Tackling the Burden of Substandard and Falsified Medicines and Health Technologies in the wake of Poor Regulatory Environment in Somaliland and Somalia

Abstract

The problem posed by the substandard and falsified (SF) medicines is a rising global challenge. WHO estimates that sales of SF medical products in low- and middle-income countries is around US$ 30 billion whereby 1 in 10 medical is substandard or falsified. IGAD regional PMS survey conducted in 2019 to assess quality of oxytocin and amoxicillin samples collected from cross border sites of six member countries involving a total of 86 samples of oxytocin and 37 and 29 of amoxicillin DT & suspension respectively showed that 20.9 percent (18/86) of the oxytocin were substandard (8 out of 9 from Somalia).

The purpose of this article was to enlighten the actions by the Somali NRA to tackle the scourge of SF medicines in Somalia. The literature was reviewed on the issue and evidence from other accessible sources were incorporated including reports of PMS surveys and assessments at national and regional levels as well as author's experiences.

The medicines regulatory capacity is weak in Somaliland and Somalia, where only 16% of total indicators for the regulatory system was in place as per WHO/IGAD rapid benchmarking of the NRA in 2017, increasing the risk of circulation of SF medicines in the local private sector dominated and exclusively import relied pharmaceutical supply chain.

Key actions taken by the NRA to tackle this problem include: enhanced licensing and medicines registration procedures by utilization of good reliance practices, i.e., direct reliance on registration and GMP certificates, WHO PQ/EUL recommendations for COVID-19 vaccines and technical collaboration with NRAs, risk based post-marketing surveillance conducted on quarterly basis with the use of GPHF minilabs and technical collaboration with WHO - WHO Global GSMS.

However, a lot has to be done and considering the weak laboratory capacity and the porous national borders, the risk of local circulation of SF medicines is high and swift actions are needed to ensure access to safe and quality medicines and health technologies in Somaliland. This could be achieved through strengthening the medicines regulatory capacity of the National Medicines Regulatory Authority under the Ministry of Health Development, particularly in areas such as the regulatory system and frameworks, laboratory capacity and testing, post-marketing surveillance, medicines registration and imports control.

1. **Introduction**

Falsification of products that are believed to cure illness goes back to ancient history as in 1500 BC, Queen Hatshepsut of Egypt hired a team to go out hunting for genuine medicinal plants because the market was flooded with worthless fakes(1). The problem posed by the substandard and falsified (SF) medicines is a rising global challenge. Substandard medical products are authorized medical products that fail to meet either their quality standards or their specifications, or both, whereas, falsified medical products are those that deliberately/fraudulently misrepresent their identity, composition or source(1). WHO estimates that sales of SF medical products in low- and middle-income countries account on the order of US$ 30 billion(2).

TABLE 1: EXAMPLES OF SUBSTANDARD AND FALSIFIED PRODUCTS REPORTED TO THE GSMS (2013–2017)

Type of product	Number of Member States reporting	Total no. of product reports	Percentage of all products reported to database [a]
Anaesthetics and painkillers	29	126	8.5
Antibiotics	46	244	16.9
Cancer medicines	19	100	6.8
Contraception and fertility treatments	19	29	2.0
Diabetes medicines	7	11	0.8
Heart medicines	22	75	5.1
HIV/hepatitis medicines	9	43	2.9
Lifestyle products [b]	37	124	8.5
Malaria medicines	26	286	19.6
Mental health medicines	19	45	3.1
Vaccines	11	29	2.0

[a] Since only selected products are reported in this table, the percentages in this column do not add up to 100%. A table showing the breakdown of all reports using the anatomical therapeutic chemical classification is provided in the Annex to the main report.

[b] So-called lifestyle products include products for cosmetic use, erectile dysfunction, body-building and dieting.

Figure 1 Some Examples of the 1500 SF Products Reported to WHO GSS

An estimated 1 in 10 medical products in low- and middle-income countries is substandard or falsified(2). The U.S. Pharmacopeial Convention (USP) reported that a total of 848 samples out of 15, 063, representing 5.6% of total samples, failed the quality test from results of data collected from medicines quality monitoring (MQM) activities spanning the period of 2003–2013 in 17 countries of Africa, Asia, and South America(3). SF medicines are danger to the public health and are associated with detrimental health and socio-economic implications. WHO's report of the situation of counterfeit (fake) medicines in WHO regions for Africa and East Mediterranean revealed that 20 of the participating countries in the survey reported to have carried out seizures of counterfeit medicines (4). IMPACT stakeholders estimate proportions ranging from around 1% of sales in developed countries to over 10% in developing countries, depending on the geographical area(5).

