized in a raid Tuesday. [...] Drugs found included 10 grams of Alprazolam, 5.9 grams of Amphetamine, about 30 grams of acetaminophen/ oxycodone and about 22 grams of oxycodone hydrochloride suspected to be fentanyl. [...]

57 Ringleader of major dark web drug operation strikes plea deal in NYC

Publication date	2022-03-09
Create date	2022-03-13
Score	6.14
Report id	1423253
Category	Anxiolytic
Quality	Falsified
Source	Website(s)
Curation	Manually curated
Incident or General	Incident

Snippet: Ringleader of major dark web drug operation strikes plea deal in NYC New York Post

Click here to see the Original Article

Table 129: Places for report 1423253

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Manhattan	40.78343	-73.96625

Table 130: Drugs for report 1423253

Medicine Name	Medicine Class	Action	ATC Code
alprazolam	Benzodiazepine derivatives	anxiolytics	N05BA12

Notes: The ringleader of a major dark web operation that raked in millions of dollars dealing in counterfeit Xanax stuck a plea deal in Manhattan court Wednesday. [...] The men sold and shipped counterfeit Xanax tablets, fentanyl-laced heroin and other substances to buyers in 43 states, who purchased the drugs using bitcoin, according to court documents. [...] During what eventually turned into a massive probe, undercover Manhattan DA investigators purchased about 10,000 counterfeit Xanax pills along with ketamine and GHB, a date rape drug, from the online storefronts.

Authorities raided the suspects' homes and vehicles and seized a historic quantity of pills, including 420,000 to 620,000 in counterfeit Xanax – worth roughly $3 million on the street — as well as 500 glassines of fentanyl-laced heroin and other substances. [...]

58 Bail of suspects involved in substandard drug manufacturing rejected

Publication date	2022-01-03
Create date	2022-01-10
Score	5.96
Report id	1352117
Category	Antipyretic
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Bail of suspects involved in substandard drug manufacturing rejected DAWN.com

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Table 131: Places for report 1352117

Region Name	Country	Location	Latitude	Longitude
Southern Asia	Pakistan	Islamabad	33.72148	73.04329

Table 132: Drugs for report 1352117

Medicine Name	Medicine Class	Action	ATC Code
paracetamol	Anilides	other analgesics and antipyretics	N02BE01

Notes: The drug court of Rawalpindi on Monday dismissed the bail before arrest of the accused involved in manufacturing and selling substandard medicine. [...] As per the complaint, the drug inspector during inspection of some medical stores on Feb 17, 2021 found that the suspension campol, manufactured by Syntex Phamaceuticals Attock, was not according to the prescribed standard. [...] The complainant on the other hand opposed the bail petitions stating that the drug in question was declared substandard and the report indicated that it was not in accordance with the prescription. [...]

59 Citing manufacturing 'deviations,' Macleods recalls drugs to treat high blood pressure, schizophrenia

Publication date	2022-03-17
Create date	2022-04-18
Score	5.73
Report id	1449973
Category	Cardiovascular medicine, Antipsychotic
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Citing manufacturing 'deviations,' Macleods recalls drugs to treat high blood pressure, schizophrenia FiercePharma

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Table 133: Places for report 1449973

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5
Southern Asia	India	Republic of India	22	79

Table 134: Drugs for report 1449973

Medicine Name	Medicine Class	Action	ATC Code
amlodipine	Dihydropyridine derivatives	selective calcium channel blockers with mainly vascular effects	C08CA01
olmesartan medoxomil	Angiotensin II receptor blockers (ARBs), plain	angiotensin ii receptor blockers (arbs), plain	C09CA08
olanzapine	Diazepines, oxazepines, thiazepines and oxepines	antipsychotics	N05AH03

Notes: "[...] The New Jersey-based arm of the Indian drugmaker issued a nationwide recall on

Feb. 15 for 3,672 bottles of amlodipine and olmesartan medoxomil tablets, which are used to treat high blood pressure.

Additionally, the company issued a recall on Feb. 16 for one lot of 10 mg, 30-count bottles of olanzapine, which is used to treat schizophrenia. That recall also cited manufacturing ""deviations" as the cause of the action. [...]"

60 NAFDAC orders distributors to withdraw Lefin Pediatric Suspension drug with immediate effect

Publication date	2022-01-24
Create date	2022-01-25
Score	5.44
Report id	1378693
Category	Antipyretic
Quality	Substandard
Source	Distributor/Wholesaler
Curation	Manually curated
Incident or General	Incident

Snippet: NAFDAC orders distributors to withdraw Lefin Pediatric Suspension drug with immediate effect Nairametrics

Click here to see the Original Article

Table 135: Places for report 1378693

Region Name	Country	Location	Latitude	Longitude
Western Africa	Nigeria	Federal Republic of Nigeria	10	8
Southern Asia	Pakistan	Islamic Republic of Pakistan	30	70

Table 136: Drugs for report 1378693

Medicine Name	Medicine Class	Action	ATC Code
paracetamol	Anilides	other analgesics and antipyretics	N02BE01

Notes: The National Agency for Food and Drug Administration and Control (NAFDAC) has warned drug importers and distributors to stop the sale and use of Lefin Pediatric Suspension drug and return remaining stock to NAFDAC warehouses over reports of substandard supplies in Nigeria.

NAFDAC disclosed this in a statement titled, "Public Alert No.0047/2021 Recall Of Substandard Lefin Pediatric Suspension Manufactured By M/S. Leama Chemi Pharma (PVT) Ltd."

