Author’s response to reviews

Title: Scarce quality assurance documentation in major clinical trial registries for approved medicines used in post-marketing clinical trials

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Reviewer #1:

The ms has been improved but two aspects remain in need of attention:

Page 7 - line 52

'While solely falsified medicines are addressed by law and security enforcement authorities, all three types of SF medicines are assessed by drug regulatory authorities (DRAs) based on criteria determining their quality as shown in Box I.'

is not correct

Suggest edit to:

All three types of SF medicines are assessed by drug regulatory authorities (DRAs) based on criteria determining their quality as shown in Box I. Falsified medicines especially will need involvement of law and security enforcement authorities'
Soley is not correct as law enforcement is also potentially relevant to substandard and unregistered medicines

Author’s response

The author appreciates the Reviewer’s proposal which was implemented, accordingly. The following wording was deleted.

‘While solely falsified medicines are addressed by law and security enforcement authorities, all three types of SF medicines are assessed by drug regulatory authorities (DRAs) based on criteria determining their quality as shown in Box I.’

The wording was replaced by the following one:

“All three types of SF medicines are assessed by drug regulatory authorities (DRAs) based on criteria determining their quality as shown in Box I. Falsified medicines especially will need involvement of law and security enforcement authorities.”

Page 9, line 19:

'The CONSORT guidelines were followed for the reporting of this study.'

This is incorrect - please see the CONSORT guidelines that are for reporting clinical trials and not for reviews

Author’s response

The wording 'The CONSORT guidelines were followed for the reporting of this study.' Was deleted and replaced by: “The CONSORT guideline when reporting a randomised trial were followed.”
Comments from associate editor:

Thank you for clarifying that the WHO abstract is not publicly available and so does not need referencing. However, I note that there are some on-line references, which do not have an access dates. Please include an access date. Please refer to https://trialsjournal.biomedcentral.com/submission-guidelines/preparing-your-manuscript for guidance.

Author’s response: sources access dates are added in the manuscript version 3.