

BMJ Open Impact of the COVID-19 pandemic on the quality of medical products in Zimbabwe: a qualitative study based on key informant interviews with health system stakeholders

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ABSTRACT

Objective To explore the impact of the Coronavirus disease 2019 (COVID-19) pandemic on the quality of medical products in Zimbabwe, including market risks for substandard and falsified products and impacts on quality assurance activities.

Design Qualitative study based on in-depth key informant interviews.

Setting Health system stakeholders across the medical product supply chain in Zimbabwe.

Participants 36 key informants were interviewed between April and June 2021.

Results We found that the COVID-19 pandemic disrupted quality assurance and regulatory activities of medical products in Zimbabwe, resulted in observations of poor-quality personal protective equipment (PPE) and other COVID-19-related products and led to increased risks to quality. Risks to quality due to COVID-19-related disruptions included increased layers of agents in the supply chain and an influx of non-traditional suppliers. COVID-19-related movement restrictions reduced access to health facilities and thus may have increased the usage of the informal market where smuggled and unregistered medical products are sold with less oversight by the regulator. Most reports of poor-quality medical products were for PPE, such as masks and infrared thermometers, used for the COVID-19 response. Besides these reports, many participants stated that the quality of essential medicines in the formal sector, not related to COVID-19, had largely been maintained during the pandemic due to the regulator's stringent quality assurance process. Incentives for suppliers to maintain quality to retain large donor-funded contracts, and the need for local wholesalers and distributors to comply with quality-related aspects of distribution agreements with global manufacturers of brand-name medical products, mitigated threats to quality.

Conclusions The COVID-19 pandemic presented opportunities and market risks for circulation of substandard and falsified medical products in Zimbabwe. There is a need for policymakers to invest in measures to safeguard the quality of medical products during emergencies and to build resiliency against future supply chain shocks.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Key informants in our study represented a broad range of stakeholders and included perspectives and insights from national, provincial and district levels of the country.
- ⇒ In-depth qualitative interviews allowed for a rich and nuanced exploration of Coronavirus disease 2019 impacts on the quality of medical products during the pandemic.
- ⇒ Insights from our study mostly represent the regulated formal health system and supply chain where our participants were drawn from.
- ⇒ Our qualitative findings should be corroborated and triangulated with quantitative surveillance and pharmacovigilance data to present a comprehensive picture on the impacts of the pandemic on the quality of medical products.

INTRODUCTION

Coronavirus disease 2019 (COVID-19) is a respiratory disease that was declared a pandemic by the World Health Organization (WHO) in March 2020 and has caused more than 6 million deaths globally.¹ There are concerns and reports that the COVID-19 pandemic may have increased risks for circulation of substandard and falsified medical products, including essential medicines and other products.²⁻⁴ As of December 2021, the Medicine Quality Research Group at the Infectious Diseases Data Observatory identified 959 reports globally of COVID-19 medical product quality issues spanning vaccines, diagnostics, personal protective equipment (PPE), sanitisers and disinfectants and medicines.⁵ Other reports during the pandemic documented large seizures of substandard and falsified medical products and other regulatory enforcement actions

such as withdrawal of substandard and falsified products from the market.^{2,4}

According to the WHO, substandard medical products are ‘authorized medical products that fail to meet either their quality standards or specification, or both’, while falsified medicinal products are ‘medical products that deliberately/fraudulently misrepresent their identity, composition, or source’.⁶ Using substandard and falsified medical products results in substantial health and socioeconomic impacts including wasted resources, increased mortality and morbidity, lost productivity and threats to public health objectives through increased disease and development of antimicrobial resistance.^{7–12} The attainment of multilateral global health agendas, such the United Nations’ Sustainable Development Goals and Universal Health Coverage, may be impacted by the circulation and use of substandard and falsified medical products.^{13–16} Quality-assured medical products are therefore key to reducing the global burden of disease and reducing mortality and morbidity.

Despite reports of surges in circulating substandard and falsified medical products during the COVID-19 pandemic,^{4,5} there have not been in-depth primary studies examining how the pandemic impacted quality assurance activities of national medicine regulatory agencies (NMRAs) and how supply chain disruptions impacted the quality of medical products.⁴ Most of the extant accounts of substandard and falsified products during the COVID-19 pandemic are from reports of criminal enforcement actions or surveillance reports; these do not examine COVID-19’s specific impacts on the supply chain that culminate in the reports of quality issues.^{2,4,17} Thus, there is a need to gather primary data to examine the impact of the COVID-19 pandemic on the supply chain and market risks for substandard and falsified medical products.¹⁸ Understanding the impacts of COVID-19 on the quality of medical products is even more urgent across low-income and middle-income countries (LMICs), where the overall prevalence of substandard and falsified essential medicines is as much as 13.6%.^{7,19} Further, NMRAs across LMICs are often under-resourced and have weaker regulatory capacity, compared with higher-resource settings where there may be more resilience in a pandemic.^{20–22}

This study explored the impact of the COVID-19 pandemic on the quality of medical products in Zimbabwe, including market risks for substandard and falsified products and impacts on regulation and quality assurance activities. Zimbabwe, an LMIC in Southern Africa, has a strong technical capacity for medical product quality assurance. This is evidenced by Zimbabwe having one of the few WHO prequalified national medical product quality control laboratories in sub-Saharan Africa.^{23–25} Zimbabwe’s NMRA, the Medicines Control Authority of Zimbabwe, is recognised as a regional centre of regulatory excellence by the African Union and provides training to other regulators in the region.^{26,27} However, Zimbabwe’s health system has also experienced historical challenges

related to underfunding, labour disputes and strikes, and there have been anecdotal reports of COVID-19 exacerbating these long-standing challenges.²⁸ Findings from this study can help inform measures to safeguard the quality of medical products during emergencies and to build resiliency against future supply chain shocks. In this paper, the term ‘medical products’ is used as an umbrella term that refers to both medicines and other products such as PPE and diagnostics. The term ‘medicines’ in this paper is reserved for essential medicines, such as antibiotics and antimalarials, unless the term is part of a noun, such as ‘Medicines Control Authority of Zimbabwe’.