FIG. 1: COUNTRIES IN WHICH SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS HAVE BEEN DISCOVERED AND REPORTED TO THE WHO GSMS, 2013–2017

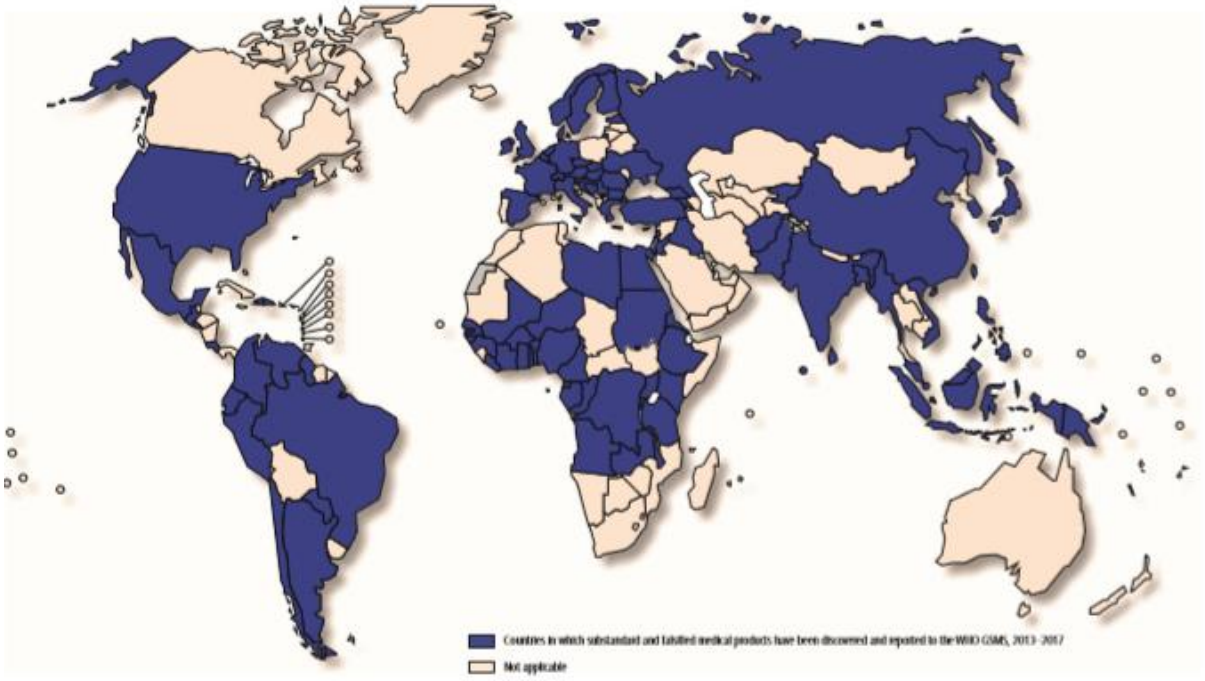

Figure 2 World Map showing Countries Reporting SF Seizures to the WHO GSMS; blue: SF reported, pink: not applicable.

It is impossible to quantify the extent of the problem, but in some areas of Asia, Africa and Latin America, counterfeit medical products can form up to 30% of the market(6). The United States' Food and Drug Administration (FDA) issued an alert about a counterfeit antiretroviral medicine and the UK officials seized 5000 packets of counterfeit flu medication oseltamivir in 2007 and 2006 respectively(5). In light of this, due to the regulatory capacity of the health authorities, it's reasonable to assume that counterfeit and under-quality medicines are prevailing in Somaliland.

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Figure 1. Genuine (Left) and Counterfeit (Right) Cotexcin (Dihydroartemisinin) from Tanzania (Photograph by Manuela Sunjio)

Figure 3 Genuine & Counterfeit Medicines Present Challenge to Differentiate on a Bare Eye.

Substandard and falsified medicines (SF) have dire health and socio-economic impact and poses a global challenge. The health implications include therapeutic failure, drug resistance, serious morbidities or even death of the exposed. In 2004, fake medicines led to a trail of death in Argentina where a healthy 22-year old woman, living in Viedma, Argentina,

who had mild anaemia was given injections of an iron-based preparation, she became very sick and died of liver failure after receiving the seventh of a 10injection treatment(5).