NAFDAC warned that the home country of the drug maker, Pakistan, informed NAFDAC

through its Drug Regulatory Authority of Pakistan (DRAP) over recalls due to substandard stock. [...]

61 Grand County traffic stop leads to arrest, recovery of heroin, thousands of illegal pills

Publication date	2022-01-02
Create date	2022-01-11
Score	5.44
Report id	1347138
Category	Opioid
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Grand County traffic stop leads to arrest, recovery of heroin, thousands of illegal pills Gephardt Daily

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Table 137: Places for report 1347138

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Utah	39.25024	-111.75103

Table 138: Drugs for report 1347138

Medicine Name	Medicine Class	Action	ATC Code
hydrocodone	Opium alkaloids and derivatives	cough suppressants, excl. combinations with expectorants	R05DA03
oxycodone	Natural opium alkaloids	opioids	N02AA05
oxycodone and paracetamol	Opioids in combination with non-opioid analgesics	opioids	N02AJ17

Notes: [...] The officer's report says a vehicle search turned up "roughly 2,000 M30 pills along with roughly 1,000 Percocets, and roughly 500 Norco pills. Conclusion: Joshua was arrested and transported to the Grand County Jail to be booked. Upon review of my cage camera, Joshua made a statement about me possibly missing something on the initial search."

M30 fentanyl pills are counterfeit oxycodone pills, which can cause a serious risk of overdose, according to this Department of Department of Justice Drug Enforcement Administration fact sheet. [...]

62 Omaha DEA seizes 100,000 counterfeit fentanyl-laced pills so far in 2022

Publication date	2022-03-29
Create date	2022-04-05
Score	5.31
Report id	1443341
Category	Opioid, Analgesic
Quality	Falsified
Source	Street vendors
Curation	Manually curated
Incident or General	Incident

Snippet: Omaha DEA seizes 100,000 counterfeit fentanyl-laced pills so far in 2022 WOWT

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Table 139: Places for report 1443341

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Omaha	41.25626	-95.94043

Table 140: Drugs for report 1443341

Medicine Name	Medicine Class	Action	ATC Code
hydrocodone	Opium alkaloids and derivatives	cough suppressants, excl. combinations with expectorants	R05DA03
oxycodone	Natural opium alkaloids	opioids	N02AA05
paracetamol	Anilides	other analgesics and antipyretics	N02BE01

Notes: Deadly, fake pills are being taken off the street at a higher rate than ever before.

Since the start of the year authorities have taken 100,000 fentanyl-laced pills off the streets of Nebraska.

The issue is so bad, the DEA in Omaha is urging you to be aware of where you get your medications. [...] "The very troubling side is the pharmaceutical side where people would get on the internet and look for a cheaper pain pill or whatever. Then they make an online purchase and

they have no idea what they are getting. They think they are getting a Tylenol or oxycodone or hydrocodone when in fact they are getting a tablet that's mixed with fentanyl," said Bell. [...]

63 Sioux City Man Sentenced for Selling Misbranded Erectile Dysfunction Drugs as Dietary Supplements ”All-Natural Male” and ”Supermale” - 2022-03-22

Publication date	2022-03-22
Create date	2022-03-28
Score	4.93
Report id	1436284
Category	Erectile dysfunction medicine
Quality	Diverted/Unregistered
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: FDA OCI, David Kempema, Sioux City IA, sentence, misbranded, Rx, drug, ED, erectile dysfunction, dietary supplements, All-Natural Male, Supermale, prison, India, Germany, Viagra, Cialis, 2011, conviction, drug trafficking,

Click here to see the Original Article

Table 141: Places for report 1436284

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Sioux City	42.49999	-96.40031

Notes: A man who unlawfully sold unapproved versions of drugs used to treat erectile dysfunction for the second time was sentenced on March 15, 2022, to more than one year in federal prison. David Kempema, age 61, from Sioux City, Iowa, received the prison term after an October 26, 2021 guilty plea to introducing misbranded drugs into interstate commerce with intent to defraud. Information from a plea agreement and sentencing hearing shows that between February 2014 and December 2018, Kempema advertised and offered for sale pills that he had ordered from India or Germany. The pills contained the same active ingredients as Viagra and Cialis, which were prescription drugs approved by the Food and Drug Administration (”FDA”) to treat erectile dysfunction. To advertise his pills, Kempema placed advertisements in men’s restrooms in businesses along the Interstate 29 corridor. The advertisements referred to the pills as male enhancement ”dietary supplements” called ”Supermale” and ”All Natural Male.” Kempema obtained or attempted to obtain at least 4,059 pills for resale. When interviewed by an FDA agent, Kempema admitted that he knew the drugs were not the FDA-approved versions and that they contained the same active ingredients as the FDA-approved versions. [...]

64 Pfizer Recalls Blood Pressure Drugs Over Carcinogen Concerns

Publication date	2022-03-24
Create date	2022-04-18
Score	4.34
Report id	1451502
Category	Cardiovascular medicine
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Pfizer Recalls Blood Pressure Drugs Over Carcinogen Concerns Healthline

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Table 142: Places for report 1451502

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5

Table 143: Drugs for report 1451502

Medicine Name	Medicine Class	Action	ATC Code
hydrochlorothiazide	Thiazides, plain	low-ceiling diuretics, thiazides	C03AA03
quinapril	ACE inhibitors, plain	ace inhibitors, plain	C09AA06

Notes: ”Drugmaker Pfizer has announced a voluntary recall of its blood pressure medication Accuretic and two authorized generic versions.

