Author’s response to reviews

Title: Cost benefit of investment on quality in pharmaceutical manufacturing: WHO GMP pre- and post certification of a Nigerian pharmaceutical manufacturer

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Version: 2 Date: 06 Sep 2017

Reviewer reports:

YINKA ABIOLA ADOJUTELEGAN, MPH (Reviewer 1): How is the conclusion of the cost benefit been 5 times more when the company does not invest in quality arrived at? Quality may be termed relative, some other companies may not carry out as much quality processes but have done enough to qualify for local approvals. I suggests that a comparative analysis with a company investing in lesser quality practices and investment is done to conclude on the relative benefit of quality investments.

Response: In this study we are able to capture the procurement by International Organisations from CHI as a result of their perceived quality of products. The local businesses were the baseline. This is the case with all the other companies in Nigeria. Currently CHI is the only company that donor/international agencies adjudge worthy of procurement due to their quality investment. This paper surveys the benefit of that investment. In other words the benefit here is the international procurement which is currently happening with only CHI.
Chaisiri Angkurawaranon (Reviewer 2): Reviewer comment

MS title: Cost benefit of investment on quality in pharmaceutical manufacturing: WHO GMP pre- and post certification of a Nigerian pharmaceutical manufacturer

An interesting study, highlighting the positive return of investment of local pharmaceutical companies in Nigeria. I have a few minor comments mostly regarded to clarity and flow of the manuscript. The objective of the study was

a. To evaluate the cost-benefit of investing in GMP using Chi Pharmaceutical Limited as a case study

b. Discuss how to drive local manufacturers to invest and offers practical recommendations.

Comment 1) In the study design section as it's written (page 5), it is not totally clear how objective (b) was to be achieved. I assumed that some of the data is obtained from the interview from Dr. Onya. But to have a true qualitative component, perhaps more interviews are needed so that the data is more saturated and not just from one informant.

Response: Given the sensitive nature of the data obtained, the MD of Chi was not comfortable with our interviewing other staff of the company. However, we corroborated the cost data obtained during the interview by checking the market prices of some of the items.

Comment 2) Following up on comment 1) The results section only demonstrate the cost-benefits analysis. For objective (B) and the qualitative component is now written in the discussion from page 11. This flow again caused me some confusion between what parts should be in the results and what should be in the discussion.

Response: We stated as the secondary objective of the article that “this paper also discusses how to drive more local manufacturers to invest in quality to attain GMP compliance; and proffers practical recommendations for local manufacturers who would want to invest in quality to meet ethical and regulatory obligations”, which naturally falls under discussion section.

Comment 3) please re-check your cost-benefit ratio. From Table 2, I calculated it as 6,500,000/1,141,753, which is 5.7 not 5.3 as stated in the text.

Response: Yes, with average estimate of the parameters, one will arrive at benefit-cost ratio of about 5.7. However, the benefit-cost ratio reduces to 5.3 (95% confidence interval of 5.0–5.5) considering the uncertainties (or variations) in the parameter estimates. To simply use the
average estimates will be misleading as the cost parameters varies widely in reality. Suffice to state that probabilistic sensitivity analysis allows for exploration of the joint uncertainty or variation in parameter estimates used in the analysis. A point estimate is drawn randomly from the distribution of each parameter used in estimating BCR. This was repeated for 1000 times (a thousand iterations) and then the average of the 1000 iterations with 95% confidence interval calculated. We have discussed this in the manuscript.

Cecily Banura, M.D., Ph.D (Reviewer 3): Page 2-4 Background: Are there no other countries on the African continent that have attained WHO GMP certification?

Response: There are companies in some other countries that have attained WHO GMP PQ but in West Africa there is no other countries with WHO GMP certification.

Page 5: The aim of the study is usually not under the methods section

Response: We have moved the aim of the study to the background section (last paragraph of the background session).

Page 5& 6 Table 1: Incomplete. What were the possible data sources for recalls & PMS?

Response: The sources have been provided in the paper on table 1. The source for both is interview.