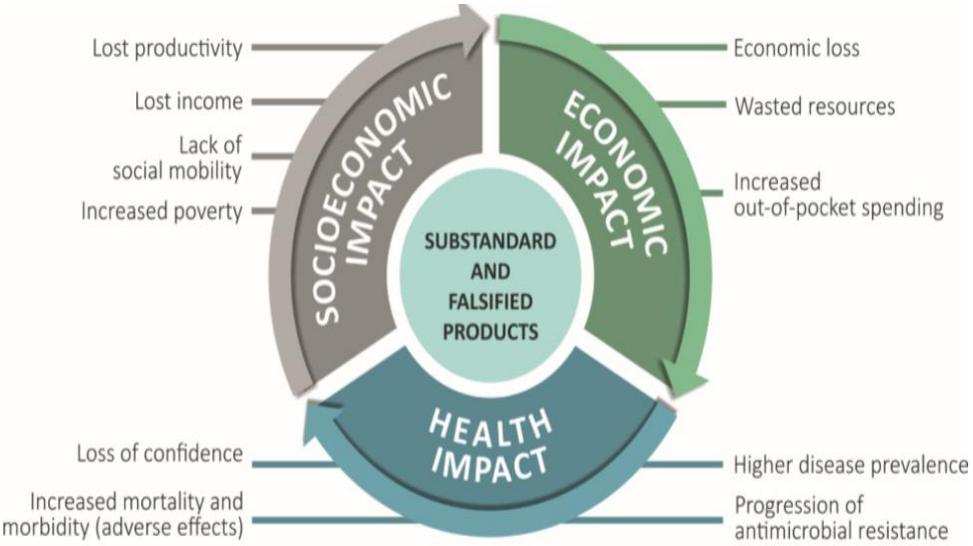


Figure 4 Impact of SF Medicines illustrated

Due to the limited research available to measure the impact of SF medicines, WHO commissioned the development of two models focused specifically on childhood pneumonia and on malaria in sub-Saharan Africa and these models were developed for WHO by the University of Edinburgh (childhood pneumonia model) and the London School of Hygiene and Tropical Medicine (malaria in sub-Saharan Africa model).

Table 3: Impact of substandard and falsified medical products on childhood pneumonia

Prevalence of substandard and falsified products (percentage)	Number of excess deaths in most likely scenario (two-fold increase in CFR)	Number of excess deaths in alternative scenario (four-fold increase in CFR)
1	8 688	18 372
5	37 018	85 438
10	72 430	169 271

CFR: case fatality rate.

Based on a 10% prevalence of substandard and falsified antibiotics, this model estimates that:

- **Up to 72 430 deaths from childhood pneumonia can be attributed to the use of substandard and falsified antibiotics that have reduced antibiotic activity.**
- **This increases up to 169 271 deaths if substandard and falsified antibiotics have no activity.**

Figure 5 Impact of SF Medicines on Childhood Pneumonia: WHO Study on Impact Model

2. Objectives

The purpose of this article was to describe and provide analysis of the current state of medicines and health technologies regulation in Somaliland, illustrate the capacity of the regulatory system and present recommended and immediate interventions and actions needed by the Medicines Regulatory Authority to tackle the burden of substandard and falsified medical products in Somaliland.

In-depth analysis and presentation of the regulatory capacity and existing gaps is made to present the core regulatory functions in line with the WHO Global Benchmarking Tool (WHO GBT) used for benchmarking and assessment of regulatory systems.

3. Methods

The literature was reviewed on the issue and evidence from other accessible sources were incorporated including reports of PMS surveys and assessments at national and regional levels as well as author's experiences

4. Findings

4.1. Country Profile & the Healthcare System

The Republic of Somaliland is situated north of the equator in the Horn of Africa. The total area of the Republic of Somaliland is 137, 600sqkms, and it has a coastline which is 850kms long. Somaliland was formerly a British protectorate and reclaimed its independence from the republic of Somalia after non-successful unity with the southern Somalia which was an Italian colony. Somaliland declared its independence from Somalia in 1991. The Somali civil war seriously affected the country politically, economically and socially. The population of Somaliland was estimated at 3.85 million in 2009 with an annual population growth rate of 3.14%. Life expectancy at birth is between 49 to 60 years. The population consists of nomads 55% and urban and rural dwellers 45%(7). The healthcare system was affected and the healthcare facilities were totally destroyed. The Ministry of Health of Somaliland is charged with health policy development and service delivery oversight functions. There are 10 hospitals including six regional hospitals, 73 MCHs, 152 health posts and 7 TB centers in Somaliland(8). The private sector is estimated to comprise about: 80 clinics and hospitals as well as 779 pharmacies(9). Though reliable data is lacking, it's estimated that the private sector takes approximately 70- 75% of total medicines imports into the country.

4.2 The Medicines Regulatory System

Medicines regulation is needed to ensure that all pharmaceutical products on the market are safe, effective and consistently meet approved quality standards (10). The legal provisions are not in place to support the functions of the National Medicines Regulatory Authority (NMRA).