An impurity called N-nitroso-quinapril was found in six lots of Accuretic, one lot of generic quinapril and hydrochlorothiazide, and another four lots of quinapril HCl/hydrochlorothiazide tablets, according to Pfizer.

This compound is one of several known as nitrosaminesTrusted Source. [...]”

65 NAFDAC secures seven years imprisonment against falsified drug merchant in Anambra

Publication date	2022-02-09
Create date	2022-02-14
Score	3.87
Report id	1395283
Category	Anti-malarial
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: NAFDAC secures seven years imprisonment against falsified drug merchant in Anambra Tribune Online

Click here to see the Original Article

Table 144: Places for report 1395283

Region Name	Country	Location	Latitude	Longitude
Western Africa	Nigeria	Onitsha	6.14978	6.78569

Table 145: Drugs for report 1395283

Medicine Name	Medicine Class	Action	ATC Code
pyrimethamine, combinations	Diaminopyrimidines	antimalarials	P01BD51

Table 146: Other Stories

ID	Title	Link
1395354	Man jailed for falsifying anti-malaria drug – The Sun Nigeria	Link
1395563	Fake Emzor paracetamol producer Ogbodo jailed 7 years	Link
1395600	Man bags 7-year jail term over drug falsification in Anambra	Link
1396852	Man jailed 7 years for drug falsification	Link
1397776	Man bags 7-year imprisonment for packaging paracetamol tablets as anti-malarial drugs	Link

Table 146: Other Stories(continued)

ID	Title	Link
1398488	Court jails fake Emzor paracetamol producer	Link

Notes: he National Agency for Food and Drug Administration and Control (NAFDAC) has secured a judgement of seven years jail term without option of fine on Tuesday against a falsified drugs merchant at the Federal High Court in Awka, Anambra State. [...] The statement further disclosed that Ogbodo was arrested by the Investigation and Enforcement officers of NAFDAC in his residence at 18, Abagana street, Fegge, Onitsha, Anambra State where falsified Maldox (Sulfadoxine and Pyrimethamine) a brand of anti-malaria tablet manufactured by a registered Nigerian Pharmaceutical Company, was recovered from him. [...] "On 26th January 2022, he was arraigned at the Federal High Court in Awka, Anambra State before Justice H.A. Nganjiwa on a two-count charge bordering on possession of Fake Maldox (Sulfadoxine and Pyrimethamine) and packaging of Emzor paracetamol in a manner that is misleading. [...]

66 Pfizer pulls blood pressure medicines in US over cancer-causing impurities

Publication date	2022-03-22
Create date	2022-03-29
Score	3.73
Report id	1436860
Category	Cardiovascular medicine
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Pfizer pulls blood pressure medicines in US over cancer-causing impurities FiercePharma

Click here to see the Original Article

Table 147: Places for report 1436860

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5
Americas	Canada	Canada	60.10867	-113.64258

Table 148: Drugs for report 1436860

Medicine Name	Medicine Class	Action	ATC Code
quinapril	ACE inhibitors, plain	ace inhibitors, plain	C09AA06
hydrochlorothiazide	Thiazides, plain	low-ceiling diuretics, thiazides	C03AA03

Table 149: Other Stories

ID	Title	Link
1436459	Recon: FDA approves Merck's Keytruda for advanced endometrial cancer; Pfizer recalls some BP drug lots due to nitrosamine impurity	Link
1440985	Pfizer recalls 2nd blood pressure med in a week, again on potential carcinogen fears	Link

Table 149: Other Stories(continued)

ID	Title	Link
1445497	What is nitrosamine? Cancer-linked chemical found in Pfizer drugs	Link
1479634	More Drug Recalls Due to High Levels of Nitrosamines	Link
1547264	Accuretic users annoyed over contaminated blood pressure medication muddle	Link

Notes: Earlier this month, Pfizer kicked off two recalls in Canada for two of its blood pressure medicines. Now the company is pulling three of its blood pressure drugs off shelves in the United States because of the presence of cancer-causing agents.

On Monday, Pfizer issued a voluntary recall of its blood pressure drug Accuretic along with a pair of its generic hypertension treatments distributed by Greenstone. [...] Pfizer is recalling six lots of Accuretic that it provided to distributors in the U.S. and Puerto Rico between November 2019 and this month. The meds carry expiration dates between next month and August 2024.

Also recalled are five lots of generic Accuretic with expiration dates between February and March of 2023. [...] Earlier this month, the company pulled eight lots of Accuretic in Canada. That came just three days after Pfizer recalled 15 lots of another blood pressure medicine, Inderal. [...]

67 Hubei Kangzheng Pharmaceutical Co., Ltd. - 616581 - 11/23/2021 - 2022-01-11

Publication date	2022-01-11
Create date	2022-01-17
Score	3.44
Report id	1357900
Category	Ophthalmic medicines
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: CGMP/Finished Pharmaceuticals/Adulterated

Click here to see the Original Article

Table 150: Places for report 1357900

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5
Eastern Asia	China	Anlu	31.2575	113.67833

Table 151: Drugs for report 1357900

Medicine Name	Medicine Class	Action	ATC Code
naphazoline	Sympathomimetics, plain	decongestants and other nasal preparations for topical use	R01AA08
naphazoline	Sympathomimetics, combinations excl. corticosteroids	decongestants and other nasal preparations for topical use	R01AB02
naphazoline	Sympathomimetics used as decongestants	decongestants and antiallergics	S01GA01

Notes: [...] This warning letter summarizes significant violations of Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals. See Title 21 Code of Federal

Regulations (CFR), parts 210 and 211 (21 CFR parts 210 and 211).

