Master of Public Health

Master de Santé Publique

The role of GS1 global standards in helping combat substandard and falsified medical products in African region: A case study

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MPH 2, 2020-2022

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Acknowledgments

First and foremost, I would like to express my sincere gratitude to my professional advisor, Tania Snioch, for giving me a great opportunity to work at GS1 Healthcare and enabling me to participate in various projects past four months. I literally have learned a lot from these projects and got the opportunity to work with different experts. In addition, I appreciated all of her support, advice, guidance, and feedback on my work and thesis throughout the internship. I am so glad to work with you and learn from you.

I would also like to extend my appreciation to interviewees who were willing to join my study and give their insight and share their experiences. Especially, many thanks to my colleague, Nuran and Ulrike, for supporting me in recruiting interviewees.

Additionally, I would like to thank my academic advisor and tutor, Michael Padget and Odessa Petit dit Dariel, for their guidance and advice on my thesis. Particularly, when I was struggling to create this thesis framework, their feedback was very helpful.

Last but not least, to my family and my boyfriend, I would like to thank you for their emotional support, patience, and encouragement throughout this two-year journey in EHESP.

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Acronyms

CMS	Central Medical Stores
LSM	Living Standards Measure
SBAR	Situation–Background–Assessment-Recommendation
SF	Substandard and falsified medical products
WHO	World Health Organization

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Abstract

Background: Substandard and falsified medical products (SF) enter the global supply chain every day leading to economic costs and harm to patients. Consequently, SF is a big burden to health systems by diverting resources to ineffective or harmful therapies, which may cause medical complications and prolong illnesses. It could also lead to a loss of confidence in medicines, healthcare providers, and further health systems. Especially, Africa is the most affected continent by the SF. The African region has the highest prevalence of poor-quality medicines. In this regard, the GS1 standard is one of the means to reduce their burden in that it allows regulators to identify, capture, and share the information regarding SF and recall them easily and more efficiently.

Methods: For qualitative analysis, in-depth interviews with 7 selected internal and external experts who are familiar with GS1 standards and know well about the African situation related to SF were conducted individually in the online setting. The interviews were semi-structured and followed by a formalized Situation–Background–Assessment-Recommendation (SBAR) framework. The collected interview data were transcribed and analyzed. In addition, this qualitative analysis was complemented by literature reviews.

Results: Four themes (Situation, Background, Assessment Recommendation) were deduced from the interviews. Through these four themes, this study provides an insight into what are actually problematic situations related to SF in the region. It also identifies the role of GS1 standards and current challenges. And further, a few recommendations were suggested on how to overcome current challenges and/or problematic situations.

Conclusions: The findings would be helpful to determine adopting GS1 standards for the African community that is interested in improving interoperable and traceability systems to address these situations. Also, this study highlights that the African communities and donor organizations should note that solving the challenges is not an individual's responsibility or a country's responsibility. In other words, to apply suggested recommendations successfully, all the stakeholders across the supply chain have to work together. Also, internal cooperation in the continent and external support from international organizations should be accompanied.

Keywords: GS1 standards, GS1, Substandard and falsified medical products, counterfeited medicine, the role of GS1 standards, global standards, traceability, track and trace system, African region.

Résumé

Contexte: Des produits médicaux (SF) falsifiés et de qualité inférieure entrent chaque jour dans la chaîne d'approvisionnement mondiale, entraînant des coûts économiques et des préjudices pour les patients. Par conséquent, les SF représentent un lourd fardeau pour les systèmes de santé en détournant des ressources vers des thérapies inefficaces ou nocives, qui peuvent entraîner des complications médicales et prolonger les maladies. Elle peut également entraîner une perte de confiance dans les médicaments, les prestataires de soins et les systèmes de santé. En particulier, l'Afrique est le continent le plus touché par le SF. La région africaine a la plus forte prévalence de médicaments de mauvaise qualité. A cet égard, le standard GS1 est l'un des moyens de réduire leur fardeau dans la mesure où il permet aux régulateurs d'identifier, de capturer et de partager les informations concernant les SF et de les rappeler facilement et plus efficacement.

Méthodes: Pour une analyse qualitative, des entretiens approfondis avec 7 experts internes et externes sélectionnés, qui sont familiers avec les standards GS1 et connaissent bien la situation africaine en matière de SF, ont été menés individuellement en ligne. Les entretiens étaient semi-structurés et suivis d'un cadre formel Situation-Background-Assessment- Recommendation (SBAR). Les données recueillies lors des entretiens ont été transcrites et analysées. En outre, cette analyse qualitative a été complétée par des analyses documentaires.

Résultats: Quatre thèmes (Situation, Background, Assessment Recommendation) ont été déduits des entretiens. Grâce à ces quatre thèmes, cette étude donne un aperçu des situations problématiques liées aux SF dans la région. Elle identifie également le rôle des standards GS1 et les défis actuels. Enfin, quelques recommandations ont été suggérées sur la manière de surmonter les défis actuels et/ou les situations problématiques.

Conclusions: Les résultats seraient utiles pour déterminer l'adoption des standards GS1 pour la communauté africaine qui est intéressée à améliorer le système d'interopérabilité et de traçabilité pour faire face à ces situations. En outre, cette étude souligne que les communautés africaines et les organisations donatrices devraient noter que la résolution des défis n'est pas la responsabilité d'un individu ou d'un pays. En d'autres termes, pour appliquer avec succès les recommandations suggérées, toutes les parties prenantes de la chaîne d'approvisionnement doivent travailler ensemble. Il convient également d'accompagner la coopération interne du continent et le soutien externe des organisations internationales.

1. Introduction

1.1 Problem statement

Substandard and falsified medical products (SF) enter the global supply chain every day leading to economic costs and harm to patients[1]. The WHO estimates that SF may be responsible for over 1 million deaths annually, causing $21 billion in global financial impacts[2]. This is because SF may contain no active ingredient, wrong active ingredient, or other toxic chemicals. Moreover, they are highly likely to be produced in poor and unhygienic environments by unqualified people, leading to impurities or contaminated ingredients. Consequently, SF is a big burden to health systems by diverting resources to ineffective or harmful therapies, which may cause medical complications and prolong illnesses[3]. It could also lead to a loss of confidence in medicines, healthcare providers, and further health systems.