METHODS

Study design

To understand the impact of the COVID-19 pandemic on the quality of medical products using Zimbabwe as a cross-sectional case study, we conducted in-depth semistructured qualitative interviews with stakeholders across the medical product regulation, health system and medical product supply chain sectors.

Sampling and study procedures

A combination of purposive sampling and snowball sampling was used to recruit key informants for the interviews. We recruited participants from key organisations and entities across the supply chain involved in the regulation, procurement, distribution and usage of medical products, to provide insights on medical product quality. Our minimum target sample size was 16 participants, consistent with evidence from literature that such a sample size is sufficient to reach 90% thematic saturation through in-depth interviews.²⁹ Beyond the minimum target sample, we sought variation in the type of participants and wanted to balance the number of participants across the three major categories of organisational affiliation (government, non-governmental and other types of organisational affiliations).

Our sample of participants represented all levels of the supply chain, ranging from participants involved in importing medical products to those involved in storage and distribution, as well as at the retail service level. For example, in addition to participants involved in medical product regulation, we also interviewed participants responsible for procuring, storing and distributing medical products to all public health facilities in the country. Other participants were drawn from private medical product wholesalers and distributors, retail pharmacists, government ministry, donors and other non-governmental organisations. Participants in our sample also represented national, provincial, and district perspectives.

Interviews were conducted between April and June 2021 in Zimbabwe by the first author, a global health researcher trained in qualitative research methods. Interviews were conducted in English either in-person or virtually using Zoom, based on participants’ preferences and

logistical considerations. The interviews lasted between 30 minutes and 1 hour. All participants provided verbal informed consent prior to participating in the interviews. The interviews were recorded with participants' permission and supplemental written notes were taken during each interview.

Data collection instrument

Interviews were conducted using a semistructured guide with open-ended questions that were developed based on the main research question of how the COVID-19 pandemic impacted the quality and regulation of medical products in Zimbabwe (online supplemental file). Feedback from country-based research collaborators who had contextual knowledge through involvement in COVID-19 clinical and research work also guided the development of the interview guide. The questions and follow-up probes were then tailored to each participant's organisational affiliation and role within the medical product supply chain or health system. Interview questions and probes were modified for subsequent interviews based on new topics and issues that arose during other participants' interviews. Interview questions sought participants' perspectives on how the COVID-19 pandemic affected quality assurance activities and the quality of medical products in Zimbabwe, including impact on postmarket surveillance and inspections. Follow-up probes included questions about changes in the medical products market and the potential risk of circulation of substandard and falsified medical products due to COVID-19 disruptions. Participants were also asked about adaptations within the supply chain and health system to mitigate the impact of the COVID-19 pandemic on quality of medical products and support continued access to quality-assured products during the pandemic.

Data analysis

Data from the qualitative interviews were analysed using thematic analysis in an iterative manner.^{30–32} First, we used transcriptions of audio recordings from the interviews and the interview notes to write qualitative memos for each interview. The qualitative memos captured contextual information about the respondent's background, such as their role within the health system and medical product supply chain and summarised the content of each interview. After reviewing all the memos, we developed and applied codes that synthesised emergent themes about the impacts of the COVID-19 pandemic on the quality of medical products across all interviews (online supplemental file). We used Microsoft Excel spreadsheets to group and synthesise similar themes across all the interviews and we selected representative quotes from key informants that best captured the data within each broader theme. Trustworthiness of the study was maintained through techniques such as data collection triangulation, where we administered the same data collection instrument to a variety of respondents and we corroborated responses across similar clusters of respondents.³³

Internally, we discussed among study authors to reach consensus on the themes drawn from the data. Additional validation checks included presenting our preliminary findings to a seminar of key country stakeholders and comparing our results to findings from other qualitative studies that examined the broader impacts of the COVID-19 pandemic on the health system in Zimbabwe.

Patient and public involvement

This study consisted of key informant interviews with professionals and did not involve patients. Findings from the study have been disseminated via conference and seminar presentations, which have been attended by key stakeholders and policymakers from Zimbabwe. These findings are published open-access to allow for greater public accessibility.

RESULTS

We interviewed 36 key informants whose professional roles included medical product regulatory officers, pharmacists, academics, clinicians, and other roles in procurement and supply chain management in Zimbabwe (table 1). The study participants' organisational affiliations included Government ministry (N=13), Non-governmental/Multilateral organisations (N=5), Donors (N=5), Medical product wholesaler/distributor/retailer (N=5), Regulatory authority/Technical agency (N=5) and Academic/Independent consultant (N=3). We identified the following themes: (1) pre-COVID-19 context; (2) disruptions to quality assurance and regulatory activities; (3) reports of poor-quality medical products; (4) increased risks to quality; (5) quality perceived to be maintained; (6) mitigatory factors and (7) adaptations to COVID-19 (table 2). Figure 1 illustrates where the reported impacts of COVID-19 on the quality of medical products occurred on the continuum from procurement to the health facility/patient level. Additional representative quotes from key informants are included in online supplemental file 1.

Pre-COVID-19 context

Participants described a pre-COVID-19 pandemic context in which the national medicines regulator was perceived to have succeeded in enforcing stringent quality assurance measures on the market (table 2). However, the national medicines regulator's lack of policing powers over the informal medical product sector was a significant limitation where poor-quality medical products could be sold in the unregulated informal sector:

Generally, the formal channels and the formal market is well regulated. The informal sector, that's where we have a big challenge in the sense that our borders are too porous, and we do not have a presence at the ports of entry. So, a lot of unregistered medicines get smuggled into the country from neighboring countries, mostly places like Zambia for example, and they would have come as far as DRC