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug product is adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B). [...] You failed to demonstrate that your manufacturing process is capable of preventing microbial contamination of your over-the-counter (OTC) drug product, pi yen chin ophthalmic redness reliever drops, containing naphazoline hydrochloride (HCl) 0.1%. [...]

68 CardioQuip, LLC - Center for Devices and Radiological Health - CGMP/QSR/Medical Devices/PMA/Adulterated - 2022-03-08

Publication date	2022-03-08
Create date	2022-03-11
Score	3.15
Report id	1421934
Category	Medical device for screening/diagnosis/monitoring
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: WARNING LETTER CardioQuip, LLC MARCS-CMS 621738 — February 11, 2022 Share Tweet Linkedin Email Print Delivery Method: VIA Electronic Mail Product: Medical Devices Recipient: Recipient Name Douglas E. Platt Recipient Title CEO CardioQuip, LLC 8422 Calibration Ct. College Station , TX 77845 United States dplatt@cardioquip.com Issuing Office: Center for Devices and Radiological Health United States WARNING LETTER CMS: 621738 February 11, 2022 Dear Mr. Platt, During an inspection of your firm located in College Station, TX from August 19, 2021 through September 17, 2021, an Investigator from the United States Food and Drug Administration (FDA) observed that your firm manufactures a cardiac heater-cooler product in various configurations. Under section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h)(1), each of these products is a device because it is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. We received a written response from you dated October 4, 2021, concerning our investigator's observations noted on the Form FDA 483 (FDA 483), List of Inspectional Observations, that was issued to your firm. We address this response below, in relation to each of the noted concerns. These concerns include, but are not necessarily limited to, the following: Your firm currently holds a 510(k) clearance (K102147) for the CardioQuip Modular Cooler-Heater Model MCH-1000 device ("MCH-1000 Device"), which was issued on November 19, 2010. However, since the time it was cleared, the MCH-1000 Device has been, in multiple ways, significantly changed or modified in design, components, method of manufacture, or intended use within the meaning of 21 CFR 807.81(a)(3). Specifically, your firm has made significant changes that include, among other things, the addition of an optional airflow hood, a dripless external hose kit, and thermoelectric cooling technology in certain MCH models. The addition of an optional airflow hood is intended to reduce the risk of infection via aerosolization of contaminated water. The airflow hood impacts how potentially contaminated water droplets are dispersed in the operating room. The addition of a dripless antimicrobial external hose kit modifies the same risk by attempting to mitigate biofilm and water-borne

pathogen buildup in the hose kit. The final significant change outlined in this warning letter, the addition of thermoelectric cooling technology, is a major operating principle change as the original 510(k) (K102147) was cleared with the use of optional compressor cooling and not thermoelectric cooling. These and other changes could significantly affect the safety or effectiveness of the device within the meaning of 21 CFR 807.81(a)(3). Accordingly, your firm was required to submit a new premarket notification submission under section 510(k) of the Act, 21 U.S.C. § 360(k), to FDA at least 90 days before you proposed to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of the modified Modular Cooler-Heater devices ("Modified MCH Devices"). (See 21 CFR 807.81(a)(3).) You did not submit any new 510(k) in association with the Modified MCH Devices despite your statement made October 4, 2021, in your written response, that your firm is (b)(4) The Modified MCH Devices are therefore misbranded under section 502(o) the Act, 21 U.S.C. § 352(o), because your firm did not timely notify FDA of its intent to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of the Modified MCH Devices, as required by section 510(k) of the Act. Our inspection revealed that the Modular Cooler-Heater (MCH) devices are also adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption under section 520(g) of the Act, 21 U.S.C. § 360j(g). For a device requiring premarket approval, the notification required by section 510(k) of the Act, 21 U.S.C. § 360(k), is deemed satisfied when a PMA is pending before the agency. 21 CFR 807.81(b). The kind of information that your firm needs to submit in order to obtain approval or clearance for the device is described on the Internet at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm . The FDA will evaluate the information that your firm submits and decide whether the product may be legally marketed. Our inspection also revealed that these devices are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. These deficiencies include, but are not limited to, the following: 1. Failure to establish and maintain adequate procedures to control the design of the device in order to ensure that specified design requirements are met, as required by 21 CFR 820.30(a). Specifically, your firm has not adequately controlled and documented the design of your MCH devices. Specifically, a. Your firm has not adequately conducted design validation for your MCH devices as required by 21 CFR 820.30(g) or validated changes as required by 21 CFR 820.30(i). For example, i. Your firm changed your specification for microbial load measured by heterotrophic plate count (HPC) from (b)(4) CFU/ml to (b)(4) CFU/ml and removed requirements for (b)(4) testing. Your firm did not validate this change to ensure that it meets the intended uses for the device. ii. On March 3, 2020, your firm added an optional airflow hood to your MCH devices intended to redirect the flow of exhaust air downward. Your firm did not validate this change to ensure that it meets the intended use of the device. Your firm's validation of this change only addressed impact to temperature of the unit. The change validation did not address impact to potential microbiological infection to patients. iii. Your firm modified the external tubing of your device between November 23, 2015 and November 11, 2016 to change to a PVC antimicrobial tubing. However, your firm did not adequately document or validate this change. Your firm conducted microbial testing between November 24, 2015 and February 3, 2016 as a water quality comparison when using the old hose and the antimicrobial hose. However, your firm's testing was not conducted to an approved protocol that identified full test methods, sample methods, acceptance criteria, or support for