4.2.1 Legal Framework

Strengths: The country has National Medicines Regulatory Authority (NMRA) under the Ministry of Health. The National Medicines Policy (NMP) which designates NMRA and defines its functions has been formulated in 2014. Also, the National Health Policy (NHP II) which calls for establishment for NMRA has been developed by the ministry of health in 2011. The NMP and the Ministerial decree of April 2016 and July 2016 that establish the NMRA are the main available legal documents with provisions and statements to define regulatory framework of registration and/ or marketing authorization. Both documents recognize procedures to hold, suspend, and/or withdraw or cancel a MA in case there is/are finding(s) on quality, safety or efficacy issues. Furthermore, NMP explains the establishment of the National Pharmacy Regulatory Board (NPRB) as the regulatory framework, which will be responsible for quality control, evaluation, registration, pharmacovigilance, control of standards of production, importation and marketing(11). A rapid benchmarking (Assessment) of the NRA's

capacity by WHO-IGAD Joint Initiative was done in 2017 which found that only 16% of the total indicators for the regulatory system has been implemented.

Weaknesses: The regulatory environment is at its infancy and the government has a limited role in the pharmaceutical sector (7). The government does not provide the necessary political and economic support for the NMRA to effectively carry out its national duties. The legal provisions and guidelines are not in place to support the functions of the NMRA. There are some overlaps in the government bodies engaged in the regulation of the pharmaceutical sector and no clear boundaries of responsibilities are drawn. For instance, the Ministry of Health, National Health Professions Commission (NHPC) as well as the Somaliland's Quality Control Commission (SQCC) have overlapping areas in respect to health facilities licensing, registration and inspections. To address this problem, a nationwide consultation forum is needed to revise and amend the legal acts in place as well as exclude the conflict of authorities so do allow mutual coordination and cooperation to improve the government's capacity to regulate the health sector.

Regulatory Functions	Indicators Implemented	Expected	% Impl.	ML
01-NATIONAL REGULATORY SYSTEM (NRS)	2	10	16%	1
02-REGISTRATION AND MARKETING AUTHORIZATION	2	6	15%	1
03-VIGILANCE (PVL)	1	6	0%	1
04-MARKET SURVEILLANCE AND CONTROL (MSC)	4	6	0%	1
05-LICENSING PREMISES (LIC)	4	6	17%	1
06-REGULATORY INSPECTION (RI)	4	6	20%	1
07-LABORATORY ACCESS AND TESTING (LAT)	0	10	30%	1

Figure 6 Summary of Rapid Benchmarking of the NRA by Joint WHO/IGAD Assessment, 2017

4.2.2 Medicines registration (Marketing Authorization)

Medicines imported into the country are not registered for the ministry of health which increases the likelihood of SF medicines as well as those of unknown origin to circulate in the pharmaceutical supply chain. An important task for a drug regulatory authority (DRA) is to institute a system which subjects all pharmaceutical products to premarketing evaluation, marketing authorization and post marketing review to ensure that they conform to required standards of quality, safety and efficacy(12).

4.2.3 Licensing & Inspection Activities

The licensing of pharmaceutical premises and healthcare facilities is in place. However, standard operating procedures did not exist previously whereby some of the premises' licenses were not regularly issued and when in the case, initial inspection and assessment of the facility in regards to storage practices, infrastructure, human resources and procurement systems was not mandatory requirement until recently the NMRA has developed inspection tools to assess each facility as part of the licensing procedure. Moreover, Inspection guidelines and adequately trained staff to carry out inspection activities are not available. The NMRA should carry out effective inspections to ensure Good Storage Practices (GSPs) and Good Distribution Practices (GDPs). It's a key function of NRAs to require that medicinal products are imported, distributed and manufactured by an authorized persons as well as license and inspect manufacturing premises, importing agents, wholesalers, distributors and retailers (13).

4.2.4 Medicines Safety & Rational Use

There are a tremendous patterns of irrational medicines use though scientific studies to measure the burden are lacking in Somaliland. This increases the risk of medication errors and antimicrobial resistance as well as puts patient safety at risk considering the lack of intact regulations to ensure the rational medicines use and safety. Nationwide implementation & effective use of the evidence-based Somaliland Standard Treatment Guidelines (STGs) developed by the MoH in 2017 through the support of WHO could address the burden of irrational medicines use.

Though relevant data is limitedly available in developing countries, many studies report high burden of medication errors in the developed world. For instance, the U.S. Institute of Medicine estimated that up to 98,000 people die each year from medication errors in U.S. hospitals at a cost of up to USD 29 billion per year (14). A study on adverse drug reactions resulting from medication exposure estimated that over 70 percent of ADRs resulted in hospitalization in the United Kingdom could have been avoided (15). A meta-analysis estimated that ADRs alone—excluding medication errors—killed over 100,000 people in 1994 and were the fourth to sixth leading cause of death in the United States (16).