Table 1 Summary of study informants' organisational affiliations and roles

Type of organisation/affiliation	Informant roles	Number of informants
Government ministry	District pharmacists (n=6), Provincial pharmacist (n=3), Chief pharmacist (n=2), Laboratory logistics unit manager (n=1), Paediatric oncologist (n=1)	13
Non-governmental/Multilateral organisation	Country director (n=1), Executive director (n=1), Palliative care nurse (n=1), Director for non-communicable diseases (n=1), Country director (n=1)	5
Donor	Procurement and supply management specialist (n=1), Health systems strengthening specialist (n=1), Chief of health and nutrition (n=1), PSM consultant (n=1), Health office director (n=1)	5
Medical product wholesaler/distributor/retail	Pharmacist (n=2), Managing director (n=1), Business development lead/Pharmacist (n=1), Sales manager (n=1)	5
Regulatory authority/Technical agency	Chief regulatory officer (n=1), Projects and public relations officer (n=1), Chief procurement officer (n=1), Procurement and logistics specialist (n=1), Public health specialist (n=1)	5
Academic/Independent consultant	PhD student/researcher (n=1), Medical product procurement professional (n=1), Committee member/Specialist physician (n=1)	3
<i>Total number of informants</i>		36

[Democratic Republic of Congo], Tanzania and they just come through these ports of entry. That's where our biggest challenge is [informal sector], because our enforcement activities are limited. —[Regulatory authority/Technical agency]

Disruptions to quality assurance and regulatory activities

COVID-19-related disruptions led to a reduction in some medical product quality assurance activities. Participants also described an overall shift of regulatory focus to COVID-19-related issues, in lieu of regular enforcement activities. Participants affiliated with the national medicines regulator described a reduction in the number of routine local premise inspections and an inability to conduct good manufacturing practice (GMP) inspections of manufacturers abroad, due to COVID-19-related travel restrictions. GMP inspections are an important quality assurance mechanism, where the regulator's representatives verify compliance with GMP standards in the manufacturing of medical products that are registered for in-country use. GMP inspections are traditionally conducted in person at the manufacturing sites, and thus the inability to conduct inspections during the COVID-19 pandemic limited the regulator's ability to verify GMP compliance. Further, GMP inspection fees are an important revenue source for the regulator and the reduction in number of inspections affected revenue flows, which could impact the NMRA's other regulatory activities dependent on the fee revenue:

If a manufacturer wants to register their medicines, they invite us for an inspection, and we charge for those services. Because of COVID-19, unfortunately, we haven't been able to conduct as many GMP inspections, as we would have done pre-COVID-19. So that's one of the ways that I feel as an organization we have been affected, in terms of resource mobilization

through those GMP inspections. We then actually moved to virtual GMP desk audit inspections, whereby we look at the paperwork and we speak to them via Zoom, and they take us through the facility. We have realized some revenue through that [virtual inspections], but it's not as much as we used to get pre-COVID. —[Regulatory authority/Technical agency]

Participants affiliated with the national medicines regulator also described how movement restrictions and global logistical disruptions had caused delays to renovate the regulator's national microbiology laboratory for certification by the WHO. Other participants cited potential disruptions to the regulator's autonomy through political pressure to waive regulatory processes for medical products procured through government-to-government channels in response to COVID-19:

We had then seen some commodities from non-traditional suppliers, including pharmaceuticals from China coming to government, through government-to-government deals. So, for those types of products, definitely, you cannot vouch for their quality because they would not have gone through the necessary quality assurance process...however, because we were in the pandemic it was a balancing act. —[Donor]

Reports of poor-quality medical products

Most reports of poor-quality medical products among participants were for PPE such as masks, gowns and infrared thermometers used for the COVID-19 response (table 2). Participants stated that most of the poor-quality PPE products came from new suppliers who took advantage of the acute shortage to enter the market without following regulatory processes, including GMP compliance. Further, participants noted that PPE and other consumables were less regulated, making them an

Table 2 Summary of themes from key informant interviews on COVID-19 impacts on the quality of medical products in Zimbabwe

Theme	Summary
Pre-COVID-19 context	<ul style="list-style-type: none"> ▶ Economic factors, poor border control and lack of policing powers for the national medicines regulator over the informal sector contribute to the use of medical products from the informal market
Disruptions to quality assurance and regulatory activities	<ul style="list-style-type: none"> ▶ There was a reduction in routine local inspections of premises by the national medicines regulator due to movement restrictions ▶ Regulatory focus shifted to COVID-19-related issues in lieu of regular enforcement activities ▶ GMP inspections, a major revenue source for the regulator, were reduced ▶ Movement restrictions and logistical disruptions stalled renovation on national medicines regulator's microbiology lab for WHO certification ▶ Reduced office capacity and work-from-home arrangements disrupted traditional in-person committee work for regulator's activities
Reports of poor-quality medical products	<ul style="list-style-type: none"> ▶ Poor-quality PPE and COVID-19-related commodities were observed on the market ▶ Poor-quality products were mostly from newer suppliers who were competing with established suppliers on price ▶ PPE and consumables are less regulated compared with medicines and there are fewer barriers to entry for suppliers ▶ Treatment failures were observed in a paediatric setting where Methotrexate was used to treat Wilms tumour, suggesting that the Methotrexate used was of poor quality
Increased risks to quality	<ul style="list-style-type: none"> ▶ Increased layers of agents in the supply chain and market entry of non-traditional suppliers could have possibly impacted quality ▶ Commodities imported directly under a regulatory waiver for product registration requirements pose potential quality risks ▶ Donated medical products through government-to-government channels may not have gone through regular quality assurance processes due to political pressure to waive processes ▶ Delays in delivery and lower demand for infectious disease medicines led to increased rates of medicine expiry ▶ Pushing COVID-19-related products on to facilities with strained storage capacity may have increased risks to good storage practices/conditions ▶ Increased length of transportation routes due to logistical disruptions could have led to increased risk of uncertain storage conditions ▶ Trade in smuggled unregistered medicines from neighbouring countries ▶ Smuggling of unregistered medicines for COVID-19 remedies, such as Ivermectin, Zinc, Azithromycin ▶ Some informal traders infiltrated licensed premises and official distribution channels with unregulated medicines that are repackaged to evade regulators ▶ Restricted access to licensed outlets, due to COVID-19-related travel restrictions, and economic factors may have increased the use of medical products from illicit markets
Quality maintained	<ul style="list-style-type: none"> ▶ Quality was perceived to be maintained through the national medicines regulator's strict quality assurance programme where the regulator continued to conduct predistribution and postdistribution testing ▶ Quality was maintained through international non-governmental organisations' stringent quality assurance systems and regulations
Mitigatory factors	<ul style="list-style-type: none"> ▶ Incentives for suppliers to maintain quality of their products to retain large supply contracts ▶ Procurement through a pooled global mechanism provided incentive for manufacturers to adhere to QA measures ▶ Strict distribution agreements, especially with European manufacturers, ensured compliance with good storage and distribution practices
Adaptations to COVID-19	<ul style="list-style-type: none"> ▶ National medicines regulator pivoted to virtual GMP inspections in lieu of physical inspections due to movement restrictions ▶ National medicines regulator accelerated transition to automation of regulatory processes ▶ Greater use of virtual training opportunities by the national medicines regulator, which included training other peer regulators on virtual GMP inspections ▶ Flexibility was added to quality assurance procedures to accommodate shipping delays due to COVID-19
COVID-19, Coronavirus disease 2019; GMP, good manufacturing practice; PPE, personal protective equipment; WHO, World Health Organization.	

