Reviewer's report

Title: The policy-practice gap: describing discordances between regulation on paper and real-life practices among specialized drug shops in Kenya

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Reviewer: Paula Tavrow

Reviewer's report:

The authors have done a good job of revising the manuscript and addressing my concerns in their comments. I now appreciate that their intent was simply to determine if there was compliance with regulations, but not to determine if these regulations were essential to the public's health.

I still believe, however, that the following statement in the article, which is found in the abstract (and similarly in the conclusion) needs to be modified. Currently, the authors state:

"Under such a system, rural SDSs operating in low-resource setting, and selling a limited range of medicines, would be exempted from certain regulatory requirements."

I still believe that this is not an acceptable conclusion. No SDS should be allowed to operate in a way that could be injurious to the public's health. Rather than issue blanket "exemptions" to SDSs in low-resource settings, it would be far better to first review and revise the existing regulations, determining which are essential and which are optional/advisable, based on consumer safety. Then the new regulations could be sent to the SDSs and inspectors could be re-trained.

For example, if it is determined that a nurse has sufficient capacity to dispense pharmaceuticals safely, this could be inserted into new regulations. However, if there are some pharmaceuticals that only a trained pharmacist can safely dispense, the regulations should note that this class of drugs cannot be dispensed by a nurse but only by a trained pharmacist (or by a nurse who obtains a certain certificate).

Lastly, I think that the authors need to note in their introduction that the intent of their research was not to assess the usefulness/value of the existing regulations, but only the current compliance.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.
Declaration of competing interests:

I declare that I have no competing interests.