An Africa-focused Report on Safety Data of COVID-19-related Products, June 2020
Compiled by AU-3S Team – No. 3 Substandard and Falsified (SF) Medical Products

Background

Safety is a fundamental human right, however, in Africa, access to safe medical products continues to be elusive. According to the WHO Global Surveillance and Monitoring System 42% of the 1,500 reported cases of substandard and falsified medical products between 2013 and 2017 were from the Africa region[1]. High demand during the COVID-19 pandemic has provided opportunity for counterfeit and substandard medications and critical medical supplies, such as hand sanitizers and face masks, to flood the world market, hence there is a crucial need for surveillance and prioritization of safety.

The seventieth World Health Assembly (WHA 70, 2017)[2], adopted the definitions of three classes of medical products that qualify as Substandard and Falsified (SF) Medical Products. Substandard medical products also called "out of specification", are authorized medical products that fail to meet either their quality standards or their specifications, or both. Unregistered/unlicensed medical products are those medical products that have not undergone evaluation and approval by the national or regional regulatory authority for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation. Falsified medical products are products that their identity, composition or source is deliberately/fraudulently misrepresented[3].

Diagram 1: *Classification of substandard, unregistered/unlicensed and falsified medical products*[4]

1 Ghanem, N. (2019). Substandard and falsified medicines: Global and local efforts to address a growing problem. Clinical Pharmacist, 11(5), 1–12

2 Appendix 3 to Annex, World Health Assembly document A70/23, 2017

3 WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Product" https://www.who.int/medicines/regulation/ssffc/publications/GSMS

4 Source: World Health Organization Member State Mechanism on Substandard/Spurious/ Falsely-labelled/Falsified/ Counterfeit Medical Products. (2017). Working definitions. Geneva: Seventieth World Health Assembly

Substandard and falsified medical products are by their very nature difficult to detect. They are often designed to appear identical to the genuine product and may not cause a visible adverse reaction. They, however, often fail to properly treat the disease or condition for which they were intended and can lead to serious health consequences, including death. SF medical products pose a public health danger as they may contain no active ingredient, the wrong active ingredient, or the wrong amount of the correct active ingredient[5]. They are also found to contain corn starch, potato starch or chalk commonly. Some SF medical products are toxic with either fatal levels of the wrong active ingredient or other toxic chemicals[6]. They are often produced in deplorable and unhygienic conditions by unqualified personnel and contain unknown impurities and are sometimes contaminated with bacteria[7]. They lead to loss of confidence in medicines, healthcare providers and health systems.

SF medical products from all main therapeutic categories have been reported to WHO including medicines, vaccines, and in-vitro diagnostics. Antimalarials and antibiotics are amongst the most commonly reported substandard and falsified medical products. Both generic and innovator medicines can be falsified, ranging from costly products for cancer to very inexpensive products for the treatment of pain[8]. They can be found in illegal street markets, via unregulated websites through to pharmacies, clinics and hospitals. SF medical products contribute to antimicrobial resistance and drug-resistant infections.

Specific Cases of reported SF cases in Africa

Africa with the highest prevalence (18.7 per cent) of falsified and substandard medicines is particularly at risk from counterfeit medical supplies and fake coronavirus 'cures'[9].

Chloroquine:

Cameroon: In the first week of April 2020, Cameroon seized fake chloroquine, a much-touted possible remedy to the COVID-19, from at least 300 pharmacies and hospitals[10]. This followed a World Health Organization notification that counterfeit chloroquine was circulating in Cameroon, Chad and Nigeria.

Nigeria: The National Agency for Food and Drugs Administration and Control (NAFDAC), in response to the notification by World Health Organization (WHO) that nine (9) confirmed falsified Chloroquine products are in circulation in Africa, heightened surveillance in the country and issued a public alert to warn the public.

The WHO received nine reports of different confirmed falsified Chloroquine products from three African countries (**Cameroon, Democratic Republic of Congo and Niger**) between the period 31st March and 2nd April 2020. The nine (9) counterfeit Chloroquine products do not contain the correct amount of Active Pharmaceutical Ingredient (API)[11]. They were not manufactured by the

[5] https://www.who.int/en/news-room/fact-sheets/detail/substandard-and-falsified-medical-products
[6] https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products
[7] https://apps.who.int/iris/bitstream/handle/10665/326708/9789241513425-eng.pdf?ua=1
[8] https://www.unodc.org/e4j/en/organized-crime/module-3/key-issues/falsified-medical-products.html
[9] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7197578/
[10] https://www.voanews.com/science-health/coronavirus-outbreak/cameroon-seizes-fake-coronavirus-drugs-sold-scammers
[11] https://www.nafdac.gov.ng/public-alert-no-005-2020-alert-on-falsified-chloroquine-products-circulating-in-who-region-of-africa/

manufacturers whose names are stated on the product labels. The batch number, manufacturing and expiry dates on the falsified products do not correspond to genuine manufacturing records. The manufacturers whose names are stated on the falsified product labels do not exist.