Impact of COVID-19 on regulation and quality of medical products in Zimbabwe

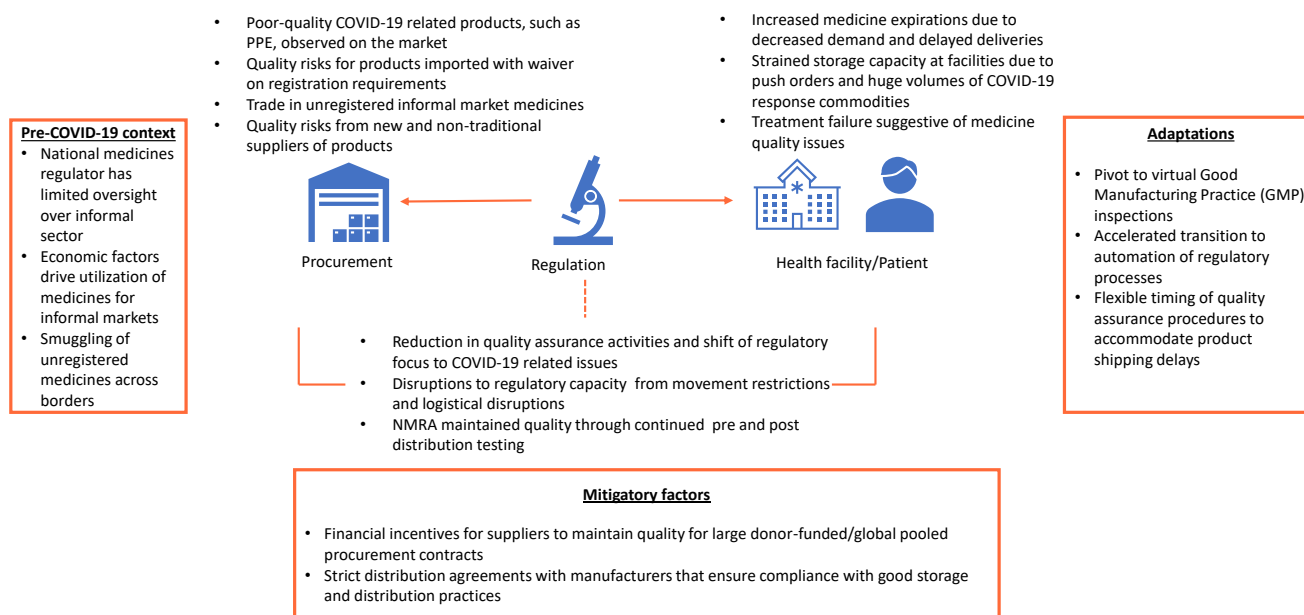


Figure 1 Impact of COVID-19 on regulation and quality of medical products in Zimbabwe. NMRA, national medicine regulatory agency; PPE, personal protective equipment.

easy target for falsification and substandard products, compared with medicines that are stringently regulated:

Although the country is working towards regulating consumables, we still get substandard products... From where I sit here, I do not have the capacity to check whether that mask you are wearing is of good quality. So, if somebody comes with something that looks like an N-95 mask, you may not be able to assess if it is of good quality. The country actually lacks such a regulator [for testing consumables and PPE], but on the medicines side that's taken care of. — [Government ministry]

In addition to COVID-19-related products, such as PPE, quality concerns were raised for paediatric oncology medicines, based on clinician observations of treatment failures. Cases of treatment failure were observed for a tumour that is considered easily treatable and were not previously observed before the COVID-19 pandemic. Clinician informants attributed these treatment failures to possible poor-quality medicines. The paediatric oncology medicines are not among the essential medicines that are procured by the central medical store for use in public sector facilities, but are procured through a non-governmental organisation:

On the issue of quality, we have no control over that. We were referred to the manufacturer because another foundation is buying from them. So, we buy from them and just give the drugs to the hospital. I know there has been a couple of cases at the hospital

involving methotrexate [oncology drug]...we lost three patients. So, we don't know whether it was a particular batch where the drug came from, what was wrong [whether the unexpected treatment failures were a result of a particular batch of poor-quality medicines]. There has been an incident [of suspected poor-quality medicines], but our drugs are never examined or taken to any lab or tested for anything [therefore the treatment failure cannot be conclusively attributed to quality issues]. As long they have been approved by the regulator, that's it. —[Non-governmental/Multilateral organization]

Increased risks to quality

COVID-19-related supply chain disruptions led to increased risks to the quality of medical products. For example, participants stated that in response to shortages and supply bottlenecks associated with COVID-19, as well as increased demand for medical products used for COVID-19 management, there was a significant increase in medical products procured under special provisions that waived registration requirements. The special provisions, colloquially referred to as 'Section 75' (in reference to the section of the legislative act governing medical products), allows entities to import unregistered medicines for clinical use when the products are not available in the country.³⁴ Some participants perceived that medicines imported under the Section 75 special provision had an increased risk of being of poor quality, since they

were not subjected to the same quality assurance process that medicines registered by the country NMRA undergo:

For quality, we bring in products that are registered with [the regulator], and when products come, we get import permits and when they come here [arrive in the country], we still submit samples to the regulator [for quality testing]. So, the issues of poor quality only come with these section 75 products, that [is] where there have been quality issues...I remember there were even reports in South Africa that they tested some of the Ivermectin [which was being imported into Zimbabwe under section 75 waivers] and some of it were non-efficacious [i.e., with low/no active pharmaceutical ingredient content].—[Medical product wholesaler/distributor/retailer]

Supply chain delays and logistical disruptions associated with the COVID-19 pandemic resulted in increased risks to the quality of medical products from expirations and degradation due to prolonged and uncertain storage conditions during new logistical routes, necessitated by unavailability or delays on regular routes. At the health facility level, participants reported that during the pandemic, they often received products that had shorter than usual shelf life, due to initial delays in delivery, thus increasing the risk of using degraded or expired products. Social distancing and movement restrictions, in response to COVID-19, led to decreased incidence of some illnesses spread by close social contact, such as influenza and colds; the consequent reduced demand for medicines for those conditions also led to an increase in the number of expired medicines. Imported products were subjected to longer than usual transportation routes, which may have increased their risk of exposure to uncertain storage conditions. Meanwhile, increased demand for PPE and other medical products for COVID-19 necessitated storage of larger than normal volumes of products at health facilities, which strained storage capacity and may have resulted in some products being stored outside optimal conditions when storage capacity was exceeded:

A problem that came with COVID-19 was storage. We suddenly received lots of products [PPE and other medical products for COVID-19], we had to prepare for an outbreak...the amount of commodities that we were supposed to hold increased by a huge margin. So, you would find that ordinarily you are supposed to keep some things on pellets [in the medical product storage room], but sometimes the stocks would be too much. So, it could have compromised somehow the way we would store the things.—[Government ministry]

The larger number of agents in the supply chain, alongside the entry of non-traditional suppliers in the market during the COVID-19 period, also increased potential risks to product quality. Shortages of active pharmaceutical ingredients (APIs) raw materials and reduced business operations and logistical challenges due to

COVID-19-related restrictions led international and other traditional local suppliers of medical products to withdraw from bidding for supply tenders. Consequently, there was an increase in third party agents and non-traditional suppliers who entered the medical product procurement and supply business, filling the gap vacated by traditional suppliers. The new market players took advantage of the COVID-19 emergency and the limited supply options to charge higher prices. The third party and non-traditional suppliers' limited experience in supply chain management may also have increased risks to product quality.

Normally, it's actually better to deal with the manufacturer of a product than to deal with an agent who will charge agent fees or to deal with a third party or fourth party. So, you will find that this chain of first, second, third, or fourth parties has got an implication on the price, and possibly sometimes on the quality of the product that you will get.—[Regulatory authority/Technical agency]

Finally, participants also perceived increased risks to quality from illicit/informal market access and the use of unregistered medicines. Movement restrictions to contain COVID-19, such as lockdowns, also had the unintended consequence of restricting access to licensed medicine outlets that sell quality-assured medicines, which may have increased the utilisation of medicines from unregulated informal markets. Some participants also described increased smuggling and sale of unregistered medicines from neighbouring countries on the informal market, including the smuggling of medicines intended for unapproved use for COVID-19 treatment such as ivermectin and azithromycin:

The system [regulatory system] continued to be there for monitoring the country [for medical product quality] but let's not forget that we have neighboring countries, so obviously grey imports started to surface. I remember the [regulators] were going to [an informal market], there were antibiotics being sold [there] during that [COVID-19 pandemic] period. During that period when somebody was sick, they would do everything [to access medicines, when access to formal retail outlets was restricted].— [Academic/Independent consultant]

Quality perceived to be maintained

Despite the aforementioned reports of disruptions to quality assurance and regulatory activities, some participants stated that the quality of medical products had largely been maintained during the COVID-19 pandemic period. The maintenance of quality, in spite of COVID-19-related impacts, was attributed to the pre-COVID-19 regime of strict quality assurance processes implemented by the national medicines regulator, especially in the formal sector and for essential medicines. Participants also cited continuity in some quality assurance activities, such as predistribution and postdistribution quality

testing, as a factor in maintaining product quality during the pandemic. Participants also stated that the quality of medical products was maintained during the COVID-19 pandemic through additional stringent quality assurance systems and regulations of donors and international organisations that support the procurement of medical products in Zimbabwe:

I think it [absence of quality issues among donor supported products] is because of the quality issues which were being well regulated. I don't think there would be any manufacturer who would want to take advantage of the situation...there are strong and resilient systems which are able to provide checks and balances.—[Donor]

Mitigatory factors

Participants described mitigatory factors and/or adaptations that moderated the impact of COVID-19 on the quality and regulation of medical products in Zimbabwe. Among suppliers for large donor-funded contracts or for multilateral organisations, such as the United Nations Children's Fund (UNICEF), there were strong financial incentives for suppliers to maintain the quality of medical products and continue adhering to quality assurance measures, despite challenges from COVID-19, in order to maintain the large contracts. Quality is one of the performance criteria for these contracts, and failing to maintain medical product quality would result in financial loss for the suppliers by losing large contracts and being precluded from bidding for future supply contracts. Further, the procurement of donor-funded products was often pooled at the global level through global supply divisions that had their own quality assurance mechanisms, in addition to the local quality assurance processes through the NMRA. Thus, the multilevel nature of quality assurance processes for medical products procured at the global level served as an extra safeguard against threats to quality during the COVID-19 pandemic:

Looking at the commodities that the [name of bilateral donor] supports, we have such rigorous quality assurance programs in place before commodities even get into the country [where they are subjected to further quality checks by the national regulator]. That's part of what we pay [name of international implementing organization contracted by donor to provide supply chain and quality assurance services] to do. So, the quality of the items that were coming into the country that we procure were still at the same standards.—[Donor]

Another example of external mitigatory factors is that local medical product wholesalers and distributors, who had distribution agreements with global manufacturers of brand-name medical products, still had to comply with Good Storage Practices and Good Distribution Practices, where compliance was verified by the global manufacturers' compliance departments:

There are standard operating procedures that exist in any distribution agreement. The bigger European companies, they have got quite big departments that deal with compliance to ensure that your operation [as a distributor] is in line with their standards. They work on the principle that a warehouse and drug distribution in Harare must be the same as drug distribution in the UK or US, etc.—[Medical product wholesaler/distributor/retailer]

Adaptations to COVID-19

An example of the adaptation of operational processes in response to COVID-19 disruptions is that the regulator quickly adopted virtual GMP inspections when it was challenging to conduct traditional in-person inspections. The virtual inspection approach provided assurance and some confidence in the application of GMP principles by manufacturers. Though not ideal, the adoption of the virtual inspection protocol demonstrated the regulatory agency's resilience in trying to assure the quality of medical products even during a pandemic:

We have had to adjust to what are called virtual inspections...we connect with the manufacturer, and they provide their documentation...we even go into the facility, and they use videos and things like Zoom and other platforms...that's how we have been operating since last year, virtually, mostly with the international players [manufacturers].—[Regulatory authority/Technical agency]

Another procurement organisation introduced flexibility in the timing of preshipment quality testing, as an adaptation to accommodate shipping delays caused by logistical disruptions from COVID-19. Instead of waiting for quality testing results before shipping, as was the policy prior to the COVID-19 pandemic, they would collect samples for testing and allow shipment while results were pending, and any follow-up actions based on testing results were conducted when products arrived in the country.

Previously before a product shipped, [name of contracted technical partner responsible for quality assurance] would go in and do the quality assurance testing and if a product passes it ships...but during this COVID-19 period, they would collect product samples and go ahead and ship it [shipment of medical products] and do the quality assurance testing while the products are sailing and before it's [shipment] received in-country they would let us know [results of the pre-shipment quality assurance testing]...— [Non-governmental/Multilateral organization]

Finally, participants stated that COVID-19-related disruptions allowed the regulatory authority to accelerate efforts to automate and streamline regulatory processes:

It [COVID-19] actually helped us to quickly adapt our IT [information technology] infrastructure...Before

COVID-19, there were a lot of suggestions on how the regulator should move towards automation of their systems, to be able to respond quickly to the needs of the customers. So, when COVID-19 came, we then realized that we were not moving quick enough. So, we had to move quickly enough to sort out our automation and automate most of our key business processes.—[Regulatory authority/Technical agency]

DISCUSSION

Our study found that the COVID-19 pandemic disrupted quality assurance and regulatory activities of medical products in Zimbabwe, resulted in observations of poor-quality PPE and other COVID-19-related products and led to increased risks to quality. However, incentives for suppliers to maintain quality to retain large donor-funded contracts, and the need for local wholesalers and distributors to comply with quality-related aspects of distribution agreements with global manufacturers of brand-name medical products, were mitigatory factors to threats to quality. The NMRA was able to adapt and pivot to innovative ways of continuing regulatory activities, such as virtual GMP inspections, to try to maintain the quality of medical products during a period when travel restrictions impeded traditional in-person inspections. Our study is among the first to examine the impacts of COVID-19 on the quality of medical products in an LMIC setting.

Our findings on observations of poor-quality PPE and COVID-19-related medical products in Zimbabwe are consistent with evidence of increased circulation of substandard and falsified medical products in past pandemics,⁴ and several recent studies which have highlighted the risks of substandard and falsified medical products from the current COVID-19 pandemic.^{3 4 35–37} Given Zimbabwe's stringent regulatory authority,^{25 26} many participants perceived that the quality of other essential medical products, besides COVID-19-related medical products, had been maintained during the pandemic. However, this may not be the case in other countries where there are less stringent regulatory authorities and where there are reports of other substandard and falsified medical products in addition to PPEs and COVID-19-related medical products.^{2 4 38} This underscores the need to strengthen medical product regulatory capacity to achieve resiliency to risks of substandard and falsified medical products.

Our results are also consistent with a framework for identifying market risks for substandard and falsified medical products, which examined the supply and demand side factors that create opportunities for substandard and falsified medical products on the market.¹⁸ For example, due to supply chain disruptions, manufacturers might be forced to consider alternative procurement sources for APIs, whose adherence to quality assurance mechanisms may be unknown.¹⁸ Market shortages of medical products, increased demand and price increases might

create market opportunities for suppliers of substandard and falsified medical products.^{18 39} In Zimbabwe, during the COVID-19 pandemic, there was acute demand for PPE and COVID-19-related medical products. Supply constraints, together with lower barriers to entry for suppliers of these products compared with suppliers of essential medicines, increased the risks for substandard and falsified products being sold on the market. The inadequacy of current regulatory frameworks for PPEs in the context of COVID-19 across low-resource settings has been highlighted in prior literature and the pandemic presents an opportunity for revamping the regulatory frameworks.^{40 41} Therefore, there is a need for policymakers to urgently address apparent gaps in the regulation of products such as PPE, which were used in large volumes during the pandemic.

Increased risks to quality from products imported under special waiver provisions on registrations, as well as products donated through government-to-government channels for the COVID-19 response, highlight the inherent tensions between ensuring access to medical products and safeguarding quality. The waiver on registration requirements allows imports of medical products that would be in short supply on the domestic market and thus helps avoid acute shortages. However, in the context of the COVID-19 pandemic where there was heightened demand for medicines including therapies that were not efficacious against COVID-19,⁴² there was a risk that waiving registration requirements would result in substandard and falsified products being imported. Similarly, while government-sourced medical product donations can be an important tool to ensure access, there may also be increased risks for donated medical products to be poor-quality if they are not subjected to regular quality tests.^{43 44} Therefore, regulatory authorities should work with policymakers to counter any political pressure to waive quality assurance procedures in the context of prioritising access to medical products in a pandemic.

The disruptions to the quality assurance and regulatory activities of the national medicines regulator and the shift of regulatory focus towards COVID-19 highlights the need to adequately resource NMRAs to accommodate surges in emergency regulations such as emergency use authorisations. However, the ability of regulators to adapt to virtual GMP inspections when physical inspections were not feasible could provide a template for resiliency in regulatory systems, although virtual inspections may not be as effective as physical inspections in identifying GMP violations. More funding and investment in building a resilient medical product supply chain would help ensure continuity in quality assurance and regulatory activities during pandemics and future emergencies.