Based on new research from WHO, an estimated 1 in 10 medical products is either substandard or falsified in low- and middle-income countries. Especially, Africa is the most affected continent by the SF. The African region has the highest prevalence of poor-quality medicines, with an 18.7% prevalence of SF amongst low- and middle-income countries worldwide[4]. According to a WHO study, 42% of all SF were from the African region between 2013 and 2017[5]. Coupled with that, the recent expansion in industrialization and trade has aggravated the scale of the problem[6]. In the example at the top, internet marketing of pharmaceuticals through online chemists has further contributed to the pervasion of SF[7]. WHO estimates that up to 50% of the medicines being sold on the internet are fake[8].

The problems SF brings about have an enormous economic impact. Counterfeit goods including pharmaceuticals have resulted in hundreds of millions of dollars in lost tax revenue throughout the African continent[9]. Aside from that, it also has social and public health impacts. The African region has been facing the global public health crisis of SF. The WHO indicates that consuming fake anti-malarial or tuberculosis drugs contributes to the death of 700,000 Africans annually[10]. Especially, in sub-Saharan Africa, more than 120,000 children died in 2013 from counterfeit, substandard, or degraded anti-malarials[11]. As a result, although regional governments and multiple international organizations - such as the WHO, the Global Fund, and NGOs - put funds and resources to eliminate SF within their supply chains, SF still remains a huge barrier to fighting against such diseases of major public health concern in the region[12].

Although there are drug regulatory agencies that evaluate, monitor, and guarantee the safety of medical products in the majority of countries, in the case of Africa, such agencies are absent in a number of regions[13]. According to WHO, Africa has 54 National Medicines Regulatory[14]. Also, only

7% of the region has moderately developed capacity, while more than 90% have minimal or no capacity to undertake medicine regulatory functions[15]. This could lead to 1) exposing the population to potentially unsafe medical products of variable quality and effectiveness; 2) facilitating the proliferation of SF; 3) threatening rational use of medical products, all of which are detrimental to public health and patient safety[16]. In short, many African countries are suffering from an immature regulatory framework due to a lack of resources, capacity, technical expertise, and weak infrastructures to undertake surveillance to guarantee the safety of pharmaceutical products[17].

Box 1. Substandard and falsified medical products

The terminology for "counterfeit" drugs has been defined differently in different organizations and countries. To address this problem, in 2017, the 70th World Health Assembly adopted the "Substandard and falsified medical products" term and dropped the term counterfeit drugs[18]. The term "Substandard and falsified medical products" includes branded and generic pharmaceuticals, correct or wrong or no active ingredients, incorrect quantities of active ingredients, or fake packaging[19]. To be specific, "substandard" medical products are authorized but fail to meet either their quality standards or specifications or both. "Falsified" medical products mean the medical products that deliberately/fraudulently misrepresent their identity, composition, or source. Furthermore, "medical products" include medicines, excipients, and active substances, as well as medical devices, their parts and materials, and accessories used in conjunction with medical devices[20].

1.2 A case study: GS1 Standards

GS1 standards are a trademarked name for data standards including barcodes. Globally, GS1 focuses on three global industry sectors – retail, healthcare, and transport & logistics. Especially, it is broadly understood that the GS1 global standards are the most commonly used for medical products in the world[21]. The GS1 standards are managed by GS1 which is a global not-for-profit organization registered in Belgium. With over 100 local Member Organizations, GS1 is working with communities of trading partners, industry organizations, governments, and technology providers[22]. GS1 standards bring together companies representing all parts of the supply chain. All GS1 standards are established by these companies cooperating together under the global leadership of GS1 to agree upon standards. Without a neutral, non-for-profit, and global organization like GS1, such very diverse companies would probably not be able to agree on standards[23].

GS1 is governed by a management board composed of key leaders and drivers from multinationals, healthcare providers, retailers, manufacturers, and GS1 Member Organizations. Moreover, GS1 Global Office is working on the development and maintenance of GS1 global standards. On the other hand, local Member Organizations are responsible for the implementation of the standards and GS1

Healthcare initiative[24]. They enhance the coordination with local bodies through liaisons or alliances with local regulators, trade bodies, solution providers, and others. And they provide services for member companies to support the adoption of GS1 standards.

The foundation of the GS1 standards is identification. The members of GS1 use globally unique identification numbers to identify all elements of the supply chain[25]. The barcode is a representation of the identification number. In the healthcare industry, supply chains have become increasingly complex and vulnerable to falsified medicines[26]. Every step in the supply chain offers an opportunity for counterfeiters, and the impact of product counterfeiting and diversion is global. Adoption of the GS1 standards could be one of the solutions to overcome such a challenge by creating identifying information at all levels of production. To trace medical products throughout the supply chain, standardized identification is crucial[27]. GS1 automatic identification system (barcode or RFID) uses the globally recognized GS1 identification keys to identify trade items, locations, logistic units, and assets. It helps prevent counterfeiting[28]. Thus, WHO encourages the Member States to use global standards for product, stakeholder, production, and location identification for medical products, as well as for data capture automatic elements including barcodes or radio frequency identification tags[29]. The application of global standards can enable the international interoperability necessary for international vigilance.

For example, in August 2021, the WHO found fake Covishield vaccines in Kolkata. Thus, in India, there is a need for a traceability system for vaccines and other medical products to address the issue of counterfeit products[30]. A health system with transparency and visibility can check the movement of medical products across the supply chain, helping to deal with counterfeit medical products and to manage product recalls[31]. This requires the use of global common standards as well as the necessary systems to support traceability. This is because using GS1 standards and identifiers for counterfeit protection, each individual product unit is given a serial number, as well as the unique GTIN identifier. The combination of GTIN and serial number, represented in a suitable GS1 barcode, makes the product uniquely identifiable worldwide, contributing to reducing the opportunity for counterfeiters and the impact of product counterfeiting[32].

GS1 plays a crucial role in the development of global standards, services, and solutions to cope with the growing counterfeit problem globally. In this regard, it seems to be important to identify the role of GS1 standards and the current challenges of applying or implementing the standards. Further, to combat SF, we need to explore how the challenges can be addressed.

2. Research Objectives

The aims of this study are to provide an insight into the magnitude of the increasing burden, impact, and threat that the African region is facing. Also, this article highlights the roles and challenges of GS1 global standards to improve such problematic situations. Furthermore, this article suggests recommendations to overcome the challenges and these situations.

The main objectives of this study are:

- To see where GS1 global standards are used for fighting against substandard and falsified medical products;
- To figure out current challenges in the implementation of GS1 global standards;
- To suggest how to overcome the current challenges.