sample sizes. iv. On July 29, 2016, you effected a change to the MCH-1000 Mini allowing for optional refrigeration technology using (b)(4) technology. This change was not validated. b. Your firm has not adequately conducted risk analysis for your MCH devices, as required by 21 CFR 820.30(g). Specifically, your firm added a new hazard of "Bacteria such as m. chimaera or other biological agents being aerosolized into patient environments" to your MCH-10ARH Risk Assessment document on August 6, 2021; however, your firm has been aware of this hazard since at least 2018. Additionally, this hazard has not been considered as part of your design activities, see item "a" above. c. Your firm failed to establish and maintain adequate procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient, as required by 21 CFR 820.30(c). For example, some of your design inputs are ambiguous and do not align with known risks and user needs. i. Design input #001-DI-02, titled "Cleanability," states " (b)(4) " and documents the Target Specification as " (b)(4) ". This design input does not establish a specific target criteria for cleanliness. ii. Design input #001-DI-10, titled "Device Stability," states " (b)(4) " and documents the Target Specification as " (b)(4) ". This design input does not define "easily". iii. Design input #001-DI-32, titled "Air Exhaust Vent on Cooling Unit," states " (b)(4) ," and documents the Target Specification as " (b)(4) ." This design input does not address potential impact on exhaust air disruption of the cleanroom environment which is one of your firm's identified risks. 2. Failure to ensure that when the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedure, as required by 21 CFR 820.75(a). Specifically, Your firm has not validated your cleaning processes recommended in your product manuals and utilized during servicing of your devices. Your firm conducted HPC testing on water samples collected pre- and post-cleaning in February 2016 and March 2017; however, these tests do not have the necessary information to support that the process consistently meets specification. For example, the records do not identify sample collection methods, sample sizes, disinfectant residue, or acceptance criteria. We acknowledge your firm has initiated CAPA 63 to address deficiencies with process validations to include your cleaning processes. However, your firm has not provided evidence you have completed an adequate validation of your cleaning processes. Additionally, your response does not include a systemic review of your processes to verify that all processes requiring validation have been validated. 3. Failure to establish and maintain procedures for implementing corrective and preventive action, as required by 21 CFR 820.100(a). For example, a. Your firm initiated CAPA 77 in response to an increase of complaints for device contamination with NTM on December 14, 2020. Your firm closed this CAPA on June 2, 2021. However, the CAPA does not show your firm accurately investigated the cause of this quality problem. Your CAPA records state your firm has not linked your device to patient infection; however, your firm has reported events in which you confirmed your device was linked to infection. Additionally, your firm identified revisions to your cleaning procedures as a corrective action for this CAPA. However, your firm has not validated these cleaning procedures despite the closure of this CAPA. b. Your firm initiated CAPA 63, on August 6, 2020, to address lack of validation of your MCH cleaning processes. Your firm has not yet validated your cleaning process despite this CAPA being open for over 15 months. c. Your firm initiated CAPA 2018-027 on January 29, 2018 to address complaints associated with leaking MCH devices. Your firm determined the cause of this issue involved tolerance stacking with certain device specifications when manufactured at the edges of your specification limits. Your firm determined to add a bushing to the device to address this issue. However, the CAPA record does not include documentation to show this change was affected or verification activities to show this corrected the quality problem. Additionally, the CAPA states this corrective action was not feasible on the MCH 1000(m) and it does not identify what corrective actions if any