There are some limitations to our study's findings. First, despite assuring study informants about privacy and confidentiality, they may have been reluctant to talk about quality of medicines candidly because it is potentially a sensitive issue. We had obtained necessary permissions and assured privacy and confidentiality to best facilitate

our conversations. Second, our data collection took place in the midst of the COVID-19 pandemic. There may be a time lag to observe the COVID-19 pandemic's full effects on the quality of medical products. Third, we conducted a qualitative analysis through 36 key informant interviews. Our qualitative findings should be corroborated and triangulated with quantitative data, such as surveillance and pharmacovigilance data to present a comprehensive picture of the pandemic's impacts on the quality of medical products. Finally, insights from our study mostly represent the regulated formal health system and supply chain where our participants were drawn from. However, we also found that there is an unregulated medical product market where there is trade in smuggled products and where medical products are sold in informal markets. The movement restrictions during the pandemic that reduced access to licensed health facilities, along with economic factors that drove the use of medical products from the informal market, may have further driven the utilisation of non-quality-assured medical products from the informal market. Thus, future studies should examine the impact of COVID-19 on informal market trade in medical products, where quality risks could be higher.

CONCLUSION

The COVID-19 pandemic presented opportunities and market risks for the circulation of substandard and falsified medical products in Zimbabwe. We found that the COVID-19 pandemic disrupted quality assurance and regulatory activities of medical products in Zimbabwe, resulted in observations of poor-quality PPE and other COVID-19-related products and led to increased risks to quality. Strong quality assurance and regulatory systems play a critical role to ameliorate the health and economic burden of poor-quality medical products and build a resilient supply chain. Therefore, there is a need for policymakers to invest in quality assurance mechanisms that are responsive to emergencies that may disrupt medicine supply chains.

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Impact of the COVID-19 pandemic on the quality of medical products in Zimbabwe: a qualitative study based on key informant interviews with health system stakeholders

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Supplemental Materials

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Questions for key informants in the medicine procurement sector

1. How did COVID-19 affect procurement of essential medicines, including vaccines and contraceptives, in Zimbabwe?
2. What procurement-related challenges did/have you encountered as a result of COVID-19?
3. Have you had to change procurement processes as a result of COVID-19? If so, how?
4. How have prices of essential medicines been affected as a result of COVID-19?
5. How did COVID-19 impact demand for medicines?
6. How did COVID-19 impact patient access to medicines?
7. What have been the socio-economic effects (if any) of COVID-19 on end users of medicines?
8. Are there publicly available data on procurement activities that you could share that would help me understand the impact of COVID-19 on procurement in Zimbabwe?
9. Are there other informants I should interview?

Questions for key informants in the medicine regulation sector

10. How did COVID-19 affect your activities as a regulator of essential medicines in Zimbabwe?
11. Have quality of essential medicines been affected by COVID-19?
12. Have there been supply chain disruptions? If so, have they impacted medicines quality in Zimbabwe?
13. What have been the socio-economic effects (if any) of COVID-19 on end users of medicines?
14. Are there publicly available data on regulatory/quality assurance activities that you could share that would help me understand the impact of COVID-19 on medicine quality in Zimbabwe?
15. Are there other informants I should interview?

Questions for key informants in the medicine retail sector

16. How did COVID-19 affect procurement of essential medicines in Zimbabwe?
17. What procurement-related challenges did/have you encounter as a result of COVID-19?
18. Have you had to change procurement processes as a result of COVID-19? If so, how?
19. How have prices of essential medicines been affected as a result of COVID-19?
20. How did COVID-19 impact demand for medicines?
21. How did COVID-19 impact patient access to medicines?
22. What have been the socio-economic effects (if any) of COVID-19 on end users of medicines?
23. Are there publicly available data on medicine prices that you could share that would help me understand the impact of COVID-19 on medicine prices in Zimbabwe?
24. Are there other informants I should interview?

Codebook

Variable	Codes & Definitions
Procurement	<ul style="list-style-type: none"> • Shortages <ul style="list-style-type: none"> ○ Informant describes medicines shortages at procurement sources due to COVID-19 supply chain disruptions. • Stockouts <ul style="list-style-type: none"> ○ Informant describes medicine stockouts at health facilities due to COVID-19 supply chain disruptions • Price changes <ul style="list-style-type: none"> ○ Informant describes significant medicine price changes at procurement sources after COVID-19 • Procurement source changes <ul style="list-style-type: none"> ○ Informant describes changing procurement sources due to COVID-19 disruptions of regular suppliers. • Procurement procedure changes <ul style="list-style-type: none"> ○ Informant describes changes in procurement procedures due to COVID-19 • Procurement resilience and adaptations <ul style="list-style-type: none"> ○ Informant describes factors that made procurement resilient to and withstand COVID-19 related disruptions ○ Informant describes adaptations and changes made to mitigate COVID-19 impact on procurement • Pre-COVID-19 factors and context <ul style="list-style-type: none"> ○ Informant describes contextual factors related to procurement that predate COVID-19 but mediated COVID-19 impact • Indirect impacts <ul style="list-style-type: none"> ○ Participant describes COVID-19 impacts that indirectly affected procurement
Medicine quality	<ul style="list-style-type: none"> • Substandard and falsified medicines identified <ul style="list-style-type: none"> ○ Informant describes changes in SF medicines identified in the market during COVID-19 • Product recalls or confiscations <ul style="list-style-type: none"> ○ Informant describes changes in medicine recalls in the market during COVID-19 • Adverse events <ul style="list-style-type: none"> ○ Informant describes changes in reported adverse events reported in the market during COVID-19 • Quality assurance activity changes <ul style="list-style-type: none"> ○ Informant describes changes in regulatory medicine quality assurance activities in the market due to COVID-19 related disruptions, such as frequency of inspections, postmarketing surveillance activities etc. • Quality assurance resilience and adaptations <ul style="list-style-type: none"> ○ Informant describes factors that made quality assurance mechanisms resilient to and withstand COVID-19 related disruptions ○ Informant describes adaptations and changes made to mitigate COVID-19 impact on quality • Pre-COVID-19 factors and context <ul style="list-style-type: none"> ○ Informant describes contextual factors related to procurement that predate COVID-19 but mediated COVID-19 impact

