

PROSECUTION AND PUBLIC AWARENESS: KEY LINES OF DEFENCE AGAINST FALSIFIED MEDICINAL PRODUCTS DURING PANDEMIC

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Abstract: In the beginning of 2020 the world faced a new, unknown health threat caused by a novel coronavirus outbreak. The preceding 2009 H1N1 pandemic urged many health authorities and organizations worldwide to revise and update their prevention and control protocols in case of infectious diseases but the present situation caught them unprepared for the magnitude of morbidity and mortality that COVID-19 causes. Thousands of people lost their lives in just few months, health services are seriously upended and the economic losses are expected to reach unexpected levels. While the authorities are desperately trying to protect the public health and mitigate the negative economic impact of the measures designed to keep people safe, criminal organizations actively engage in benefiting from the vulnerability of the legal and regulatory frameworks. The medicinal shortages combined with the lack of awareness in the society pose serious threat as panicked people turn to unauthorised and dangerous sources to buy pharmaceuticals and medical products. Their irrational and dangerous behaviour facilitate and significantly contribute to the uncontrolled spread of fakes as Internet provides perfect conditions for the unscrupulous dealers. The public is overwhelmed by a constant flow of disinformation that contain misleading and potentially dangerous recommendations and online offers for “miracle cures”. The disrupted legitimate supply chains provide further options for illegal structures to exploit the fear of the society and profiteer from the global crisis. The present material aims to review and analyse the main reasons that incite people to voluntarily take part in such offences. It also points out the relevant areas that stakeholders should focus their efforts to fight back a parallel health threat – the falsified medicinal products. The key counteractions and recommendations undertaken by renowned international and European organizations and institutions are summarized and a discussion is raised with reference their adoption, stricter implementation and further development. If policymakers engage more actively to strengthen their legal and regulatory frameworks against falsified medicinal products, their efforts would result in better preparedness and response in case of future health crises and in increased trust in governments and healthcare systems.

Keywords: falsified medications, medicinal products, COVID-19, counteraction, public policy, regulation

1. INTRODUCTION

In the beginning of 2020 the world faced a new, unknown health threat caused by a novel coronavirus outbreak. The preceding 2009 H1N1 pandemic urged many health authorities and organizations worldwide to revise and update their prevention and control protocols in case of infectious diseases but the present situation caught them unprepared for the magnitude of morbidity and mortality that COVID-19 causes. Thousands of people lost their lives in just few months, the health services are seriously upended and the economic losses are expected to reach unexpected levels. The global health crisis inevitably influences all sectors of the national economy and while the governments are desperately trying to protect the public health, criminal organizations seek for profit. The increasing demand of pharmaceuticals and protective equipment lead to shortages that unscrupulous dealers eagerly exploit. The present health crisis might be caused by a novel virus but it triggered a well-known menace: the ever-growing illegal trade with falsified medications and medicinal products.

International and regional organizations and authorities alarm for the parallel threat and try to effectively counteract the spread of fakes in the disrupted pharmaceutical supply chains. But while policymakers worldwide focused their attention to develop and implement elaborate legal and regulatory tools to protect the legitimate pharmaceutical supply chains, the parallel illegal sources still remain underregulated and hard to be prosecuted.

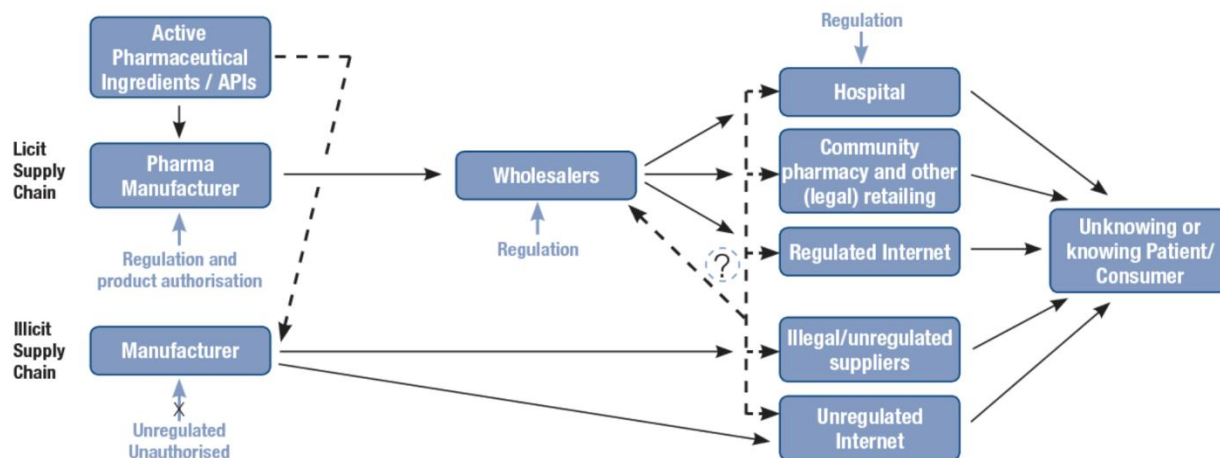
The main research goal of the present material is to review and analyse the measures and recommendations of key official stakeholders on global and European level aimed to protect the society from a parallel pandemic of falsified medicinal products. What are the key prerequisites that facilitate the criminals, who and how is engaged to fight back and how the present situation may lead to positive outcomes in the future, shape and guide the present analytical review.