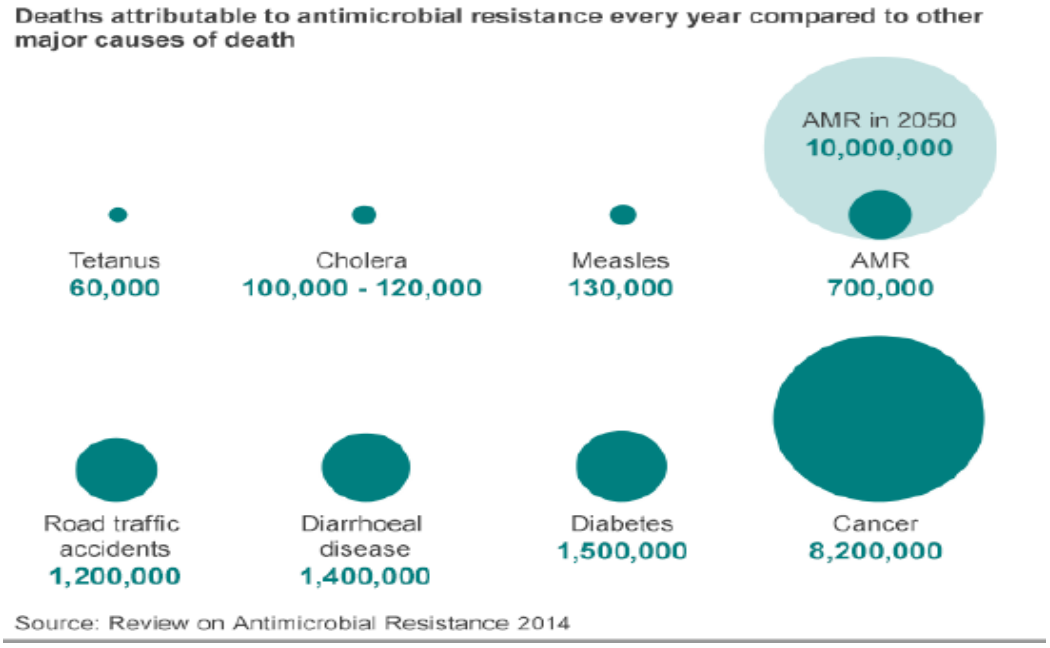


*Figure 7*Global attributable mortality to AMR

4.2.5 Sources of Medicines & the Pharmaceutical supply chain

The pharmaceutical sector is the least-investigated segment of the health system in Somalia or Somaliland. There are no local pharmaceutical manufacturing companies in the country whereby all medicines and other health commodities are imported. Majority of the supply is shared among the international aid organizations and the private sector. Some International NGOs and UN agencies such as WHO, UNICEF & UNFPA provide drug donations and kits to public health facilities such as MCHs and hospitals. The MoH has Central Medical Stores department which oversees the public supply system of medical supplies. It has well trained and adequate staff at the central office who handle the central medical warehouse operations. The SCM department also oversees six regional warehouses.

However, the CMS has not yet started public procurement function and there are no regional supply chain officers, the latter a challenge which hinders the operational efficiency of the public supply management system. Health facilities are irregularly supplied, with an inadequate selection of drugs through a kit system (meaning that every month there is wastage and stock-outs (WHO/UNFPA, 2009). Availability of essential medicines is a critical component of health services & irregularities in their supply system hampers efforts to provide quality & effective healthcare. Inappropriate storage of essential medicines that need cold chain storage such as Oxytocin and biological products is also widespread. To address these challenges in the public supply sector, there is a National Supply Chain Master Plan 2014-2019 developed by the MoH in collaboration with partner agencies to guide efforts to improve the public supply sector.

Other challenges in the public procurement system includes inadequate rules, regulations and structures; public sector staff with little experience in responding to market situations; lack of decentralized supply system, absence of a comprehensive procurement policy; government funding which is insufficient and/or released irregularly; donor agencies with conflicting procurement regulations; fragmented drug procurement at provincial or district level; push supply which leads to frequent oversupplies which expire at public warehouses. Moreover, there is a problem with medicines selection at national level. The NMRA has finalized the first ever national essential medicines list (nEML) in 2017, an evidence-based document reflecting the national epidemiological patterns as well as the safety, efficacy and cost profile of medicines included, with WHO's technical support which can serve as the policy document to guide public procurement and donor aid. WHO recommends that public sector procurement should be limited to an essential drugs list or national/local formulary list (17).