were taken for those devices. Lastly, your CAPA record states the effectiveness checks for this CAPA would include monitoring of complaints over time; however, there is no record of this having been conducted in relation to this CAPA. This CAPA was closed on, or about, August 15, 2018. 4. Failure to maintain complaint files and establish and maintain adequate procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). Specifically, Your firm's "Complaint Procedure", CQ-SOP-12 Ver 11, dated January 7, 2021 is inadequate. Specifically, your procedure does not provide adequate details to ensure complaints are processed in a uniform and timely manner. Your complaint procedures do not define what methods of investigation may be used when conducting investigations under 21 CFR 820.198(e). Additionally, section 7.9 of your procedure requires a complaint committee to review complaints against your risk analysis procedures. However, the procedure does not provide clear instruction on the frequency and scheduling of these reviews. For example, a. Your firm received 11 complaints on July 28, 2021 in which a hospital reported finding bacterial contamination on several of your MCH devices. Your firm's complaint records assert these isolates did not match the environmental and patient isolates and therefore further investigation was not conducted. However, your firm did not investigate the level of contamination or the cause of the contamination. All of these complaints were subsequently reported under 21 CFR 803. b. Your firm received complaint DI-13886 on January 29, 2021 which alleged biofilm buildup in the tubing of a MCH device. The risk assessment section of this complaint record states, "No change in risk as the device did not malfunction and no new risk identified." However, your firm's current risk matrix "MCH-1000" dated June 11, 2021 does not identify biofilm growth. Additionally, risks associated with bacterial contamination were not added until April 1, 2021. Your complaint record is unclear as to what risk evaluations were conducted as part of this complaint's risk assessment. c. Your firm received complaint DI-13930 on March 15, 2021 involving an alleged patient infection. This complaint does not include an Investigation Questionnaire which your firm provides to some complainants to obtain information associated with the alleged event. Your firm's Director of Quality and Regulatory acknowledged this was an oversight. "Complaint Procedure", CQ-SOP-12 Ver 11, dated January 7, 2021 does not address the use of your "Investigation Questionnaire" form. Our inspection also revealed that your firm's MCH devices are misbranded under section 502(t)(2) of the Act, 21 U.S.C.§ 352(t)(2), in that your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 803 - Medical Device Reporting. Significant concerns include the following: 1. Failure to submit a report to FDA no later than 30 calendar days after the day that the firm received or otherwise became aware of information, from any source, that reasonably suggests that a device that the firm markets has malfunctioned and this device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur, as required by 21 CFR 803.50(a)(2). a. For example, the information included for #DI-14346 reasonably suggests that your firm's MCH malfunctioned in that the water level sensor did not function as designed. Such malfunction resulted in a fire inside the unit that burned out device components. The service form states that the PVC assemblies were burnt out and inoperable due to the fire inside the unit. The fire department was called. A device malfunction that results in fire, and burning of the device components, represents a malfunction that would be likely to cause or contribute to a death or serious injury, if it were to recur. As such, the referenced complaint meets the definition of a reportable malfunction, as defined in 21 CFR 803.3. The date your firm became aware of the event was October 28, 2020. However, no MDR for the referenced complaint has been received by FDA. We have reviewed your firm's response dated October 4, 2021. While acknowledging the "need" for your firm to make "improvements," your response contains insufficient detail or supporting records to show these corrective actions will be ade-

quate to address any violations or planned timeframes for their completion. We request that your firm immediately cease any activities that result in the misbranding or adulteration of the MCH devices, such as their commercial distribution as discussed above. We further request in response to this letter you provide a more comprehensive corrective action plan. Please include supporting records to show completion of your corrective actions and timeframes for ongoing corrections. Additionally, we request you continue to provide ongoing updates to these actions monthly through completion of all corrective actions. This letter notifies you of our concerns and provides you with an opportunity to address them. Your firm should take prompt action to correct any violations. If you believe that your products are not in violation of the FD&C Act, please provide your reasoning and any supporting information for our consideration within 15 days. Failure to adequately address the matters discussed in this letter may result in legal action being initiated by the FDA without further notice. These actions may include, but are not necessarily limited to, seizure, injunction, and civil money penalties. Other federal agencies may take your compliance history into account when considering the award of contracts. Should FDA determine that you have Quality System Regulation violations that are reasonably related to premarket approval applications for Class III devices, such devices will not be approved until the violations have been corrected. Should FDA determine that your devices or facilities do not meet the requirements of the FD&C Act, requests for Certificates to Foreign Governments (CFG) may not be granted. More information on processes for persons denied a CFG can be found at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/process-request-review-fdas-decision-not-issue-certain-export-certificates-devices . We ask that you please notify this office in writing within fifteen business days from the date you receive this letter of the specific steps your firm has taken to address the concerns noted in this letter. Include documentation of any corrections and/or corrective action (which must address systemic problems) that your firm has taken. If any corrections and/or corrective actions your firm plans to take will require more time, please include a timetable for implementation of those activities. If any corrections and/or corrective actions your firm plans to take cannot be completed within fifteen business days, state the reason for requiring additional time and the time within which these activities will be completed. Please provide a translation of documentation not in English to facilitate our review. We will communicate with you regarding your firm's response(s) and any need to re-inspect your firm's facility to verify that any appropriate corrections and/or corrective actions have been made. Your firm's response should be sent to: US Food and Drug Administration, Division 3/West, Office of Medical Device and Radiological Health Operations at ORADevices3 FirmResponse@fda.hhs.gov. Please identify your response with FEI 3007899424. If you have any questions about the contents of this letter, please contact Compliance Officer Jeff R. Wooley at 214-253-5251, or via e-mail at Jeffrey.wooley@fda.hhs.gov. Finally, you should know that this letter is not intended to provide an all-inclusive list of any deficiencies at your firm's facility or associated with your firm's devices. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific concerns noted in this letter and in the Inspectional Observations, FDA 483, issued at the close of the inspection may be indicative of, or in addition to, other issues with your firm's devices, manufacturing, and quality management systems. Your firm should investigate and determine the causes of any deficiencies and take prompt actions to correct any violations and bring the products into compliance. Sincerely, /S/ Bram Zuckerman, M.D. Director OHT 2: Office of Cardiovascular Devices Office of Product Evaluation and Quality Center for Devices and Radiological Health /S/ Shari J. Shambaugh Program Division Director Office of Medical Device and Radiological Health, Division 3 Content current as of: 03/08/2022 Regulated Product(s) Medical Devices More Warning Letters Warning Letters About Warning and Close-Out Letters

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Table 152: Places for report 1421934

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Texas	31.25044	-99.25061

Table 153: Other Stories

ID	Title	Link
1424371	FDA issues CardioQuip, Wickimed warning letters for adulterated devices	Link
1424377	FDA issues CardioQuip, Wickimed warning letters for adulterated devices	Link

Notes: [...] You did not submit any new 510(k) in association with the Modified MCH Devices despite your statement made October 4, 2021, in your written response, that your firm is (b)(4) The Modified MCH Devices are therefore misbranded under section 502(o) the Act, 21 U.S.C. § 352(o), because your firm did not timely notify FDA of its intent to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of the Modified MCH Devices, as required by section 510(k) of the Act.