2. MAIN DRIVERS FOR A PARALLEL PANDEMIC

The legal and regulatory measures against falsified medicinal products are one of the most significant mechanisms to fight their uncontrolled spread and many international, regional and local organizations and institutions have engaged in their development and implementation. Some of them are rather elaborated and even include technological solutions to track and trace products through their long way to the end-users. But parallel to the

legitimate supply chains there are illegal structures that operate under the “radar” and pose serious health risk for the patients and consumers (Figure 1). Criminals take advantage of the weaknesses and gaps in the existing regulatory frameworks as health crises like the COVID-19 pandemic provide perfect environment for their illegal operations. Among the key acknowledged prerequisites for their success are the low levels of prosecution and sanctions as well as the lack of awareness of the general public. When the traditional pharmaceutical chains are disrupted and people are exposed to diverse and often misleading information, the adoption, implementation and promotion of measures in both directions is crucial for the effective protection of the society.

Figure 1: An illustrative model of the licit and illicit pharmaceutical supply chain



Source: Kahn et al, 2011

In the beginning of February 2020, the World Health Organization (WHO) alarmed for “infodemic” related to COVID-19 and defined it as an over-abundance of information, some accurate and some not, that makes it hard for people to find trustworthy sources and reliable guidance (WHO, 2020 February 2). “Miracle” cures for the disease are constantly promoted and advertised through various social media channels as they are usually unauthorised, ineffective and even dangerous. EUROPOL also highlighted the problem in a recent publication (EUROPOL, 2020 April 3) and warns that the spread of disinformation and fake news put at risk the society. People are more vulnerable and receptive due to the paradoxical oversaturation with available information that leads to potentially harmful consequences related to the increased supply of falsified products.

The importance of adequate and properly tailored for the society risk communication protocols in case of health crises is long ago recognised by renowned supranational and state authorities. It represents a key component of many official guidelines and protocols such as:

- “Framework for a Public Health Emergency Operations Centre” and “Pandemic influenza risk management” issued in 2015 and 2017 by the WHO;
- “Framework for a strategy for infectious disease surveillance in Europe (2006-2008)” and “Guide to public health measures to reduce the impact of influenza pandemics in Europe: The ECDC Menu” published in 2005 and 2009 by the European Centre for Disease prevention and control (ECDC);
- “National strategy for pandemic influenza” and “Pandemic Influenza Plan” from 2005 and 2017 developed by the US Homeland Security Council and the Department of health and Human Services, etc.

The authorities already have at their disposal the necessary tools to take control of any disinformation flow. However, a problem seems to occur with reference to their proper and timely implementation that often results in confusion, delay and limited reach to the target groups.

COVID-19 pandemic also results in serious supply chain disruptions that may lead to substantial shortages of pharmaceuticals and medicinal products on global level. Five are the main reasons that contribute to the problem (EMA, 2020 April 24): temporary lockdowns of manufacturing sites, travel restrictions impacting exports, export bans, increased demand for medicines used to treat COVID-19 patients and stockpiling by hospitals, by individual citizens or at county level. Some national states have already indicated that they are starting to experience or are expecting shortages to occur shortly of certain medicines used to treat COVID-19 like anaesthetics and antibiotics. WHO already warned for a severe and mounting disruption to the global supply of personal protective equipment (PPE) caused by rising demand, panic buying, hoarding and misuse (WHO, 2020 March 3). Since the world’s two

largest producers of medical supplies - China and India, are among the most affected by the pandemic (Piranty, 2020), the demand is already surpassing the availability and the risk of distribution of falsified medications is increasing.

