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EDITORIAL

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Medicines counterfeiting in Africa: a view from Zimbabwe

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ABSTRACT

With the sprouting of unregulated outlets on the streets of Zimbabwe, common questions that are raised include: (i) what is the Medicines Control Authority of Zimbabwe (MCAZ) doing about these street vendors? and (ii) is the law against unregulated markets and proliferation of substandard and falsified (SF) medicines being actively enforced? There is no doubt that this is a new challenge for MCAZ because of the risks involved with SF medicines. Notwithstanding the rather strong regulatory framework for the regulated market that the MCAZ has major control over, and its demonstrable regulatory prowess over the last 20 years as a National Medicines Regulatory Authority (NMRA), MCAZ is increasingly challenged to take a leading role in addressing this rising phenomenon. MCAZ has attempted to address the problem through collaboration with the Zimbabwe Republic Police (ZRP), public education and inspections by port officials at ports of entry. However, the problem still persists. A general lack of concrete qualitative and quantitative data on the commonly encountered SF medicinal products on the Zimbabwe market is another major issue. This is evidently a multi-layered problem and as the Shona adage goes *"chara chimwe hachitswanye inda"* (loosely translated "one thumb cannot crush all lice"), there is need for engaging local and regional partners in a bid to fulfil the MCAZ's mandate of protecting public health by ensuring medicines and medical devices intended for sale and distribution in Zimbabwe, are safe, effective and of good quality.

Keywords: Counterfeits, Falsified, Medicines and Allied Substances Control Act (MASCA), Medicines Control Authority of Zimbabwe (MCAZ), Public health, Substandard

The real magnitude of the problem?

As the sun sets in the western horizon of the "Sunshine city" – Harare, the streets become alive with inviting calls from vendors in a frantic effort to sell various wares and products, and worryingly, there has been an increase in the sales of unregistered pharmaceutical products. These unlicensed medicine vendors are strategically located in areas witnessing high volumes of commuters, ready to capitalize on their inquisitive nature. An assortment of skin-lightening creams, steroidal products, sex-enhancing products, oral contraceptives, pain killers, various herbals remedies and other products are often on display at very negotiable prices. Further inquiries for "off-the-shelf" products such as antibiotics and opioid analgesics are often met with some degree of apprehension; however, a theatrical display of desperation reveals a significant stock of pharmaceuticals which would otherwise be for sale and supplied by regulated premises and professionals such as licensed pharmacies, hospitals, clinics and dispensing surgeries manned by pharmacists and doctors. This rising phenomenon of unregulated outlets such as street stalls, peddlers and backpack dealers is significantly affecting the integrity of the medicines supply chain (Fig. 1).

This one-of-many brief encounters highlights the way in which patients are increasingly exposed to substandard and falsified (SF) pharmaceutical products, often commonly referred to as counterfeits or fake medicines, and how society has been conditioned to believe in the non-existence of a medicines regulatory body. Such exposure presents a major health challenge as the market is likely to be proliferated with SF pharmaceutical products for major diseases such as antiretroviral therapy (ART), anti-tuberculosis (anti-TB), antimalarial therapy and other essential medicines. Interestingly, different commentators within Zimbabwe often use the terms "counterfeit", "substandard" and "fake" interchangeably, in an attempt to define these poor-quality medicines. However, according to World Health Organization (WHO), the definition of counterfeit medicines captures the intentional

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Fig. 1 - Typical street stall from which unregistered medicinal products are sold, increasing risk of availability of substandard and falsified (SF) medicines.

and deliberate tampering of medicinal products in an attempt to imitate a genuine product. These products may not include any active ingredient, may include insufficient active ingredient and/or substituted ingredients (1). Whereas, substandard medicines may be genuine products whose specifications fail to meet quality expectations set by National Medicines Regulatory Authorities (NMRAs) (1). Adopting these WHO definitions and adapting these to the Zimbabwe context, will provide guidance for more focused and unified public health interventions. The Zimbabwe NMRA, the Medicines Control Authority of Zimbabwe (MCAZ) recognizes these WHO definitions and closely works with the parent ministry, the Ministry of Health and Child Care (MOHCC) and other development partners, to protect the integrity of the medicines supply chain.