3. Methods

3.1 Setting

For this case study, we combined a literature review and in-depth interviews with 7 selected key experts who are familiar with GS1 standards and know well about the African situation related to SF. The interviews were followed by a formalized Situation-Background-Assessment Recommendation (SBAR) framework. Table 1 summarizes the steps this study took during this two-phase study.

Table 1. Summary of study steps

Phase 1: Deductive approach
Initial literature review Identified key themes and evidence to support interview data through the literature review
Phase 2: Qualitative analysis
Conducted 7 semi-structured interviews Transcribed interviews Coded interviews Identified common patterns Explore patterns using matrices Interpreting findings

3.2 Data collection

An initial literature review was conducted to figure out the background and current situations on substandard and falsified medical products in African regional settings. This review began by searching for evidence related to the causes and consequences of SF. Then, after conducting semi-structured interviews, an additional literature review was carried out to support the interview data. In addition, using a semi-structured interview guide (Appendix A) based on SBAR framework, interviews were conducted to have knowledge and experiences related to the study objectives. Altogether, 7 individual interviews were conducted. The subjects were 6 internal experts from GS1 and 1 external expert. The 6 internal experts consisted of GS1 Global Office or Member Offices including a former employee. And an external expert was a formal USAID employee. The choice of subjects was based on their role in the African regional settings with direct or indirect links to SF among internal and external experts who are familiar with GS1 standards. Their expertise were ranging from pharmaceutical supply chain, traceability, and technology to standard leads.

All the interviewees were contacted individually, and their written consent was given through an electronic informed consent before conducting interviews to get an agreement to participate in this study. In addition, the following points were clearly explained to the interviewees: 1) Some general things they should know about this study; 2) The purpose of this study; 3) The time required; 4) What would happen if they took part in this study; 5) Possible benefits from being in this study; 6) Possible risks from being in this study; 7) How to protect their privacy; 8) Rewards; 9) What if they have questions about this study.

The interviews were conducted on Zoom or Teams considering various places the interviewees live. Each interview lasted approximately 30-45 minutes. The interviews were conducted in English and were audiotaped and transcribed verbatim. All transcripts were not included any personally identifying information.

3.3 Data analysis

The qualitative data analysis was conducted through the following four steps: 1) Reading data; 2) Identifying themes or patterns (coding); 3) Exploring the patterns; 4) Interpreting findings. To develop a draft coding structure for data analysis, this study used NVivo software. Finally, study findings from the data were interpreted in order to suggest solutions to address current challenges in its implementation to combat substandard and falsified medical products.

All of the transcripts were read several times to become familiar with the interview data. Then, the interview data were reviewed repeatedly to identify common patterns. Using a tool of matrices, the

identified patterns were explored, generating and categorizing key codes. After coding the data, they were reviewed and revised repeatedly, drawing the themes and subthemes[33].

The SBAR-based analysis was conducted to develop an analysis of the interview data. In the interviews, 7 cases of SBAR were collected and analyzed, and each was categorized into the four stages of SBAR.

Table 2. The four stages of SBAR

Stage 1) Situation
• What are the problematic situations related to SF across the supply chain in the region?
Stage 2) Background
• What are the major causes of such problematic situations?
Stage 3) Assessment
• What is the role of GS1 global standards to support fighting against SF in the region? • What are the current challenges in the implementation of GS1 global standards as a toolkit against SF in the region?
Stage 4) Recommendation
• How could we overcome the current challenges for the region?

3.4 Ethical considerations

An Individual consent form was provided to each participant before each interview. This consent included information explaining the purpose, possible risks, and how to protect their privacy. In addition, interviewees were asked if they agreed to participate in this study and audiotape their interviews. By signing this consent, the participant's agreement was confirmed. To be specific, for participants' privacy, it indicated that the information they shared during the interview would be treated confidentially and would be destroyed after qualitative analysis has been completed.

4. Results

The results show findings derived from literature reviews and documentation together with the data collected in semi-structured interviews. In the situation where there is no specific reference, the findings come from only interview data. To achieve the objectives of this study, the qualitative content analysis of interviews revealed four themes based on SBAR framework. To deepen the understanding, in some cases, the literature reviews were combined with the qualitative analysis of interviews. The findings of the research are presented as follows:

Theme 1. Situation: What are the problematic situations related to SF

Despite the fact that the African region is suffering from problematic situations regarding SF as described in the introduction part, there is little reliable research and information on the true picture of SF in the region. Thus, this study will show what has happened regarding SF in the region in terms of reality through interview analysis.

The interviewees were questioned about the problematic situations they have heard about or identified related to SF in the African region. There was an agreement on the problematic situation of the higher prevalence of SF in the African region.

> *"If you are a mother and you have an ill child, you have 420 kilometers to the next town and pharmacy to get a drug for your child who's really seriously ill. You will take this 50% chance to have medicines for your child because it's better than nothing. Even if you are made aware that could be a risk if it's nothing or 50%. We should not forget that people in Africa often, really, are glad to have just something. They are taking their chances there, which we just can't imagine living here in Europe. It's part of the daily life in Africa." (Interviewee 3)*

The two typical situations were identified based on descriptions by interviewees. First of all, there is a situation where the quality of medicine is depending on where people buy medicine. For example, if a person goes to an informal shop, not a pharmacy, he or she is highly likely to get an SF.

> *"Since a few months ago, social media has been fueled by consumers who are posting their reviews when they suspect a medical product is falsified or substandard. So, there was this post about a pharmaceutical drug called Grandpa. ··· They bought it from a kind of spaza shop which is very informal. They said they bought it to relieve their headache but it gave them a stronger headache. Also, when they bought it at a pharmacy like a more formalized shop, there were differences in color." (Interviewee 5)*

Generally, if a citizen buys medicine from a pharmacy, the chance he or she gets an SF is very low. This is because, in most African countries, usually there are Central Medical Stores (CMS)[1] that aggregate the demand from different pharmacies and hospitals. But, the problem is that the government cannot procure all the demand and there is a shortage problem all the time. In this case, some pharmacies may look for private sellers which are smuggling drugs. That's why the quality of

[1] Central Medical Stores (CMS) is responsible for the supply chain management of all health commodities including medicines in the public sector. The department supports the mission of the Ministry by providing preventative, curative and diagnostic medicines that are of acceptable quality, safe and effective. (Source: Eswatini Government)

medicine is depending on the quality or reputation of not only informal shops but also pharmacies people go to.