The expanding global quarantine additionally contributes to supply chain disruptions. People started to increasingly rely on online sources to buy pharmaceutical products (Instinctif Partners, 2020) as the need, combined with uncontrolled spread of disinformation make them less cautious. Pharmaceutical quality is vulnerable to fear, desperation, and disinformation and while people are stockpiling with essential medications (Newton et al, 2020) criminal organizations exploit all available options. Various illegal online platforms offer unauthorized, suspicious and even harmful medications and medical supplies for COVID-19 treatment and protection. According to a study of the Alliance for Safe Online Pharmacy in the European Union (ASOP EU) there are more than 35,000 websites selling medicines at any time as 96% of them operate illegally (ASOP EU, 2019). The COVID-19 pandemic threatens a global surge in substandard and falsified medical products not just for those directly related to it (Newton et al, 2020) - many essential products are at risk, including face masks, hand sanitisers, and diagnostic tests.

Patients are rarely aware of the risk of falsified medicinal products when surf the web. Although many organizations and regional and state institutions have engaged prior to the pandemic to educate the society for the risks they pose, people still show high levels of unawareness. Their irrational behaviour successfully contributes to the expansion of the illegal sources and make them victims as well as unintentional accomplices in the crimes. Education is one of the key factors for effective response against the risk of “a parallel pandemic of substandard and falsified products” (Piranty, 2020). Carefully designed and targeted awareness campaigns should be focused not only on how to properly maintain personal hygiene, but should also advise general public to be more cautious and suspicious in terms of preferred sources of information and medicinal products. If such awareness campaigns include also increased promotion of the authorities’ corresponding prosecution activities, the society will be more educated for the threat, feel more secure and would increase their trust and support for the local governments and their policies.

3. COUNTERACTIONS AND RECOMMENDATIONS REVIEW

The institutions and organizations that alarm for a parallel health threat related to falsified medicinal products especially marketed for COVID-19 treatment and protection, are those who have already been engaged for many years to resolve the problem. They constantly initiate, support and develop various policies and counteractions to fight pharmaceutical fakes. The following review reveals that at present, they are actively working to promote the existing legal and regulatory measures and raise awareness in both society and policymakers for the benefits of their adoption and proper implementation. They also develop new strategies to strengthen the public health protection measures as many non-profit and commercial organizations support their activities.

WHO is a pioneer in the fight against falsified, substandard and unlicensed medicines and global leader when epidemics and pandemics occur. With reference to the growing infodemic, the Organizations actively alerts consumers, healthcare professionals, and health authorities for the increasing number of falsified medical products that claim to prevent, detect, treat or cure COVID-19 (WHO, 2020 March 31). It constantly reminds the society that there are still no approved vaccines and medications as all such promoted products should be considered falsified and may pose significant risks. End-buyers and consumers are advised to exert due-diligence when purchasing any medical products online since unregulated websites increased their activities. WHO technical risk communication and social media teams work closely to track and respond to myths and rumors (WHO, 2020 February 2). To educate the general public WHO uses a wide range of methods (WHO, 2020 April 15) such as timely and accurate technical guidance, scientific briefs and situation reports, regular press conferences, educational videos and trainings, “myth-busters,” active engagement on social media platforms and tailored guidance for key sectors. Experts from all over the world under the lead of the WHO Information Network for Epidemics engaged in the establishment of a COVID-19 infodemic framework to guide actions of governments and public health institutions.

INTERPOL has a long history of counteraction to falsified medicines and medicinal products. Between 3rd and 10th of March operation Pangea XIII (EUROPOL, 2020) united the efforts of police, customs and health regulatory authorities from 90 countries in collective action against the illicit online sale of such products. The operation resulted in 121 arrests worldwide and the seizure of potentially dangerous pharmaceuticals worth more than 13 million EURO such as surgical masks, “corona spray” and coronavirus medicines”. More than 2500 links were taken down (websites, social media, online marketplaces, adverts) and 37 organized crime groups are dismantled. Authorities seized around 4.4 million units of illicit pharmaceuticals worldwide. Compared to the week of action in 2018, the latest edition of the operation reported an increase of about 18 % in seizures of unauthorized antiviral medication, and an increase of more than 100 % in seizures of unauthorized chloroquine, which could also be connected to the COVID-19 outbreak (INTERPOL, 2020). Under the operation, INTERPOL member countries also

reached out to the general public – through videos, brochures, exhibitions and talks at hospitals and schools – to raise awareness of the dangers of buying pharmaceuticals from unregulated online sources.