Zimbabwe, like other low- and middle-income countries (LMICs) within Africa, is witnessing major changes in healthcare delivery, as a result of various global forces that determine how health commodities reach the intended users. Yadav et al (2) reports that in most LMICs, the healthcare delivery and distribution systems are fragmented to an extent that the integrity of the medicines supply chain is increasingly under threat due to proliferation of poor-quality medicines onto the market, and Zimbabwe is no exception (2). Initiatives such as the WHO rapid alert system for reporting and monitoring suspected SFs, will certainly give Zimbabwe a platform to actively contribute towards protecting the global medicines supply chain. To date, more than 200 case reports have been noted globally and these have resulted in 5 international alerts (3). Notwithstanding the value of this reporting system, the extent of the problem in Zimbabwe remains virtually unknown and much of what we know on SFs flooding the Zimbabwe market is reported in newspapers and grey literature, with very little evidence-based reports available. Estimates within the African region have been difficult to quantify; however, results reported from Ghana, Kenya, Mali, South Africa, Tanzania and Uganda, indicated variable prevalence estimates of selected samples of commonly suspected SFs (3, 4). Most SFs encountered by MCAZ officials are veterinary products such as water-soluble anti-infectives for use in poultry, cattle de-wormers and dipping chemicals. A few anti-infectives and anti-malarial drugs have also been encountered with human medicines. However, these have not been quantified to determine the real magnitude of the problem.

Identifying these SFs is one challenge, but quantifying the extent of proliferation appears to be a mammoth task. At regional level however, a few authors have attempted to describe the problem and come up with recommendations tailored to the African context (5-9). Needless to say, the problem is largely associated with the economic landscape, pharmaceutical environment, coordination of enforcement activities and availability (or lack thereof) of a robust regulatory framework; however, bear in mind that even the more stringent jurisdictions are not immune to this. In Zimbabwe, opportunists are swooping in and taking advantage of the desperation for affordable healthcare. The question of why the public were opting for medicines being sold on streets was then asked recently and the common sentiments amongst the vendors and general public was, “It is cheaper to buy medicines on the streets”. To put this into perspective, a 7-day course of amoxicillin costs US$0.50-US$1.00 on the streets, whilst selling for as much as US$3.00 in a retail pharmacy. This translates to a difference of up to 75%. Whilst this obviously demonstrates why one may prefer the cheaper option, these products are certainly not guaranteed to be safe, effective and of good quality.

What about health insurance coverage? Affordability and access to health services is dependent on health insurance coverage, which is very low. According to the Zimbabwe Demographic and Health Survey (ZDHS) 2015, only 11% of women and 12% of men are estimated to have health insurance, which is mostly employer based (Fig. 2) (10).

Truth of the matter is, because the majority of Zimbabweans do not have health insurance, they are forced to turn to the cheaper informal markets in an effort to escape the high out-of-pocket costs at the regulated outlets. Furthermore, availability of essential medicines in public health institutions is another determinant. If essential medicines are not available and affordable, one would be forced to turn to the streets where there is risk of buying SF medicines. There is therefore a need for equitable access to quality affordable healthcare and protection from financial hardship, to ensure the goal of Universal Health Coverage (UHC) is realized.

Zimbabwe, through collaborative efforts from local and international players, has made significant improvements in fighting major public health threats such as human immunodeficiency virus/acquired immune-deficiency syndrome (HIV/AIDS), TB and malaria. This has been characterized by decreasing trends in incidence and prevalence rates for these major diseases. However, efforts to achieve other targets such as 2020 UNAIDS 90-90-90 Strategy to ensure (i) 90% of people with HIV know their status, (ii) 90% of all people diagnosed with HIV infection receive ART and (iii) 90% of those receiving ART will have viral suppression, will be rendered fruitless if patients and the general public are continuously exposed to SFs (11). Notwithstanding these concerns, infiltration of SFs onto the Zimbabwe market may also contribute significantly to antimicrobial resistance (AMR), ineffective