> *"The quality of medicine is depending on the quality of the pharmacy we go to. ··· Usually to know which pharmacy to go to is really dependent on word of mouth. So, I would need to check with my friends or with the locals." (Interviewee 1)*

Secondly, there is a situation where the availability of the right amount of medicine is not guaranteed in the right place.

> *"One of the major products, unfortunately, is being substandard circulating in Africa market, for example, it is malaria medicine. You know, malaria is a huge problem in Africa. In a lot of places, this malaria drug has been found in many parts of Africa as a substandard product mainly because it's consumed a lot." (Interviewee 7)*

Such a problematic situation adds a further complication that people are forced to buy medicine in the market, not in a pharmacy or governmental hospital. For example, in Ethiopia,

> *"Actually, in many African countries, the malaria medicine is supposed to be given for free. Because it's a program medicine. ··· There are a lot of donor agencies who are procuring these life-saving medicines to try to make them available to the population free of charge. The problem is, like I said, sometimes the medicines are stolen and smuggled out and sold in the private market. ··· So, people would buy if you go to the government hospital and you ask for malaria medicine, but they are stocked out. So, the next option you have is to go and buy it in the market" (Interviewee 7)*

Moreover, a few factors that exacerbate these problematic situations were identified - regional disparities, growing online space, high illiteracy rates, and a longer supply chain. In the first place, of all seven interviewees, four participants highlighted the fact that such problematic situations were worse in smaller cities or remote areas compared to big cities. Further, a respondent mentioned that there also was a big gap in the possibility of getting SF depending on the size of the pharmacy.

> *"There are differences mostly from the distribution channel like where they get their medicines. That's usually the distinguishing factor. And obviously the smaller the pharmacy means that the longer there's a distribution chain. Generally, it was thought that if it's a big pharmacy then hopefully they get the products directly from a distributor who gets them directly from a manufacturer. But when you go to a smaller pharmacy located in obviously smaller capital, you have a longer supply chain which means there is a higher risk." (Interviewee 1)*

"If I bought it directly from Pfizer with 100% confidence, I'm getting a genuine product. But if I was to buy it from somewhere else on the Internet. I'm not sure I'd even be confident it was 25% genuine product. So I think there's a difference between, you know, which environments the product is coming through." (Interviewee 2)

Aside from that, all interviewees agreed that, during COVID-19 crisis, issues of SF have been increasing and more apparent in the region. Also, after the outbreak of COVID-19, in Africa, the online space is growing. Although many people, in the African region, still go to the physical pharmacy as the online pharmacy is rare and often limited to more advanced countries, a few issues lead by online platforms which sell medical products also need to be considered in that they are not regulated. For example, there is an online platform called "Jumia[2]" which is in the three areas of the leading economies – Nigeria, Kenya, and South Africa. It is a legal platform but there seems a trust issue. For instance, in February 2022, the Pharmaceutical Society of Kenya (PSK) has called out online marketplace Jumia for allowing the sale of the prescription-only medicine Augmentin by unlicensed individuals[34]. Moreover, an interviewee expressed worrying points about an online platform that sells medical products, giving an example as a follow.

"There were companies that were offering e-solutions, but purely for distribution. ··· They're the ones who provide space for the delivery and logistics part, not administering. I would say most people who sell pharmaceuticals online, I think 80% of that, they are fake. That's why they are selling them online. Because you don't have a point of reference. If I buy a medicine from a pharmacy and I have an adverse effect, I can come back to this pharmacy. But, if I buy medicine online, there is no physical interaction thus it is very difficult to trace back. ···if it's not on a platform that is trusted, I wouldn't go for it." (Interviewee 5)

In fact, the African Pharmaceutical Forum (APF) has called on drug regulators in Africa to enact laws to regulate and control internet-based pharmacy services[35]. However, considering the African environment where online shopping is very limited, a more worrying factor is the high illiteracy rate. In fact, based on African Union data, literacy rates in African countries are estimated at roughly 70% which is lagging behind world averages of about 90%[36]. This causes another problematic situation. For example,

"People gather in a field and then they are selling or exchanging their goods. So, those are the places where they penetrate. People are illiterate. A lot of people are illiterate, so they don't know even how to read and write, so it's very hard for them to identify which products to buy, and which one is standard

[2] Jumia is a Pan-African technology company that is built around a marketplace, logistics service and payment service. The logistics service enables the delivery of packages through a network of local partners while the payment services facilitate the payments of online transactions within Jumia's ecosystem. (Source: Wikipedia)

or not. So, there is plenty of opportunities. And the substandard medicine enters the population and it's very limited opportunity to monitor them because this is not a formal setting. A very small group of people went to go to pharmacies to buy their products from pharmacies." (Interviewee 7)

Theme 2. Background: The major causes of these problematic situations

The interviewees reported different causes why the African region is the most valuable area for SF. They are summarized in Table 3. This theme consists of 4 key codes including rural nature, profit maximization, limited awareness, and lack of regulatory framework, which were stated by more than two participants. Based on interview data, the most common reason among interviewees to lead the African region is the most vulnerable for SF was a lack of regulatory framework, followed by profit maximization, longer supply, rural nature, and limited awareness.

The primary factor, a lack of regulatory framework, has been leading to more severe situations when combined with the fact that there are high rates of import pharmaceuticals. Actually, according to the United Nations Economic Commission for Africa (UNECA), it was estimated that Africa imports about 94% of its pharmaceutical and medicinal needs from outside the continent[37].

"We rely on a lot of imports ··· it's a lack of presence and vigilance in those African countries for those brand owners that are importing the products." (Interviewee 6)

Furthermore, the cultural practice was mentioned by only one participant but it seems to need to be paid attention to. This is because it shows us what is a big practice vividly in the region causes these problematic situations related to SF, in terms of a real experience taken from daily life.

"if I need medication, my first instinct is not to go to see a doctor. My first instinct is to go to a local pharmacy. I mean, not to go to a hospital pharmacy, but rather to go to a private family pharmacy, and then get my medication in there. So that's a big practice there." (Interviewee 1)

Aside from that, the environmental background also has contributed to such problematic situations as described above. It is weak border security in the African region, especially in conflict areas. Such an environmental background is combined with the high rates of dependence on imports including medical products, thereby leading to these severe situations affecting the public's health adversely.