4.2.6 Access to Quality Control Laboratories and the Risk of SF Medicines prevalence

There are no existing well established medicines quality testing laboratories in the country. The ministry of health has two minilab kits donated by WHO which is not currently fully operational due to lack of supplies and reagents. The minilab kit can perform basic quality testing and is effective to control the quality of medicines at ports of entry and remote areas in low resource countries. It covers about 90 compounds taking into account essential medicines prevailing in developing countries for priority diseases and mother & childcare. The quality standards which pharmaceuticals must comply with, as well as the methods to prove their compliance or non-compliance, are defined in the pharmacopeias, such as the International Pharmacopeia, the United States Pharmacopeia and the British Pharmacopeia. However, the equipment required for pharmacopeial analysis are expensive and delicate, requiring an appropriate laboratory and regular maintenance and operation by skilled personnel. This is a challenge for most of LMICs. The Minilab kit system is developed by Global Pharma Health Fund (GPHF), a charitable organization supported by the German Merck KGaA pharmaceutical company(18).

Ten faith-based drug supply organizations in seven countries of Africa and Asia were each equipped with a Minilab and tested 869 medicine samples, 21 were confirmed to be substandard or falsified medical products and authors concluded that surveillance of poor-quality medicines can be carried out by local organizations in low- and middle-income countries using such simple but low-cost technology(18).

Table 1 Laboratory Test Results: Report of Post-Marketing Quality Surveillance of Antimalarial & Antiretroviral Medicines Samples Collected from Public Health Facilities in Hargeisa, NMRA, MoHD.2019.

Product/Category		# Samples	Quality Control Test Parameters					
			Identity		Assay (API Content)		Disintegration	
			Pass	Fail	Pass	Fail	Pass	Fail
Antimalarials	Arthemeter + Lumefantrine (AL) tabs	1	1	0	1	0	1	0
	Quinine Sulphate tabs	1	1	0	1	0	1	0
Antiretrovirals	Zidovudine + Lamivudine (3TC/ZDV tabs	1	1	0	1	0	1	0
	Zidovudine (ZDV) tabs	1	1	0	1	0	1	0

IGAD regional PMS survey conducted in 2019 to assess quality of oxytocin and amoxicillin samples collected from cross border sites of six member countries involving a total of 86 samples of oxytocin and 37 and 29 of amoxicillin DT & suspension respectively showed that 20.9 percent (18/86) of the oxytocin were substandard (8 out of 9 from Somalia) while all amoxicillin samples have passed the quality tests. The registration status of the samples also showed that 41.7 percent of oxytocin products and 70 percent of amoxicillin products circulating in the region were not registered by the relevant Medicine Regulatory Authorities of the region.

Table 2 Assay Results & Registration Status of Collected Samples; Adapted from IGAD-MRH Expert Working Group on PMS (2019). Results of Regional Post-Marketing Survey to Assess the Quality of Oxytocin and Amoxicillin at IGAD Cross-Border Sites. Promoting the Quality of Medicines (PQM) Program. US Pharmacopeial Convention. Rockville, Maryland.2019.

Product Name	Manufacturer	Origin Country	Registration Status in Somalia	Total Samples Tested/Product	Assay Result (in Samples)	
					Passed	Non-complian

Oxytocin	Opsonin Pharma Limited	Banglades h	Not registered	9	1	8
Oxytocin	ISIS Pharmaceutical s & Chemical Works	Pakistan	Not registered			
Oxytocin	Huzhoun Pharmaceutical s	China	Not registered			
Amoxicilli n suspension	Athlone Labs limited	Ireland	Not registered	2	2	0
Amoxicilli n suspension	Riva Pharma	Egypt	Not registered			
Amoxicilli n DT	Beyoum Pharmaceutical s	China	Not registered	6	6	0
Amoxicilli n DT	Huzhoun Pharmaceutical s	China	Not registered			

Due to the lack of effective quality assurance system of medicines, it's not possible to estimate the burden of SF medicines in Somaliland. This leaves medicines imported into Somaliland to be supplied directly to consumers and patients without passing through the necessary quality screening to assure their safety, quality and efficacy. Only those medicines supplied by some of the aid agencies such as WHO and UNICEF are of assured quality from prequalified suppliers (suppliers undergoing thorough assessment of capacity to manufacture/supply quality and safe drugs including GMP inspections of source manufacturers). Its recommended that reliable suppliers of high-quality products must be preselected (prequalified)(17). Prequalification of source suppliers and closed bids helps to ensure safety, quality and efficacy of procured medicines.