Medicine price	<ul style="list-style-type: none">• Price changes<ul style="list-style-type: none">○ Informant describes changes in medicine prices (at procurement and retail level) during COVID-19• Reasons for price changes or non-changes<ul style="list-style-type: none">○ Informant describes reasons for price decreases or increases during COVID-19• Pre-COVID-19 factors and context<ul style="list-style-type: none">○ Informant describes contextual factors related to procurement that predate COVID-19 but mediated COVID-19 impact
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Additional representative quotes across themes

Theme	Representative quotes
Pre-COVID-19 context	<p>“Taking Ivermectin as a case in point, I think Ivermectin largely came from Zambia, and it arrived in Zambia from India...Zambia is quite porous in terms of its drug importations and our border with Zambia is quite porous as well.” – [Medical product wholesaler/distributor/retailer]</p>
Disruptions to quality assurance and regulatory activities	<p>“In terms of the restricted movement, we were then restricted in terms of the local inspections that we could do because we were not able to move around the country as freely and as frequently as we would have done. So, which obviously raised a few more concerns in terms of people bringing in unregistered medicines or selling unregistered medicines or products of questionable quality, because we were not as active as we would have been before COVID-19. The enforcement activities that we were doing were reduced to maybe about half the number of activities we would have done before COVID-19.” – [Regulatory authority/Technical agency]</p> <p>“We have had to do quite a number of enforcements that are COVID-19 related. For example, you find someone illegally distributing and misleading the public about a particular product. That increases some workload...it’s something that we would not ordinarily come across if it were not for COVID-19.” – [Regulatory authority/Technical agency]</p> <p>“We had then seen some commodities from non-traditional suppliers, including pharmaceuticals from China coming to government, through government-to-government deals. So, those types of products, definitely, you cannot vouch for their quality because they would not have gone through the necessary quality assurance process...however, because we were in the pandemic it was a balancing act, whether to allow the government to do what they want to do...they were just using the minimum requirement to say, ‘if this product is registered from where its coming from, then it’s probably ok’. – [Donor]</p>
Reports of poor-quality medical products	<p>“I would say for a few products that are COVID-19 linked, for example the aprons that are being produced, if you check most of those are rejects [of poor-quality]...only that we don’t have a proper way to test ‘is it [hand sanitizer] 70% alcohol for sure or not’, but [due to] mass production for things that are physically visible, you can see that something didn’t go right” – [Government ministry]</p> <p>“There are also a lot of private suppliers, someone travels to Zambia and comes in with some medication and goes to a pharmacy and gives it to them. You have no idea what the storage conditions were, cold chain [system to maintain products within temperature specifications, such as through refrigeration], no idea but you are desperate, and you say ‘Ok, I will buy it’. That to me is our biggest problem, lack of certainty of the product quality we are using for our patients.” – [Government ministry]</p> <p>“Wilm’s tumor has always been a tumor that is easily treatable. Now, all of a sudden, I started noticing children coming with relapses, which I never experienced before. I could only ascribe it to the quality of the drugs...to be honest with you, I am not 100% confident in my heart that every drug I am using is a quality drug.” – [Government ministry]</p>
Increased risks to quality	<p>“The [regulatory] system continued to be there for monitoring the country but let’s not forget that we have neighboring countries, so obviously such grey imports started</p>

	<p>to surface. I remember [regulator] were going to [informal market], there were antibiotics during that [COVID-19 pandemic] period. During that period when somebody is sick, they would do everything...So the grey imports started coming in, they were not coming through the formal channels, but they were actually being smuggled into the country.” – [Academic/Independent consultant]</p> <p>“There were ways that were done to do away with [regulator]’s controls, so when they buy from Zambia, you [the informal traders] are not supposed to buy the medicines in blister packs if you are supplying to the doctor or pharmacy, you have to buy them in a bottle. As soon as it arrives, what they do is they just replace bottles. So, if there was a jar of Amoxicillin that was bought from [pharmaceutical company], which is a registered company in Zimbabwe, you just pour [the unregistered Amoxicillin from Zambia] in the [pharmaceutical company] bottle and you discard [the original container of unregistered medicines] ...So I discovered that there was a way for formalizing the informal drugs.” – [Academic/Independent consultant]</p> <p>“There is a group of remedies that also stopped being utilized fully, as expected. Anything flu-related, if you had it in stock, the chances that it would expire on you during that high peak COVID-19 era was very high.” – [Government ministry]</p> <p>“There was a time when [procurement entity] ran a framework [for a supply tender]. The companies that ended up responding to the framework are actually companies who do something else other than COVID-19 items...things like gloves, face masks...they don’t have experience in those things...you end up just accepting things because they are not available.” – [Regulatory authority/Technical agency]</p>
Quality maintained	<p>“I think it is because of the quality issues which were being well regulated. I don’t think there would be any manufacturer who would want to take advantage of the situation...there are strong and resilient systems which are able to provide checks and balances” – [Donor]</p> <p>“The quality was not compromised...as you know Zimbabwe is quite strict when it comes to quality, particularly for medicines.” – [Non-governmental/Multilateral organizations]</p>
Mitigatory factors	<p>“Yes, we are worried [about potential threats to quality] ...the comfort that we had was that we were largely getting items from our supply division [multilateral donor’s global supply division in Europe]. The supply division has got contracts or long-term agreements for global supplies. So, such manufacturers would not want to compromise a global tender with huge volume.” – [Donor]</p>
Adaptations to COVID-19	<p>“Sometimes some of them [changes due to COVID-19] come in as opportunities. Training opportunities have been available for our inspectors, some of them are offered internationally, so they can actually participate virtually...so there are positives as well. I can say we survived [COVID-19 related disruptions] because in the [African] region, we are one of the very few that managed to carry out virtual inspections and we have managed to train the region as well on how to carry out these types of inspections.” – [Regulatory authority/Technical agency]</p>