Table 3. The key codes and quotes for the main causes of the problematic situations related to SF in the African region

Key code	Quotes used during the interview
Rural nature (Found 2)	*"As you go lower in the supply chain, there's limited awareness on these issues of counterfeit medication. Even if it exists, they don't necessarily have a lot of options in terms of distributions that you find since they have only one distributor. With one distributor, you'd really hope that distributor is actually the legit one but that's not always the case. The rural nature of some of the pharmacies could potentially be contributing to this situation" (Interviewee 1)* *"If you are living in lower LSM[3], you have to travel to go to a formalized pharmacy. So, what they tend to do is to go to spaza shops which is a pop-up shop that is around the corner that sells household goods, bread, and milk. Also, they would sell over-the-counter medication". (Interviewee 5)*
Profit maximization (Found 3)	*"As a business aspect, they want to maximize profits and that's a big thing in many small and medium-sized enterprises." (Interviewee 1)* *"There's a lot of money from counterfeit drugs, unfortunately. Criminals do not care really about the health of people." (Interviewee 3)* *"There's an opportunity for someone to make money illegally with something, that'll happen" (Interviewee 6)*
Limited awareness of SF (Found 3)	*"I think also very limited awareness of really watched counterfeit medications are or what the implications are, especially as you move away from the bigger cities" (Interviewee 1)* *"As a consumer, I would have a lot less confidence that the product being supplied to me would be the real thing. And I wouldn't necessarily know it's real until it arrived, and even then, I'm not convinced I'd be able to tell the difference between a genuine product and a counterfeit product." (Interviewee 2)* *"I would see three things, lack of regulation, lack of awareness on the possibility to identify product and the lack of awareness on the risk posed by falsified medicines." (Interviewee 4)*

[3] LSM (Living Standards Measure): The Living Standards Measure (LSM) has become the most widely used segmentation tool in South Africa. (Source: Eighty20)

Lack of regulatory framework (Found 5)	*"Lack of governance. And the African region has very loose regulations. It takes a very long time to implement guidelines or regulations, which creates a vacuum where substandard products can come." (Interviewee 5)* *"The first reason is the lack of regulatory framework." (Interviewee 4)* *"No real systems in place which could prevent and detect counterfeited drugs. So, it's really hard to detect them." (Interviewee 3)* *"The Africa region is one of the most valuable areas for the counterfeiters because many countries in Africa do not yet have national regulations for the traceability of products that are imported or identification of falsified products." (Interviewee 6)* *"Once they are in circulation, the ability of the regulatory body is to identify, capture these products and then recall them from the market, properly enforcing the law enforcement, prosecuting and putting these criminals in jail. That whole system is very weak in many of these countries, which makes it more incentivized for these illegal traders to do. They are encouraged because they know they're not going to be caught. They know they're not going to be having issues, because of the weak infrastructures and systems available in these countries. So, it's a very huge problem in the health sector" (Interviewee 7)*

Theme 3. Assessment: The role of GS1 standards and current challenges

The five key roles were identified by interviewees to combat SF in the region: 1) providing guidance to the stakeholders in the right direction; 2) meeting regulators' requirements and educating them; 3) getting the regulators to agree to work together; 4) addressing the problem of an artificial shortage; 5) Giving the same language to make communication well across all stakeholders. In this context, it can be seen that, in a few cases, interviewees tended to equate the role of GS1 global standards with the role of GS1.

The first role, providing guidance to the stakeholders in the right direction, was mentioned by half of the participants. In order to guide the stakeholders in the right and same direction, GS1 has been providing guidance on how GS1 standards can best achieve and trying to make sure manufacturers can comply easily in the region.

"What we provide is guidance on the level of the trade item hierarchy to identify. We provide guidance on what is most achievable and easier from an implementation perspective. ··· providing guidance on how GS1 standards can best achieve, making sure that our standards are robust and complete enough to be able to do with the regulator's needs so that the manufacturers can comply easily. That's why we provide guidance not only to Africa but to any region." (Interviewee 6)

"You need to talk to the stakeholders and explain. You need to identify it first, then you need to put a barcode. This is how you need to apply. It's really, a very collaborative effort because you do have to really work with everyone and everyone needs to move forward in the same direction to make a difference for patient safety." (Interviewee 4)

The second role, meeting regulators' requirements and educating them, was stated by three participants. Although GS1 global standards are heavily recognized and mostly used in a number of countries, they are still a new concept in many countries in Africa. In this context, out of seven interviewees, half emphasized that the most important role of GS1 standards is to support all regulators in the region, making sure they could use barcoding or related technology appropriate by giving expertise. Further, in order to do that, meeting their business requirements must take precedence.

"As part of GS1, our job is to make sure that our standards are there to meet the business requirements of the community." (Interviewee 2)

"We don't lobby regulators but we educate them. ··· What we're seeing is, across the continent, more and more education around the importance of the regulator being clear about what they want to do from a regulatory perspective, but allowing the how to be done by the global standards." (Interviewee 6)

The third role, getting the regulators to agree to work together. According to African Union (AU), there are 55 Member States which represent all the countries on the African continent and they are divided into five geographic regions[38]. In addition, these regional blocks work in silos. In this regard, three participants gave the same example – a Call to Action in 2019 in Nigeria – to show how GS1 global standards get the regulators to agree to work together. In 2019, at the 2nd African GS1 Healthcare Conference in Lagos, Nigeria, 25 African regulatory authorities as well as 6 health financing and donor organizations signed a Call to Action, thereby proclaiming their intention to pursue achieve greater supply chain integrity and pharmaceutical traceability by adopting GS1 global standards for fighting SF in their respective countries[39].

"I would like to say the call to action in 2019 in Nigeria. There was a GS1 healthcare conference. I think 25 regulators decided to sign a call to action. And it was to pursue pharmaceutical traceability by adopting global supply chain standards. Africa is divided into different blocks. And in those different blocks, there were different standards. 25 of them in Africa got to agree to work together, which is I think half of Africa. That's a good percentage of regulators to support one standardized harmonization via implementation of GS1 standards, I think that's one that really stands out for me." (Interviewee 5)

"When they agree about three or four years ago to collaborate 25 authoritative bodies in different African countries agreed to collaborate to put in place traceability for drugs and methods of identifying counterfeits. What that means is that they were able to look at models that work in other countries and other parts of the world can see how to adapt them." (Interviewee 6)

"I think the GS1 healthcare conference held in Nigeria made all of about 28 regulatory agencies sign a pledge where they are all going to be adopting the GS1 standards and start implementing and then all these countries are going to be supporting each other to really learn from each other, share their experiences, and then continue to do the implementation" (Interviewee 7)

Fourthly, the GS1 standards have contributed to addressing the problem of an artificial shortage with the ability to capture the data, identify the product, and share the information easily. Basically, the problem of an artificial shortage is due to data that is not properly captured and not visible to the different stakeholders. One of the main roles of GS1 standards is to allow the stakeholders to capture the information easily by scanning.