4.2.7 Factors that Help Circulation of SF Medicines

The poor medicines regulatory capacity in lower- & middle-income countries, in general, and Somaliland, in particular, increases the risk of circulation of SF medicines. Substandard and falsified medical products are most likely to be found where access to affordable, quality, safe and effective medical products is constrained, standards of governance are low and the tools and technical capacity to ensure good practices in manufacturing, quality control and distribution are limited(2). Internet sales of medicines also contributes to the

problem where illegal outlets exist selling medicines of unknown origin to the patients without medical prescriptions(5).

There is a large under-regulated private pharmaceutical sector in Somaliland which lacks the capacity and intention, to some extent, to procure safe medicines from reliable sources. The lack of marketing authorization of medicines exacerbates the situation.

4.2.8 Tackling the Challenge at Global & Regional Level

Having so far discussed on the magnitude of the problem arising from substandard and falsified medicines as well as its detrimental implications, the question comes to how it can be addressed. Facing this challenge is a global shared responsibility that needs multi-stakeholder and collaborative approaches that create partnerships and coordinated platforms to enlighten the issue, increase awareness of the stakeholders and harmonize efforts to better and effective action. These approaches can encompass on prevention of the sales and distribution of SF medicines, develop mechanisms that allow early detection of these products and subsequent regulatory action and incident management by health authorities.

On a global scale, the World Health Organization spearheaded the creation of the WHO IMPACT coalition, which is supported by national medicines regulatory authorities of WHO Member States and a number of international stakeholders including Interpol, Organization for Economic Cooperation and Development, World Customs Organization, World Intellectual Property Organization, World Trade Organization, European Commission, Council of Europe, International Federation of Pharmaceutical Manufacturers and Associations(5). To achieve its mandate, IMPACT focuses on legislative and regulatory infrastructure, regulatory implementation, the use of technology and communication as priority areas. Also, the WHO's Global Surveillance of Medicines System (GSMS) sets the three corner stone strategies of prevent, detect and respond to address the challenge posed by the SF medical products.

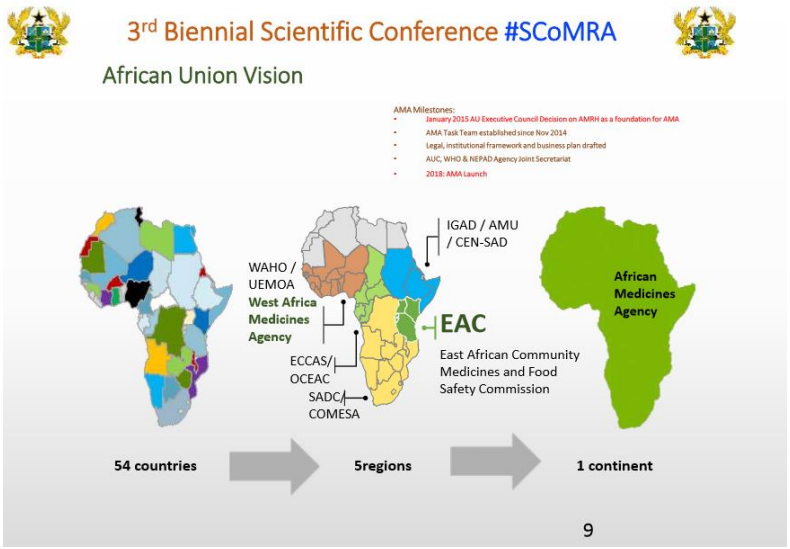
Building the capacities of National Regulatory Authorities (NRAs) as well as public supply chain systems could be an effective strategy to ensure safe, effective and quality products are manufactured, procured, distributed and consumed. Creating technical information sharing and collaboration among NRAs allows early detection and unified regulatory responses at regional, continental and international level.

Figure 8 WHO GSMS Approaches to tackle SF Medicines

The African Medicines Regulatory Harmonization (AMRH) initiative is a typical example of harmonized African initiative which aims to improve access to quality, safe and efficacious medicines by providing an enabling regulatory environment for pharmaceutical sector development in Africa. The AMRH Strategic Plan defines the strategic direction for the medicines harmonization agenda in Africa and provides direction to advance the development of the pharmaceutical sector and provides guidance in monitoring and evaluation.

The African Ministers of Health unanimously adopted the Treaty for the establishment of the African Medicines Agency (AMA) in Geneva, 2018. The AMA will promote the adoption and harmonization of medical products regulatory policies and standards, provide regulatory guidance and provide technical assistance on regulatory matters to countries that lack the capacity and resources to do so.