At European level many supranational institutions actively joined the global efforts to protect the society from falsified medicinal products related to COVID-19 pandemic. EUROPOL supported Pangea XIII by facilitating information exchange and providing analytical support. It also participates in rising the awareness for online offenders alarming the general public for shopping scams (EUROPOL, 2020 April 17). It monitors social media platforms to follow the spread of conversations around the distribution of falsified goods online throughout the pandemic in Europe and calls the EU Member States to continue to invest in prevention and awareness to disrupt the business model of the criminal profiteers. The European Anti-Fraud Office (OLAF) also launched an enquiry into fake COVID-19 related products (OLAF, 2020) and on 19th of March opened a case in relation to the imports of fake products used in the fight against the COVID-19 infection such as masks, medical devices, disinfectants, sanitisers and test kits. Since the very beginning of the pandemic, OLAF has been collecting intelligence and information on this illicit trafficking and support close contacts with competent authorities in EU Member States and third countries.

The Council of Europe (COE) in a press release from April (Council of Europe, 2020) calls on governments to be extremely vigilant against falsified medicines and medical products. It reminds them that they could rely on the MEDICRIME Convention that is first binding international instrument in the criminal law field on counterfeiting of medical products and similar crimes involving threats to public health. It is so far ratified by 16 countries and signed by 16 others not only from the EU. The MEDICRIME Committee warns of the increased risk of falsified medical products in times of shortage and makes a number of recommendations with reference to monitoring of online platforms, close cooperation between Member States, national agencies and services focused on detection and preventing the trafficking of falsified medical products, advocate for the adoption of measures to prevent the unauthorised diversion of essential medical products and emphasise on the protection of the victims' rights, including the right to be informed of the effects of falsified medical products on their health.

EMA alarmed for the problem in a press release (EMA, 2020 March 24) addressed to the general public and related to online sales of pharmaceuticals. The Agency reminds people to look for the common logo adopted as per the European Commission Directive 2011/62/EU on falsified medicines for human use. It is obligatory since 1st of July 2015 and its display on the web platform of an online pharmaceutical seller guarantees that it is authorised by the competent national authorities. EMA also reminds the general public that there are currently no treatments authorised for COVID-19 and the end-users should not buy medicines advertised as cures or preventive treatments for the infection. The agency is supported on the promotion of the common logo by the European Federation of Pharmaceutical Industries and Associations (EFPIA, 2020). It also calls on all involved parties to rely on the adopted regional regulations, imbedded in the European Falsified Medicines Directive 2011/62/EU and state that now is the time for the authorities and other stakeholders to double their efforts and make sure of its proper implementation

The efforts of the official authorities receive support from Facebook, Fight the Fakes campaign, Wikipedia, etc., but the surprise came from the biggest platform for illegal trade – The Dark Web, as some of its vendors ban drug dealers to sell fake Covid-19 vaccines (Cuthbertson, 2020). Many illegal and unauthorised sites notice a surge in useless and dangerous materials being sold with claims they could protect people from the disease. Drugs in short supply on the open market are listed at hugely-inflated prices on online black markets and impose significant health risks. For example, a vaccine offered at the Agartha marketplace and priced at \$300 proved to contain a mix of amphetamines, cocaine and nicotine. A Monopoly Market which lists drugs ranging from cannabis to steroids, announced that it would permanently remove any members attempting to peddle unproven medicines. The site also forbids users from selling items that have been impacted by shortages, such as protective face masks. Monopoly Market's principled policy towards the coronavirus pandemic is not unique on the dark web. In 2018, major operators voluntarily stopped selling the synthetic opioid fentanyl after it was linked to hundreds of accidental overdoses. A recent investigation by security software firm Digital Shadows into dark web trends revealed that there has been a pushback in criminal forums against taking advantage of the current situation for profit.

4. DISCUSSION

The reviewed materials related both to COVID-19 pandemic and falsified medicinal products reveal that awareness rising and intensified prosecution intertwine in the adopted counteractions. In times when our free access to the physical world is highly restricted, the virtual one is wide open. The global web remains comparatively underregulated and criminals constantly devise their activities to gain utmost benefit of such gaps. One-time prosecution actions are not sufficient since the illegal structures swiftly change platforms and mode of action. More permanent solution is to constantly raise the buyers' awareness as well as the authorities' involvement in developing and adopting effective policies against pharmaceutical fakes and their coordinated prosecution.