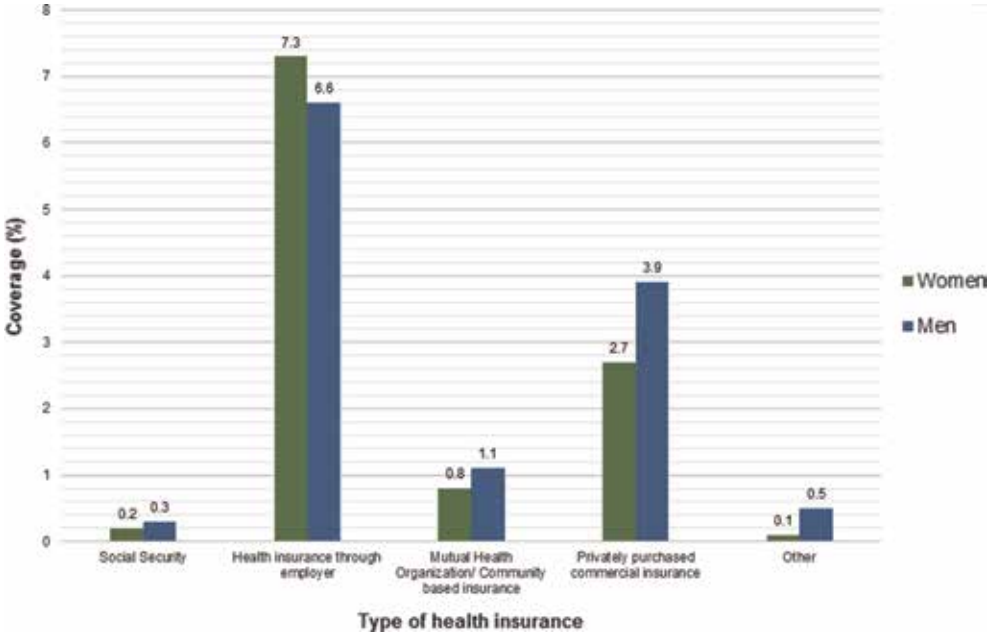

Fig. 2 - Percentage of health insurance coverage among men and women aged 15-49 years in Zimbabwe. Adapted with permission from Zimbabwe Demographic and Health Survey 2015 (ZDHS 2015). Out of a total of 9955 women and 8396 men, 88.9% of women and 87.8% of men did not have health insurance coverage.

therapy for emerging health threats and an increased double burden of diseases, i.e., communicable and non-communicable diseases. Thus, MCAZ's mandate of *"protecting public and animal health by ensuring that accessible medicines and allied substances and medical devices are safe, effective and of good quality through enforcement of adherence to standards by manufacturers and distributors",* is therefore hampered by a myriad of individual, societal and broader health system factors (12). These concerns have led to questions on the extent to which MCAZ exercises its regulatory oversight, and thus often referred to as a "toothless bulldog" by some commentators.

Regulatory oversight of SFs – does this exist in Zimbabwe?

A common question among commentators of the subject is "who is MCAZ and what are they doing about this problem?" The MCAZ is a statutory body that was formed through an Act of Parliament, and whose responsibilities in protecting public and animal health are governed by the Medicines And Allied Substances Control Act (MASCA) (13). Provisions are embedded in this statutory instrument, that specify the requirements for medicines registration, and aims to regulate the flooding of SFs onto the Zimbabwe market by clearly stipulating the conditions for registration of medicines on the basis of (i) public interest; (ii) safety, quality and therapeutic efficacy attributes; (iii) satisfactory good manufacturing practice (GMP), and (iv) in the case of a medicine manufactured outside Zimbabwe, valid certification issued by appropriate NMRA in the country of origin or other stringent regulatory authority (SRA) (13). Any violations to the statutory provisions are subject to penalties which, depending on the nature, can range from warnings, fines or imprisonment. Within the market that MCAZ has major control over, any violations to the provisions, for example stocking unregistered products, could lead to fines or revoking of premises and/or persons licenses. The question one may then ask is whether these are effectively enforced? The answer to this is yes! The Zimbabwe market is well regulated, particularly regarding import and export controls of licit medicines; however, the existence of a parallel market that has fuelled the proliferation of unregistered medicines is a major concern for MCAZ due to risk of SFs flooding the market. As a result, it therefore relies heavily on law enforcement agents to assist in the arrest and prosecution of these peddlers.

Globally, medicines regulation is constantly evolving and MCAZ attempts to stay abreast of current trends. Within the region however, there are spirited efforts to harmonize regulatory standards which will see pooling of resources for assessment of applications for registration of medical products (14, 15). As a pivotal member of the task force for the establishment of the African Medicines Agency (AMA), MCAZ is well positioned to influence policies that will see, not only improvements in reduction of time to registration and associated costs, but also measures to curtail this proliferation of SFs within the continent (15). In addition, within the Southern African Development Community (SADC), collectives such as SADC Regulators Forum are essential for closer collaborations with regard to placing market controls for unregulated products within each representative jurisdiction, thus attempting to reduce proliferation across the borders. Moving closer to home, the thrust for drafting of a national strategy on SFs led MCAZ to actively participate in several WHO-led workshops with a focus on reporting of SFs and setting up systems to effectively identify, report, investigate and disseminate to all relevant stakeholders. In a workshop held in February 2016 in Harare (Zimbabwe), various stakeholders put their heads together to draft strategies for a National Plan to Prevent, Detect and Respond to SF Medical Products.