"In many cases, there is an actual shortage. It's an artificial shortage because data is not properly captured and visible to the different stakeholders. If the medicine is not in this pharmacy, which pharmacy does have this medicine? So, you need a way to identify medical information captured. The GS1 standards allow us to really capture the information easily by just scanning. You are able to populate it into the system which makes it in a standard manner which is a really crucial component." (Interviewee 7)

Lastly, the GS1 standards give all the stakeholders the same language so that they can communicate well, thereby ultimately making traceability and interchangeable data to enable to detection of SF.

"When the regulator shares the information with the supply chain agency, it's much easier if they can talk about the same product and understand each other with the same language. One of the biggest problems is the delay between the regulator and the supply chain agency. ··· Because they are using different languages when they are talking about the same product. They are unable to communicate. So, that takes a lot of back and forth between the two organizations." (Interviewee 7)

"What makes me back up, what makes traceability or any falsified medicines detection scheme works is that the global standards and the data are interchangeable. It has based on some kind of standard that everybody uses. So if you and I were speaking in different languages, you know neither one of us will understand each other, but because we speak the same language, we understand each other." (Interviewee 6)

All interviewees expressed that they have found or faced some challenges while GS1 standards play such identified roles in the region. The majority of participants reported four challenges in common: 1) taking a long time, especially depending on political status; 2) no harmonization (different perspectives and regulations); 3) lack of proper regulatory framework; 4) lack of funding or resource to fight SF. Apart from these major challenges, interviewees raised a few challenges as follows: low awareness, limited technology use, and some solution providers. All current challenges identified are presented in Table 4.

Table 4. The Key codes and quotes for the current challenges identified by interviewees

Key code	Quotes used during the interview
Longtime (Found 4)	*"You can imagine also the time requirement. When you take a longer time to do something, it means, if you had somebody who is from the regulatory authority and they were there for five years, you can do it within five years then you get a new head and then they have to start again from scratch. You need to start teaching them again about traceability." (Interviewee 1)* *"Unfortunately, we didn't play with the best leaders. And what happens is, if you want to implement solutions to fight against counterfeits, you support the current president because they placed you there because of allegiance in a way. Then, after the next general elections, another president comes in and replaces the entire cabinet and also has his own allies. So, if you want to put traceability systems, you may start something entirely different." (Interviewee 5)* *"We see a lot of willingness to move forward with a regulatory framework with the right technology including global standards to address this issue, but nevertheless, it takes a lot of time." (Interviewee 4)* *"It's a marathon. And it's really true. It takes a lot of time and I've warned them you can't expect to implement standards and traceability today. It takes a half of a year till this is all done. It's really a very deep integration into systems, processes, and awareness in a country. So, it takes a lot of time." (Interviewee 3)*

No harmonization (Found 3)	*"I think GS1 really plays such a huge role sometimes. It's very difficult to kind of put all the connect all the dots because we play in so many industries to realize and scale their traceability or solutions." (Interviewee 5)* *"There are so many different types of medical devices that there are different regulations for them. There are different time scales for them. ··· We try and make sure that everyone who is regulating something does things in the same manner as other regulators. Now that is a challenge" (Interviewee 2)* *"When you look at African region, that collaboration is very weak. There is not even a standard regulatory monitoring system across the border in Africa. Because not only they don't want it but they don't have resources, manpower, the capacity to go beyond even their own country and then do this cross-border collaboration. There are efforts but they are very small." (Interviewee 7)*
Lack of funding (Found 3)	*"Another thing I would say is in terms of funding. Typically many African countries are changing slowly, but typically countries in Africa do not necessarily invest a lot in the information system." (Interviewee 1)* *"Africa has a really big continent with a lot of other problems. To solve these problematic situations, they need some work, education training systems, and money quite a bit to implement." (Interviewee 3)* *"The right medicines are not available at the right place. These are with the shortage of data either shortage of finance and so on." (Interviewee 7)*
Limited resource (Found 2)	*"Scanning it means you have to have a computer and have somebody who knows how to use a computer. You need to have electricity. You need to have a safe room, and while this sounds very obviously available, these are not necessarily available throughout the countries." (Interviewee 1)* *"Implementation of solutions to fight SF usually involves a lot of development work and some of them don't either have the resources to do it. That's why you see donor agencies that support them to implement those kinds of solutions." (Interviewee 5)*
Low awareness of GS1 standards (Found 2)	*"This is the lack of awareness throughout the entire level. I'm talking about government officials, hospital administrators, patients, and customers. There's very limited awareness of what the GS1 standards are and what they can do." (Interviewee 1)* *"The biggest challenge is awareness. Awareness is very low in the continent. From the policymakers, the policy implementers, the general public and other*

	stakeholders, the awareness about the GS1 standard is limited." (Interviewee 7)
Limited technology use (Found 2)	*"The Africa region probably isn't as advanced as other geographical regions with regards to the adoption of GS1 standards and other ones. So, the assumption is that the technology use isn't as advanced as in other countries like Europe, Asia, and North America." (Interviewee 2)* *"I don't think there is enough technical expertise and capacity in this sector." (Interviewee 7)*
Solution provider (Found 1)	*"The other challenges are solution providers who are coming to Africa and who are trying to really sell solutions which are claimed to be aligned with the global framework. But they are not, and ultimately they end up with the national system, which is very complicated to implement but also not interoperable across countries. So, this is not helpful to fight against counterfeited medicines." (Interviewee 4)*

Although the key code of "solution provider" was mentioned by only one participant, the reason why this study included it is that it provides an interesting point that is different from a common belief. An interviewee reported some solution providers hinder not only implanting GS1 standards but also being interoperable across countries in the region.

Theme 4. Recommendation: How to overcome current challenges and problematic situations

Finally, in order to overcome the current challenges and problematic situations, a few suggestions were made by interviewees, which are presented in the table below (Table 5).

There are four key recommendations. A few actions were suggested for each recommendation. Firstly, raising awareness of GS1 standards in the African region. Very low awareness of GS1 standards in the region is one of the challenges identified. Therefore, as a first step, it is needed to raise awareness for all the stakeholders on what GS1 standards are and what are the roles of GS1 standards. To do that, a participant suggested conducting awareness campaigns across the board.