Although the main focus of the presented counteractions is on online protection, the activities of the EU institutions reveal intensified promotion of the existing community measures designed to regulate both legitimate and illegal pharmaceutical supply chains - Falsified Medicine Directive 2011/62/EC and the Medicrime Convention. The COVID-19 pandemic provides excellent conditions to raise the discussion for their popularity among society and the local authorities' commitment to their proper implementation and stricter compliance. The Directive is obligatory for all EU Member States and is designed to protect the legitimate pharmaceutical supply chains from falsified medications. On 9th of February 2019 one of its key regulations started to operate - the verification system for prescribed (RX) medications. Due to various technical and legislative problems, at present it is not yet fully operational in all countries and this provides options for criminals to penetrate the legal supply chains. A research published in 2018 (ASOP EU, 2018) also revealed that public awareness raising activity of the Member States is not satisfactory with reference to relevant ongoing and future planned public targeted campaigns and measurement of their effectiveness. The general public is still very much unaware of the problem and the criminals eagerly exploit their vulnerability currently emphasised by the parallel infomedic. The supranational and local authorities should urgently revise their relevant policies so as to provide timely and easy access for the general public to adequate information for the risk of pharmaceutical fakes and increase the promotion of the common logo.

Since illegal operators still manage to surround the Directive's regulations, the EU authorities should focus their attention more closely to the upgrade and stricter application of the existing legal and prosecution frameworks with reference to pharmaceutical crimes. Although as per art. 118 of the Directive (European Commission, 2018) in all Member States at least some activities relating to the falsification of medicinal products are regarded as a criminal offence and the actions of the local authorities are defined as satisfactory, the European Parliament and the Council recommend the local authorities to further reinforce measures and strengthen their overall effectiveness. A well designed and comprehensive tools are provided by the Medicrime Convention. Unlike the Directive, it is not obligatory and is open for all countries worldwide that seek to improve their prosecution activities related to pharmaceutical crimes and thus increase public health protection. At present, it is ratified by sixteen countries as only six are EU Member states (Council of Europe, 2020 April 29). The question of its adoption should be investigated more actively by the national governments since it refers not only to falsification of medicines but also covers the supply, offering to supply and trafficking of fake medical products, falsification of documents and unauthorized manufacturing or supply of medicinal products and marketing of medical devices that do not comply with conformity requirements.

The two regulatory mechanisms supplement each other and their joint implementation could lead to significant protection of the public health by considerably limiting the criminal offences related to falsified medicinal products. Raising the awareness and promoting their benefits to the engaged institutions and society provide the national authorities with excellent opportunity to effectively control the present situation and at the same time to be properly prepared in case of future health crisis.

5. CONCLUSION

National policymakers seemed to have underestimated the dangers of pharmaceutical and medicinal fakes. They might have adopted measures to strengthen legal and regulatory frameworks but their implementation still suffers from gaps, low levels of prosecution and unproportionate sanctions. The COVID-19 pandemic results in increased attention to the problem and emphasises the need to actively engage society in the common fight. Education makes people more vigilant for the risks of online shopping of medications and medicinal products. It should represent a key pillar of each preparedness and response plans not only on "paper" but also in practice as the adequate and timely response to disinformation and fake news from the official sources is crucial to protect the society from its own irrational behaviour. Local public and policy stakeholders should raise the discussion for further strengthening of national legislation to counteract such criminal offences as well as to actively promote their initiatives. Now is the perfect time for coherent joint actions against pharmaceutical falsification and all engaged parties should revise and upgrade their activities to resist to future threats of such and even greater magnitude.