Fig. 3 - Television is one way of reaching out to a wider audience to educate the public on the dangers of substandard and falsified (SF) medicinal products.

Fig. 4 - Medicines Control Authority Zimbabwe (MCAZ) official testing medicines at a street stall using a Raman spectrophotometer.

What is the way forward?

As it celebrates 20 years of regulatory excellence, it is time MCAZ demonstrated its regulatory prowess through (i) development of a more robust licensing platform, (ii) tighter enforcement and post-marketing surveillance, (iii) more stringent import and export controls, (iv) stakeholder engagements such as training of port officials and law enforcement agents, (v) closer collaboration with law enforcement agents targeting the illicit market, (vi) deployment of officers to other designated ports of entry to strengthen border controls, (vii) deployment of counterfeit detecting technology, and (viii) aggressive public awareness education campaigns (Fig. 3).

Albeit patients are becoming more informed about their health and wellbeing, the general lack of public awareness on the role of MCAZ needs to be addressed promptly. Interventions such as public perception surveys, public exhibitions, lectures and live radio broadcasts, have been effective in sensitizing the public to MCAZ's stance on SFs and unregulated sales of medicines, amongst many other key issues. Activities such as community engagements and exhibitions provide a conducive environment for education and sensitizing the public on medicines regulation in Zimbabwe. Effective as these may be, the recipients of such information may appear to be a modest select group of the population, therefore providing impetus for a population-wide approach. Patient education is a key component of effective therapy therefore healthcare professionals must include education in their day-to-day interactions with patients to demystify some of the medicine-related myths or misconceptions such as, *"an antibiotic bought on the street is just the same as one bought from the pharmacy".*

Contrary to the common saying that *"what you don't know, won't kill you",* buying medicines from the streets can kill because some products may be substandard and/or falsified. Sensitisation of the public on the dangers (such as death) associated with buying medicines from the streets, is therefore necessary. This can be achieved by utilising mass media platforms to spread the message on the importance of buying medicines from licensed/regulated outlets such as clinics, pharmacies, hospitals and medical practices.

Despite the availability of legislation and standards, there appears to be a general perception that the risk of prosecution is very low; therefore, there is need for strengthening the regulatory framework around SFs and enforcing adherence to standards, policies and procedures. This can be achieved by liaising with law enforcement agents to put in place deterrent measures intended for safeguarding the health of the Zimbabwe public.

Within Zimbabwe, increased collaboration between the regulator and industry is a strategic move for safeguarding the integrity of the Zimbabwe medicine supply chain. Embedding pharmacovigilance throughout the supply chain, from upstream pre-entry processes to downstream dispensing and use, may be vital to identify loopholes in the supply chain, and may also encourage a whistleblowing culture to flag potential public health risks before infiltration onto the Zimbabwe market. There is therefore a need to put in place more robust measures that protect and incentivise whistleblowers, and not solely rely on protection orders that can be sought from the judicial system. Within Zimbabwe, as long as different institutions and stakeholders continue to operate in silos, this battle will be far from being a realized goal. Thus, there is need for strengthening public-private partnerships (PPP) towards a unified goal of curbing illicit sales of medicines and flooding of SFs onto the Zimbabwe market.

Beyond the Zimbabwean border, there is a need for leveraging on the existent regional networks and place the issue of SFs amongst the more urgent topics for discussion. There is also a need for establishment of a regional task force that will oversee the monitoring of markets for SFs within the member jurisdictions. Tightening border controls would be a vital step in reducing the porosity of the borders (Fig. 4).

Whilst reporting through the various print media is an essential dissemination tool, it holds little weight if not supported by primary studies conducted to determine the real magnitude of the problem. There is therefore a pressing need for quantitative and qualitative research to obtain evidence-based information that can guide policies and strategies intended for addressing the influx of SFs onto the Zimbabwe market.

There is need to harness the potential of technology such as the Raman spectrophotometer that can assist in detecting

whether medicinal products that are readily available to the public, are safe, effective and of good quality. Some products on sale in the informal market may appear to be authentic; however, such practices are illegal as this is a major public health risk.

In view of current changes to global health policy (e.g., in light of antimicrobial resistance) and the medicines regulation landscape, the time to act is now. With increased globalization and urbanization, there is a proportional increase in access to health information thus providing stimulus for MCAZ to capitalize on various technological advancements such as counterfeit detecting technology, social media and mobile technology. Innovatively packaging information onto these different platforms, that reaches out to all Zimbabweans, irrespective of age, gender or socioeconomic status, would be a winning step in the battle against SFs.

Disclosures

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