> *"The awareness campaigns are needed across the board, not only for regulators or governments but also for the patients. Because the issue of counterfeit medications is not only of concern to the government, but it's also concerned to individuals so I think, awareness is also one of the main things that need to be done." (Interviewee 1)*

Furthermore, as a way to raise awareness of GS1 standards in the region, interviewees stressed the importance of collaborative working, learning from each other, and sharing experiences.

> *"We have many countries in Africa that really want to do something against counterfeiting, and also improve their supply chain. I mean, some countries always start and others will follow or learn from them." (Interviewee 3)*
>
> *"At the country level, I think it's stakeholder engagement. We've actually seen that some countries have true stakeholder alignments and collaboration, they have a higher chance of success because everybody is involved in this issue." (Interviewee 1)*

Secondly, interviewees highlighted the need for more education to implement traceability well using GS1 standards.

> *"We always need more education on the benefits of technology. People still don't see the benefit of necessarily barcodes and RFID. ··· You know the prevalence now of mobile phones has certainly helped people understand the benefits of barcodes bring. Again, we're going back to some regions, they don't have that benefit yet, but the mobile phones and the increase in technology adoption have certainly helped." (Interviewee 2)*

Thirdly, most of the participants expressed the importance of the harmonized approach to address these problematic situations. It's true that there are a number of countries in the region that are no regulatory framework properly. No regulatory requirement means no voluntary basis to implement technologies including barcodes or manufacturers are not on a voluntary basis to identify medical products. In this regard, it seems essential to create a regulatory framework in a globally harmonized and interoperable way using GS1 standards. In addition, an interviewee suggested an action to get the harmonized approach as a following:

> *"The other role players also have to align and collaborate with GS1 standards. One is like the Bureau of Standards to make sure that the quality of the product is optimum. We also have other associations which are more scientific so they do the actual analysis and they call themselves SANAS. Also, we have SARS which is responsible for the collection of tax." (Interviewee 5)*

Lastly, having better vigilance locally and globally. One of the biggest issues regarding SF is that the African region has very weak border security, despite high dependence on the imported drug. On the other hand, in the European region, they protect each other's borders. The security in the collaboration between the different regulators is stronger. Thus, it is recommended that the African communities have better vigilance not only locally but globally through internal collaborations. Aside from that, scaling up their own manufacturing of pharmaceuticals can be helpful to have better vigilance.

"We need to scale up our manufacturing of pharmaceuticals because we can have more, better vigilance locally." (Interviewee 5)

Table 5. The actions suggested overcoming challenges from interviewees

Key code	Actions suggested
Raising awareness of GS1 standards	• Conducting awareness campaigns across the board • Stakeholder engagement • Learning from each other and sharing experiences
Education	• Investment in education training systems from donor organizations • More education on the benefits of technology adoption
Harmonized approach	• Creating a regulatory framework in a globally harmonized and interoperable way • Collaboration with other African standards (i.e. Bureau of standards, SANAS, and SARS) • Use the same language (i.e. GS1 standards) • Enacting a standardized method of sharing information or tracing or identifying falsified medicines
Having better vigilance	• Scaling up manufacturing capabilities • Getting the regulatory framework in support of GS1 standards

The best recommendation that all interviewees commonly stressed was working together not only externally (donor organizations) but also internally (African Union) to implement these suggested actions successfully.

5. Discussion

5.1 Beyond the current role of GS1

Despite the fact that the adoption of GS1 traceability standards has been recommended by WHO and GAVI[40], a number of African communities have still low awareness of GS1 standards. Moreover, as of 2022, there are still many countries in the region that have no strategy to address issues of SF properly (Figure 1).

Figure 1. The status of GS1 standards adoption in African countries in healthcare sector

(Resource: Internal Data)

In this context, the findings of this paper point up the need for a proper regulatory framework or strategy for SF by sharing problematic situations related to SF. Also, they will contribute to understanding the role of GS1 global standards to combat SF in the region, which can get the African communities who have no proper system or strategy to identify SF consider adopting GS1 global standards as an option.

Further, this paper suggests that stakeholders across the supply chain and further international organizations will need to engage in raising awareness of GS1 standards in order for mitigating problematic situations related to SF in the region, which ultimately lead to improving their interests. Moreover, we need to consider beyond the current role of GS1 global standards carried out in the region to move forward. In order to do that, we should look back at what could be done better and what worked well. The direct impacts of the work done by development partners are as followings: 1) increased awareness of GS1 standards at the country level; 2) several suppliers become members of GS1 Member Offices' as a result of the desire to meet procurement requirements of

donor organizations; 3) a growing number of products in circulation in the African market already have GS1 markings thus enabling pilot projects and similar activities; 4) joint effort in raising awareness of the standards thus supporting/encouraging African countries to take necessary action. In fact, they are similar to the role of GS1 standards that participants believed should be strengthened to help combat SF in the region.

5.2 How to collaborate GS1 standards with other solutions for SF

It needs to be discussed what else can contribute to supporting to fight against SF, except for GS1 global standards, and how to collaborate GS1 standards with other existing solutions for SF. Although the GS1 standard is one of the means to reduce their burden in that it allows regulators to identify, capture, and share the information regarding SF and recall them easily and more efficiently, it is not a panacea for all the problems related to SF. In this regard, it would be better or quicker to mitigate such problematic situations caused by SF if GS1 standards and other existing solutions can work together in terms of complementary cooperation.

First of all, ICMRA (International Coalition of Medicines Regulatory Authorities)'s recommendations. ICMRA has issued a broad set of recommendations outlining how regulators and industry can set up track and trace systems that are globally aligned to ensure SF does not infiltrate supply chains. According to the ICMRA recommendations, there are 5 principles for successful implementation of product identification or traceability system for pharmaceutical products: 1) Harmonized Standards; 2) Strategic Planning; 3) Stepwise Approach; 4) Framework for implementation; 5) Early Stakeholder Engagement. Based on the outputs from interview data, it is highlighted that there were no harmonized standards in the continent and even regional blocks work in silos. Thus, the harmonized approach is crucial in the region when they implement a traceability system for medical products. The GS1 standard can help it by providing the same language and one global standard. In addition, ICMRA strongly endorses the idea that regulators use international standards. This is because, for interoperable national and regional track and trace systems, using widely accepted international standards such as GS1 is essential that products can be uniquely identified on a global basis which is only possible if every country aligns on the specifications defined by compatible international standards.