Our inspection revealed that the Modular Cooler-Heater (MCH) devices are also adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption under section 520(g) of the Act, 21 U.S.C. § 360j(g). [...]

Annex C

C.6. Ventilation & Oxygenation equipment and consumables

Medicine Quality Monitoring Globe

September 7, 2022

This is a summary of the information available in the Medicine Quality Monitoring Globe for the search terms selected between the dates selected. For more information on the terminology used, caveats and the work of the medicine quality group please see the information at: https://www.iddo.org/medicine-quality

Non-Curated reports are those that have been automatically flagged as relevant by the system but have not been manually curated by the curators.

We would be grateful for any feedback on this summary and for the details of any reports that we may have missed.

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Filters applied for this report

Search ("Continuous Positive Airway Pressure" OR "Oxygen" OR "nasal catheter " OR "CPAP" OR "oximeter" OR "positive end-expiratory pressure" OR "PEEP" OR "positive end expiratory pressure" OR "bag-valve-mask" OR "self-inflating bag" OR "oropharyngeal catheter" OR "BMV" OR "nebulizer" OR "tracheostomy tube" OR "tracheal tube" OR "ambu bag" OR "ventilator" OR "bag valve" OR "nasal cannula" OR "manual resuscitator" OR "HEPA filter" OR "endotracheal tube" OR "air purifier" OR "intubation kit")

Start date	2022-01-01
End date	2022-03-31
Language	en
Report type	incident
Curation status	validated
Number of Reports	6

1 Lawrence Man Arrested for Fentanyl Distribution Involving Multiple Large Pill Press Machines

Publication date	2022-03-25
Create date	2022-03-30
Score	10.92
Report id	1439972
Category	Opioid
Quality	Falsified
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Lawrence Man Arrested for Fentanyl Distribution Involving Multiple Large Pill Press Machines Department of Justice

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Table 1: Places for report 1439972

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Lawrence	42.70704	-71.16311

Table 2: Drugs for report 1439972

Medicine Name	Medicine Class	Action	ATC Code
oxycodone	Natural opium alkaloids	opioids	N02AA05

Table 3: Other Stories

ID	Title	Link
1441989	Massachusetts man arrested on fake med-related charges - 2022-03-28	Link
1442029	Massachusetts man arrested on fake med-related charges	Link
1442133	100,000 counterfeit fentanyl pills seized in Lawrence	Link
1442533	DEA arrests Massachusetts man after seizing 100000 fentanyl pills, 1.5 kilos of fentanyl powder, ammunition, presses	Link

Table 3: Other Stories(continued)

ID	Title	Link
1543591	Lawrence Man Previously Arrested with Multiple Pill Press Machines Charged with Fentanyl Distribution	Link
1547213	Lawrence Man Previously Arrested With Multiple Pill Press Machines Charged With Fentanyl Distribution	Link
1552460	Massachusetts man charged after nearly 48000 counterfeit pills, multiple pill presses seized	Link

Notes: A Lawrence man was arrested today on drug distribution charges involving counterfeit prescription pills containing fentanyl. [...] According to the complaint, during a search of Fajardo's apartment this morning law enforcement found approximately 100,000 suspected fentanyl pills weighing an estimated seven kilograms, along with an industrial pill press and "M" and "30" pill stamps consistent with markings on pharmaceutical-grade Oxycodone pills. Pill stamps are commonly used to make counterfeit pills appear to be legitimate pharmaceutical-grade pills. Approximately 1.5 kilograms of suspected fentanyl powder and 50 rounds of .40 caliber ammunition concealed in a microwave, two individual finger presses in the living room, four kilograms of cutting agent and two air purifying respirators, which are commonly used when working with fentanyl powder, were also found. It is further alleged that investigators located two one-kilogram pill presses and another large pill press in the landing outside the apartment. [...]

2 Medical goods among B30m of fake products seized at warehouse

Publication date	2022-02-15
Create date	2022-02-18
Score	10.84
Report id	1400860
Category	Other, Herbal medicine, Medical device for screening/diagnosis/monitoring
Quality	Diverted/Unregistered
Source	Unlicensed outlets
Curation	Manually curated
Incident or General	Incident

Snippet: Medical goods among B30m of fake products seized at warehouse Bangkok Post

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Table 4: Places for report 1400860

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Thailand	Pathum Thani	14.01346	100.53049
South-Eastern Asia	Thailand	Khlong Luang	14.06467	100.64578
Eastern Asia	China	People's Republic of China	35	105

Notes: Consumer protection police and Food and Drug Administration (FDA) officials seized a large quantity of falsely labelled, sub-standard products worth about 30 million baht at a warehouse in Khlong Luang district, Pathum Thani province.

The raid followed complaints made to the Consumer Protection Police Division (CPPD) that a large quantity of fake and low quality products - cosmetics, medicines, herbal products and medical equipment - were on sale through various online platforms. [...] On Monday, with a search warrant from Pathum Thani Provincial Court, police and FDA officials raided the warehouse and found 142 illegal items. They included medical equipment, such as fingertip oximeters, temperature scanners, oxygen generators and blood pressure monitors, along with falsely labelled cosmetics, soap, shampoo, toothpaste, hair cleansers and tooth-whitening products, medicines and herbal products. [...]