Figure 9 the African Medicines Regulatory Harmonization (AMRH) Initiative: Update on Continental Progress



AMA ratification and operationalization is currently underway with so far over 27 countries signing the treaty for establishment of AMA as of February, 2024. Moreover, Technical Committees (TCs) of the agency have been restructured and currently operationalization of core TCs ongoing and the effort is led by the African Union Development Agency (AUDA-NEPAD). The technical committees will be responsible for carrying out specific assessments and conducting scientific reviews of dossiers, including quality aspects, and clinical trial applications; inspection of manufacturing facilities; and providing scientific opinion to facilitate the proper functioning of the AMA.

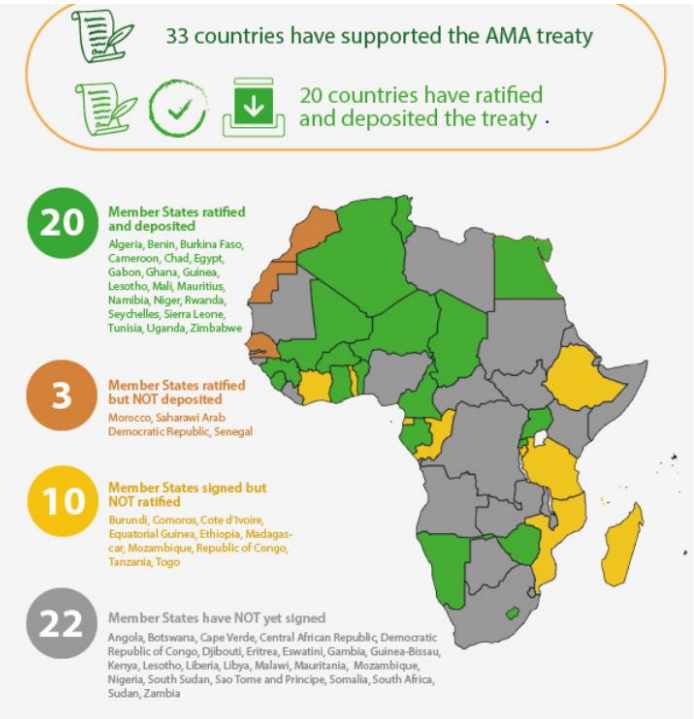


Figure 10AMA treaty signing and ratifications, by end of 2021, Source AUDA-NEPAD

https://www.nepad.org/publication/african-medicines-agency-ama-brochure

5. Conclusion & Recommendations

Considering the challenges presented in this article and in light of the weak regulatory capacity and the porous national borders, the risk of SF medicines circulating in the pharmaceutical supply chain is very high and swift actions are needed to tackle this issue. Strengthening the medicines regulatory capacity of the National Medicines Regulatory Authority, particularly in areas such as the regulatory system and frameworks, laboratory capacity and testing, post-marketing surveillance, medicines registration and imports control, is vital to ensure access to safe, quality & efficacious medicines and health technologies in Somaliland and will safeguard the public health and health security as well as contribute to achieving the national health targets as per the national medicines policy and strategic plans of the Ministry of Health Development of Somaliland.

References

1. Summary E. No Title.
2. World health organization (2018). Substandard and falsified medical products: Key facts. WHO: Geneva. 2018;2018.
3. Screening Medicines with the GPHF-Minilab ™. :881.
4. REPORT OF THE SITUATION OF COUNTERFEIT MEDICINES BASED ON DATA COLLECTION TOOL. 2010;
5. Counterfeits have harmful effects on patients ' health and can kill Counterfeits frustrate efforts to deal with high burdens of disease Counterfeits undermine the credibility of health care systems Increased international collaboration is essential to bea.
6. America L. FACT SHEET. 2010;
7. REPUBLIC OF SOMALILAND MINISTRY OF HEALTH 2 nd Edition. 2011;(November):1–48.
8. Somali FORTHE. STRENGTHENING FOR THE SOMALI. 2007;
9. THE PRIVATE SECTOR AND HEALTH : A survey of Somaliland private pharmacies.
10. Perspectives WHOP. Effective medicines regulation : ensuring safety , efficacy and quality. 2003;1–6.
11. Somaliland NMP pdf.pdf [Internet]. Available from: file:///D:/My professional docs/Reg docs/NDRA/Legal Framework policy/Somaliland NMP pdf.pdf
12. Book B. Marketing Authorization of Pharmaceutical Products.
13. National_drug_regulatory_legislation_Annex8TRS885_en.pdf.
14. Kohn LT, Corrigan JM, Molla S. To Err Is Human. 2000.
15. PV in africa primohamed citation.
16. Lazarou J, Pomeranz BH, Corey PN. Incidence of Adverse Drug Reactions in Hospitalized Patients. 2009;
17. who good procurement.pdf.
18. Sherma J. ANALYSIS OF COUNTERFEIT DRUGS BY THIN LAYER CHROMATOGRAPHY. 2007;(19):5–20.