Secondly, surveillance and monitoring system. With the globalized production chains and the increased interconnectedness of the pharmaceutical market, in 2013, the WHO launched the Global Surveillance and Monitoring System to encourage countries to report cases of SF[41]. It was established in Africa in July 2013. This system helps 1) to improve reporting of SF; 2) assess more accurate the scope, scale, and harm caused by SF; 3) provide technical support in emergencies; 4)

issue medical products rapid alerts; 4) gather validated evidence; 5) strengthen regional and national regulatory capacities to prevent, detect, and respond to SF[42]. In addition, there is also the WHO Medical Product Rapid Alert System that facilitates a rapid and accurate response to incidences related to SF for reducing the incidents of SF[43]. Through this system, a number of incidents of SF have been reported in the African region which is leading in terms of the number of reports[44]. However, according to the interview results, in reality, there is still a lack of systematic surveillance systems to detect SF. Thus, this surveillance system has to be strengthened and expanded, and further a proper monitoring system to collect information on aggregating demand should be improved as well. Also, such surveillance and monitoring systems are important not only to detect or prevent SF but also to generate evidence for police to be empowered to enforce the related law against counterfeiters. In this context, the GS1 standards can be helpful to support strengthening these systems by making sharing and capturing information/data easily which are interoperable across all the stakeholders.

Lastly, 'Track & Trace' technological innovations. Considering that generally, in the African region, there is a lack of technologies to guarantee product safety and the progress on traceability has been limited compared to other countries[45]. Aside from such WHO's global medicine directives, there are four leading 'Track & Trace' technological innovations available in the market that can be used to detect the authenticity of medicines - Coding, Tamper-Evident seal, Aggregation, and GS1 international initiatives[46]. But, it is rare that a country in the region has sufficient resources and capacity to conduct such innovations to address issues of SF. In this regard, among these innovations, implementing GS1 is one of the good options in that the organization of GS1 has already been working together with donor organizations in the African region. So, some of them already understand GS1 standards or cooperate with the GS1 system, which could allow the region to put Track and Trace systems in their supply chain easier with financial or technical support from these organizations.

5.3 Limitations

This study has a limitation in the number of participants (interviewees) involved in fetching the research data. Also, there was a lack of data from external experts. But, the data quality and reliability from interviews were not compromised and supplemented with literature reviews.

In addition, this study didn't suggest how to overcome socio-cultural challenges including cultural practices that many African citizens depend on word of mouth from their family or friends when they choose which pharmacy is reliable in order to avoid SF.

6. Conclusion

The growing phenomenon of SF continuously leads to putting people's lives at risk and hinders achieving the Sustainable Development Goals (SDGs) in the region, contributing to the death of millions of people from preventable diseases. Therefore, it is crucial to understand why Africa is the most vulnerable place to the prosperity of SF. The factors such as lack of governance of medicine stock, limited awareness of SF, and lack of regulatory framework have contributed to the problematic situation where SF has threatened public health in the region.

To mitigate these situations caused by SF, based on the research output, this study has identified the roles of GS1 global standards which is one of the existing solutions to fight SF, as a toolkit in the region. Moreover, this study demonstrates what should be considered when implementing GS1 standards by analyzing the current challenges. These findings would be helpful to determine adopting GS1 standards for the African community that is interested in improving interoperable and traceability systems to address these situations.

Further, a few recommendations were suggested to overcome the challenges. The African communities and donor organizations should note that solving the challenges is not an individual's responsibility or a country's responsibility. In other words, to apply suggested recommendations successfully, all the stakeholders across the supply chain have to work together. Also, internal cooperation in the continent and external support from international organizations should be accompanied.

Appendix A: Interview Guide

Interview Guide

The role of GS1 global standards in helping combat substandard and falsified medical products in the African region

Purpose:

- To identify the role of GS1 global standards as a toolkit against substandard and falsified medical products;
- To see where GS1 global standards are used for fighting against substandard and falsified medical products;
- To figure out current challenges in the implementation of GS1 global standards;
- To suggest how to overcome the current challenges

Population: Selected experts who are familiar with GS1 global standards

Abbreviations:

IQ: Interview Questions

Introduction: Thank you for agreeing to speak with me today. This interview will be used for only my academic thesis. I'm interested in identifying the role of GS1 global standards as a toolkit against counterfeiting medicines and figuring out current challenges in the implementation of GS1 global standards for that. I would like to ask you some questions about your experiences and expertise in these topics. I would like to learn about these things from your perspective – there are no right or wrong answers. If there are any questions that make you feel uncomfortable, feel free to tell me and we can skip or come back to those questions. Do you have any questions before we begin?

General information

First of all, I would like to begin by gathering some basic information about yourself.

- Could you introduce yourself a bit in terms of your background and expertise?
- What were your roles in organization?
- How long you have been working in this field?

Situation & Background

IQ 1: Could you describe problematic situations you have heard or identified related to substandard and falsified medical products in the African region?

Probes:

- Could you give a specific example?
- Specifically, what do you think are the problematic situations of substandard and falsified medical products threatening public health across the supply chain?
- Do you think many people in your country are using online pharmacy (or platform), is it common in African region?
    - Could you tell me a bit about problematic situations related to substandard and falsified medical products especially due to online pharmacies?
    - Do you think these situations have been affected by COVID-19 crisis?

IQ 2: **Why do you think African region is one of the most valuable areas for counterfeiting medicines?**

IQ 3: Could you describe your experience when you have identified the role of GS1 global standards to support fighting against substandard and falsified medical products in African region?

Probes:

- Did you know any kind of success story or case?
- Do you have any idea how to GS1 global standards can help combat substandard and falsified medical products beyond the current role carried out in African region?
- *If you have no experience*, what do you think where GS1 global standards can be used for fighting against substandard and falsified medical products?

Assessment

IQ 1: Based on your working experiences or expertise, what are the current challenges in the implementation of GS1 global standards in African region to help fight against substandard and falsified medical products?

Probes:

- Could you give a specific example?
- Except for GS1 global standards, do you think what else has contributed to fighting against substandard and falsified medical products?
    - Does it also have challenges?
    - If so, could you explain it in detail?

Recommendation

IQ 1: Could you suggest or recommend how to overcome the current challenges you mentioned before?

Probes:

- Except for GS1 global standards, what else can help overcome the challenges?

Closing Comments: Do you have any further comments or questions?

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