REFERENCES

- ASOP EU. (2018). Fighting Fakes by Member States: Falsified Medicines and the Common Logo– raising public awareness. Retrieved from <https://buysaferx.pharmacy/wp-content/uploads/2018/06/Fighting-Fakes-By-Member-States-report-2018-updated-May-30-2018.pdf>
- ASOP EU. (2019). Newsletter: A diary of achievements from September 2018 to May 2019. Retrieved from https://eaasm.eu/public/downloads/0KH3E/EAASM_ASOP%20EU%20Spring%20Newsletter%202019.pdf
- Council of Europe. (2020, April 29). Chart of signatures and ratifications of Treaty 211. Retrieved from <https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/211/signatures>

- Council of Europe. (2020). COVID-19: How to protect against falsified medical products? Retrieved from <https://www.coe.int/en/web/portal/-/covid-19-how-to-protect-against-falsified-medical-products>
- Cuthbertson, A. (2020). Dark web drug marketplace bans coronavirus 'vaccine' sales. Retrieved from <https://www.independent.co.uk/life-style/gadgets-and-tech/news/coronavirus-vaccine-cure-dark-web-drugs-market-covid-19-a9442671.html>
- EFPIA. (2020). COVID-19 – Fighting the fakes. Retrieved from <https://www.efpia.eu/news-events/the-efpia-view/blog-articles/covid-19-fighting-the-fakes/>
- EMA. (2020, March 24). COVID-19: Beware of falsified medicines from unregistered websites. Retrieved from <https://www.ema.europa.eu/en/news/covid-19-beware-falsified-medicines-unregistered-websites>
- EMA. (2020, April 24). Availability of medicines during COVID-19 pandemic. Retrieved from <https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/availability-medicines-during-covid-19-pandemic>
- European Commission. (2018). REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL on the Member States' transposition of Article 118a of Directive 2001/83/EC of the European Parliament and the Council of 6 November 2001 on the Community code relating to medicinal products. Official Journal of the European Union, (Brussels 26.1.2018 COM(2018) 49 final)
- EUROPOL. (2020). Pandemic profiteering how criminals exploit the COVID-19 crisis. Retrieved from https://www.europol.europa.eu/sites/default/files/documents/pandemic_profiteering-how_criminals_exploit_the_covid-19_crisis.pdf
- EUROPOL. (2020, April 3). Catching the Virus: cybercrime, disinformation and the COVID-19 pandemic. European Union Agency for Law Enforcement Cooperation. Retrieved from <https://www.europol.europa.eu/publications-documents/catching-virus-cybercrime-disinformation-and-covid-19->
- EUROPOL. (2020, April 17). Viral marketing: Counterfeits, substandard goods and intellectual property crime in the COVID-19 pandemic. European Union Agency for Law Enforcement Cooperation 2020.
- Instinctif Partners. (2020). Covid-19 and the rising tide of falsified medicines worldwide. Retrieved from <https://instinctif.com/insights/covid-19-rising-tide-falsified-medicines-worldwide/>
- INTERPOL. (2020). Global operation sees a rise in fake medical products related to COVID-19. Retrieved from <https://www.interpol.int/en/News-and-Events/News/2020/Global-operation-sees-a-rise-in-fake-medical-products-related-to-COVID-19>
- Kahn, U., Kreutzer, S., Gill, J., & Taylor, D. (2011). Falsified Medicines and the Global Public's Health. UCL School of Pharmacy and Matrix Insight. Retrieved from <https://pdfs.semanticscholar.org/33b6/3cd5523b535e58c06865befb2f67c7fa4d17.pdf>
- Newton, P. N., Bond, K. C., & 53 signatories from 20 countries. (2020). COVID-19 and risks to the supply and quality of tests, drugs, and vaccines. *The Lancet. Global Health*, (20), 19–20. [https://doi.org/10.1016/S2214-109X\(20\)30136-4](https://doi.org/10.1016/S2214-109X(20)30136-4)
- OLAF. (2020). OLAF launches enquiry into fake COVID-19 related products [Press release]. https://ec.europa.eu/anti-fraud/media-corner/news/20-03-2020/olaf-launches-enquiry-fake-covid-19-related-products_en
- Piranty, S. (2020). Coronavirus fuels a surge in fake medicines. BBC World Service. Retrieved from <https://www.bbc.com/news/health-52201077>
- WHO. (2020, February 2). Coronavirus disease 2019 (COVID-19): Situation Report – 13. Retrieved from <https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200202-sitrep-13-ncov-v3.pdf>
- WHO. (2020, March 3). Shortage of personal protective equipment endangering health workers worldwide. Retrieved from <https://www.who.int/news-room/detail/03-03-2020-shortage-of-personal-protective-equipment-endangering-health-workers-worldwide>
- WHO. (2020, April 15). Coronavirus disease 2019 (COVID-19): Situation Report – 86. Retrieved from https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200415-sitrep-86-covid-19.pdf?sfvrsn=c615ea20_4