Vaccines:

Uganda: During the month of March, in Uganda, a father and daughter duo were arrested for administering a fake vaccine against the coronavirus[12].

Fear of the virus and the inability to verify the authenticity of products are pushing the African population towards fake and substandard pharmaceutical products and medical supplies obtained from unreliable sources. This trend, which will have a dramatic effect on the health of the population, will go unabated until a vaccine or effective remedy is found. While effective enforcement is paramount to ensure that consumers are not victims of counterfeit products, enforcement is the weak link.

Alcohol-based hand sanitizers and PPEs:

Promotion, illegal distribution and sale of substandard and falsified alcohol-based hand sanitizers (failed alcohol content test), face masks and other Personal Protection Equipment (PPEs) have been reported in various African countries including ***Ghana, Nigeria, South Africa, Uganda and Zambia***. The respective regulatory authorities - Ghana FDA, NAFDAC, National Regulator for Compulsory Specifications (NRCS) of South Africa, National Drug Authority (NDA) Uganda and Zambian Medicines Regulatory Authority (ZAMRA) have taken various actions including issuance public alerts, withdrawal of violating medical products, laboratory analysis, issuance of compliance directives for corrective actions among others[13,14,15,16,17,18].

Counterfeit goods sold during the Corona crisis do not meet the required quality standards and pose a real threat to public health and safety. People who buy these fake products have a false sense of security, while they are in fact left unprotected against the virus[19]. Therefore, it is crucial not only to go after the criminals behind these scams but also, through prevention work, inform potential victims who are putting themselves and others at risk by using such fake goods.

[12] https://www.the-star.co.ke/news/world/2020-03-10-ugandans-arrested-for-giving-fake-coronavirus-vaccine/

[13] ZAMRA (27 April 2020). ZAMRA urges members of the public to be wary of falsified and substandard medicines and allied substances in wake of COVID-19 [Online] [Accessed 22 May 2020] Available from: http://www.zamra.co.zm/wp-content/uploads/2020/04/Be-Wary-of-Falsefied-Products-on-the-Market.pdf

[14] Ghana FDA (18 March 2020). Public notice - quality of products used in prevention of the spread of coronavirus (COVID-19) in Ghana. [Online] [Accessed 22 May 2020] Available from: https://www.fdaghana.gov.gh/img/press/PUBLIC%20NOTICE_QUALITY%20OF%20PRODUCTS%20%20%20USED%20IN%20PREVENTION%20OF%20THE%20SPREAD%20OF%20CORONAVIRUS.pdf

[15] NAFDAC (2020). Public Alert on illegal distribution and sale of unregistered hand sanitizers. [Online]. [Accessed 19 May 2020]. Available from: https://www.nafdac.gov.ng/public-alert-no-003-2020-alert-on-illegal-distribution-and-sale-of-unregistered-hand-sanitizers/

[16] NDA (27 April 2020). Public notice on tested hand sanitizers. [Online] [Accessed 22 May 2020] Available from: https://www.nda.or.ug/public-notice-on-tested-hand-sanitizers/

[17] NDA (15 May 2020). Public notice on tested hand sanitizers. [Online] [Accessed 22 May 2020] Available from: https://www.nda.or.ug/public-notice-on-tested-hand-sanitizers-2/

[18] NRCS (24-03-2020). Public alert. [Online]. [Accessed 19 May 2020]. Available from: https://www.nrcs.org.za/news.asp?upd=1&newsID=4144

[19] https://www.europol.europa.eu/publications-documents/viral-marketing-counterfeits-substandard-goods-and-intellectual-property-crime-in-covid-19-pandemic

Next Steps

The current focus on curbing Covid-19 spread means there is likely to be less focus on routine market surveillance, and as such there could be an influx across porous borders of substandard medical products – including those for Covid-19[20]. The importance of collecting reliable and robust data around substandard and falsified medicines should therefore not be understated. Data collection contributes to the determination of high-risk medicines, affected geographical regions and vulnerable patient populations, as well as the measurement of patterns in drug resistance and the impact of substandard and falsified medicines on patient morbidity and mortality. The AU-3S programme is a smart fit-for-purpose continental safety surveillance system (encompassing both passive and active surveillance approaches) for priority products that will support African Union Member States, at the continental level, to safeguard the health of their citizens.

Collecting, aggregating and analysing data on SF in Africa through AU-3S will complement the global public health efforts and at the same time, focus on a comprehensive safety profile of priority medical products for Africa.

[20] https://www.theguardian.com/global-development/2020/apr/30/covid-19-could-mark-a-deadly-turn-in-ghana-fight-against-fake-drugs