3 Recall Check: Philips Recalls 215 Ventilators, 51 Repair Kits Due to Risk of Death or Serious Injury

Publication date	2022-02-01
Create date	2022-02-17
Score	10.76
Report id	1398682
Category	Medical device used for cure/mitigation/treatment
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Recall Check: Philips Recalls 215 Ventilators, 51 Repair Kits Due to Risk of Death or Serious Injury Top Class Actions

Click here to see the Original Article

Table 5: Places for report 1398682

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5

Table 6: Other Stories

ID	Title	Link
1411141	Philips Trilogy Evo Ventilators, Repair Kits Recalled Because Supplier Used Nonconforming Foam	Link
1503642	FDA proposes order forcing Philips to repair, replace or refund all recalled ventilators	Link
1504788	Phillips ventilator foam recall linked to 124 deaths in one year	Link

Notes: Philips Respironics is recalling 215 of its Trilogy Evo ventilators and 51 repair kits due to the risk of death or serious injury posed by possibly carcinogenic polyester-based polyurethane (PE-PUR) sound abatement foam included in the products. [...] The company is recalling the Trilogy Evo ventilators with model numbers DS2110X11B and KR2110X15B (not distributed in the U.S.) and repair kits for Trilogy Evo muffler assembly with part number 1135257 and lot number between 210414 and 210524.

It says the devices were made and distributed in the U.S. and Korea between April and May 2021. [...]

4 FDA hands down Class I rating to Vyaire Medical's ventilator recall

Publication date	2022-02-18
Create date	2022-03-09
Score	10.52
Report id	1418955
Category	Medical device for screening/diagnosis/monitoring
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: FDA hands down Class I rating to Vyaire Medical's ventilator recall FierceBiotech

Click here to see the Original Article

Table 7: Places for report 1418955

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5

Notes: [...] According to a notice put out by Vyaire earlier this month, some of its Bellavista ventilators are at risk of malfunctioning if a certain software configuration is in place. The company initiated a voluntary correction for the affected machines at the end of December, and this week the FDA dished out a Class I rating—the agency's most serious—to the move. [...] The flaw may occur in Bellavista 1000 and 1000e series ventilators that are running at least the software version 6.0.1600.0—which was introduced in February 2021—and have their data communication ports set to "HL7." When both of these factors are present, they can create what Vyaire describes as a "conflict in memory resource allocation between software tasks." [...] So far, no deaths have been reported in connection with the software flaw, but the FDA has received 18 complaints and reports of seven injuries linked to the issue. [...]

5 Fresenius Kabi recalls IV fluid after testing finds particulates

Publication date	2022-03-08
Create date	2022-04-08
Score	5.77
Report id	1445592
Category	Other
Quality	Substandard
Source	Manufacturer
Curation	Manually curated
Incident or General	Incident

Snippet: Fresenius Kabi recalls IV fluid after testing finds particulates FiercePharma

Click here to see the Original Article

Notes: Fresenius Kabi issued a voluntary recall of seven lots of sodium acetate intravenous fluid after testing found particulates of carbon and oxygen with traces of sodium, silicon, chromium, aluminum and cellulose. [...] The voluntary recall covers 400-mEq/100-mL (4-mEq/mL) vials that were distributed across the U.S. to wholesalers, distributors, hospitals and pharmacies between September 2020 and November 2021. Fresenius Kabi hadn't received any side effect reports by the time it issued the voluntary recall on Monday. Use of the potentially tainted product could result in local irritation, swelling or infection. If the particulate matter reaches blood vessels, it can travel to various organs and block blood vessels in the heart, lungs or brain, which could cause stroke and even death. [...]

6 5 recent medical device recalls

Publication date 2022-02-04

Create date 2022-02-11

Score 5.56

Report id 1390679

Category Medical device used for cure/mitigation/treatment, Medical device for screening/diagnosis/monitoring

Quality Substandard

Source Manufacturer

Curation Manually curated

Incident or General Incident

Snippet: 5 recent medical device recalls Becker's Hospital Review

Click here to see the Original Article

Table 8: Places for report 1390679

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5

Notes: [...] 2. Philips Respironics recalled 215 Trilogy EVO Ventilators and 51 Trilogy EVO repair kits on Jan. 26 due to potential health risks from polyester-based polyurethane sound abatement foam. The foam may break down and potentially enter the device's air pathway, causing potential inhalation. There have been no reported injuries or deaths.

3. Medtronic recalled over 95,100 units of the HawkOne Directional Atherectomy System on Jan. 21 due to the risk of guidewire within the catheter moving downward or prolapsing when force is applied during use. There have been 163 complaints, 55 injuries and no deaths reported about this device issue.

4. Getinge USA recalled 50 units of the Vaporizer Sevoflurane Maquet Filling for Flow Family Anesthesia Systems on Jan. 19 due to the risk of potential chemical breakdown of sevoflurane, a general surgical anesthetic, which may result in inhalation and/or skin exposure to harmful chemicals. There have been eight complaints regarding this device issue, but no reported deaths or injuries.

5. Cardiovascular Systems recalled 697 units of its Wirion embolic protection devices on Jan. 10 because of complaints of filter breakage during retrieval. There have been reports of nine device malfunctions and no reports of death related to the issue.