

**Review Form 3**

Journal Name:	<a href="#">Asian Journal of Medicine and Health</a>
Manuscript Number:	Ms_AJMAH_127378
Title of the Manuscript:	Tackling the Burden of Substandard and Falsified Medicines and Health Technologies in the wake of Poor Regulatory Environment in Somaliland and Somalia
Type of the Article	

**PART 1: Review Comments**

<b>Compulsory</b> REVISION comments	<b>Reviewer's comment</b>	<b>Author's Feedback</b> (Please correct the manuscript and highlight that part in the manuscript. It is mandatory that authors should write his/her feedback here)
<b>Please write a few sentences regarding the importance of this manuscript for the scientific community. Why do you like (or dislike) this manuscript? A minimum of 3-4 sentences may be required for this part.</b>	The paper shines light on critical issues in Somalia's pharmaceutical supply chain. The paper provides insight into the threats facing the country and provides potential solutions. The paper has great potential to be very impactful and insightful for awareness of the problems Somalia is facing. However, the paper needs to provide further descriptions and analysis to support the proposed solutions. The authors do not provide original data	
<b>Is the title of the article suitable? (If not please suggest an alternative title)</b>	<b>I would recommend slightly changing the title my suggestion is below:</b>  <b>The Burden of Substandard and Falsified Medicines and Health Technologies in Somaliland and Somalia</b>  I am making this suggestion because the other reads that the burden is solely the result of poor regulatory action of the Minister of Health. However, your data and the Minister of Health reports tell a story of a regulatory agency that is overstretched and additionally, should not be fighting the battle alone. For example, you mentioned porous national borders contribute to the flux of adulterated medicine. I think the suggested title or some alternative form keeps the reader in a more holistic mindset instead of jumping to conclusions about the Minister of Health agency gaps.	
<b>Is the abstract of the article comprehensive? Do you suggest the addition (or deletion) of some points in this section? Please write your suggestions here.</b>	More explanation is needed around the following statement "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"	
<b>Are subsections and structure of the manuscript appropriate?</b>	Yes	
<b>Please write a few sentences regarding the scientific correctness of this manuscript. Why do you think that this manuscript is scientifically robust and technically sound? A minimum of 3-4 sentences may be required for this part.</b>	For example, the author uses the following sentence as major evidence of a poor regulatory system "WHO-IGAD Joint Initiative was done in 2017 which found that only 16% of the total indicators for the regulatory system has been implemented" However, there is no mention of what the indicators are and this is a pattern throughout the paper. The manuscript has good potential to be technically sound and robust.	
<b>Are the references sufficient and recent? If you have suggestions of additional references, please mention them in the review form.</b> =	>The references are <b>not</b> sufficient. For example, reference 1 is "Summary E. No Title." Without further context, your references are not traceable. All references should be traceable.  >Somalia's health ministry has acknowledged drawbacks and released an investment case report. I recommend incorporation information from this report. <a href="https://www.globalfinancingfacility.org/sites/default/files/Somalia-GFF-Investment-Case.pdf">https://www.globalfinancingfacility.org/sites/default/files/Somalia-GFF-Investment-Case.pdf</a>	

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<p><u>Minor REVISION</u> comments</p> <p><b>Is the language/English quality of the article suitable for scholarly communications?</b></p>	<p>&gt;&gt;Abstract and throughout:                  &gt;Abbreviations need to be fully written out before use. Example: In the abstract WHO is used, it should be "World Health Organization (WHO)"                  &gt;&gt;Introduction:                  &gt;SF medicines are dangerous to the public health and</p>	
<p><u>Optional/General</u> comments</p>	<p>General Comments Per Section                  &gt;&gt;<b>Introduction:</b>                  &gt;Table 1 appears to be a screenshot taken from a different report that is not appropriately cited. Please convert to your table and cite the source. Additionally, it is currently labeled Table 1 and Figure 1. Figure 1 is not referenced within the body of the text. Please incorporate the data in your writing. Similar comments for multiple figures throughout the manuscript. An approach I typically take when using others data or figures is to modify them and reference them appropriately. There is no need to keep the original                  &gt;&gt;"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)" Please describe how the estimate of 30% was made. I would also recommend refraining from the use of impossible and use difficult. It would strengthen the paper to explain why these estimates are difficult to obtain. There are multiple variables such as insufficient reporting, current inability to catch all, lack of analytical quality checks at the point of care (pharmacies), etc. Further, I would recommend you look at Valisure a pharmacy that provides analytical testing on its inventory to ensure quality.                  &gt;"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)." What was wrong with the medicine?                  &gt;&gt;<b>Findings</b>                  &gt;I would recommend the addition of environmental and logistical critical to quality variables associated with the country as well. For example, what ICH Stability Zone is the country in? Is there adequate cold storage? Although the historical information is interesting I recommend removing at least some of it. Saying political challenges and financial burdens with proper citations is enough to get the point across and will provide you with more space to describe technical challenges such as the availability and adequacy of cold storage, lacking advanced analytical equipment, etc. I would like to see the acknowledgment of good drugs entering the supply chain that become degraded due to improper handling as this is a major contributor to substandard drugs.                  &gt;Are pharmacies often cited for violations? Information on previous citations can strengthen the claims of this paper.                  &gt;"WHO-IGAD Joint Initiative was done in 2017 which found that only 16% of the total indicators for the regulatory system has been implemented" What were the indicators?</p>	

**PART 2:**

	<b>Reviewer's comment</b>	<b>Author's comment</b> (if agreed with reviewer, correct the manuscript and highlight that part in the manuscript. It is mandatory that authors should write his/her feedback here)
<p><b>Are there ethical issues in this manuscript?</b></p>	<p><i>(If yes, Kindly please write down the ethical issues here in details)</i></p>	

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**Reviewer Details:**

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